

SECTION 3

Criteria for Special Authorization of Select Drug Products

CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

The drug products listed in this section may be considered for coverage by special authorization for patients covered under Alberta Health-sponsored drug programs. (For Alberta Human Services clients, the special authorization criteria for coverage can be found in the Criteria for Special Authorization of Select Drug Products section of the *Alberta Human Services Drug Benefit Supplement*.)

Special Authorization Policy

DRUG PRODUCTS ELIGIBLE FOR CONSIDERATION BY SPECIAL AUTHORIZATION

Drug products may be considered for coverage by special authorization under one or more of the following circumstances, unless a specific product falls under the criteria for drug products **not** eligible for consideration by special authorization. Please see the end of this section for information regarding drug products not eligible for consideration by special authorization.

1. The drug is covered by Alberta Health under specified criteria (listed in the following sections). Drug Products and indications other than those specified are not eligible for consideration by special authorization.
2. The drug is normally covered by another government program or agency for a specific approved clinical condition, but is needed for the treatment of a clinical condition that is not covered by that government program or agency.
3. The drug is required because other drug products listed in the *Alberta Drug Benefit List* are contraindicated or inappropriate because of the clinical condition of the patient.
4. The particular brand of drug is considered essential in the care of a patient, where the LCA price policy would otherwise apply. Coverage of a specific brand may be considered where a patient has experienced significant allergic reactions or documented untoward therapeutic effects with alternate brands in an interchangeable grouping. Coverage of a brand name product will **not** be considered in situations where the interchangeable grouping includes a pseudo-generic to the brand name drug.
5. A particular drug product or dosage form of a drug is essential in the care of a patient where the MAC price policy would otherwise apply. Exceptions may occur at the product level. Coverage may be considered only where a patient has experienced significant allergic reactions or documented untoward therapeutic effects with the drug product which establishes the MAC pricing.

Prior approval must be granted by Alberta Blue Cross to ensure coverage by special authorization. For those special authorization requests that are approved, the effective date for authorization is the beginning of the month in which the physician's request is received by Alberta Blue Cross.

Special authorization is granted for a defined period as indicated in each applicable special authorization drug product criteria (the "Approval Period"). If continued treatment is necessary beyond the Approval Period, it is the responsibility of the patient and physician to **re-apply for coverage prior to the expiration date of the Approved Period, unless the Auto-Renewal Process or Step Therapy Approval Process apply** (see below).

AUTO-RENEWAL PROCESS

Selected drug products are eligible for the following auto-renewal process (for eligibility, see the Special Authorization criteria for each drug product).

1. For initial approval, a special authorization request must be submitted. If approval is granted, it will be effective for the Approval Period outlined in the drug product's Special Authorization criteria
2. As long as the patient has submitted a claim for the drug product within the preceding Approval Period (example: within the preceding 6 months), approval will be automatically renewed for a further Approval Period (example: a further 6 months). There is no need for the prescriber to submit a new request as the automated real-time claims adjudication system will read the patient's claims history to determine if a claim has been made within the preceding Approval Period.
3. If the patient does not make a claim for the drug product during the Approval Period, the approval will lapse and a new special authorization request must be submitted.

STEP THERAPY APPROVAL PROCESS

Select drug products are eligible for coverage via the step therapy process, outlined below.

1. If the patient has made a claim for the First-Line* drug product(s) within the preceding 12 months, the claim for the step therapy drug will be approved.
2. The automated real-time claims adjudication system will read the patient's claims history to determine if the required First-Line* drug product(s) have been claimed within the preceding 12 months.
3. Subsequent claims for drug product(s) permitted by step therapy will continue to be approved as long as the drug product has been claimed within the preceding 12 months.
4. The regular special authorization approval process will continue to be available for step therapy approvals for those patients whose First-Line* drug claims cannot be adjudicated through the automated real-time claims adjudication system.

* A First-Line drug product includes any drug(s) or drug product(s) that, under the drug product's Special Authorization criteria, are required to be utilized before reimbursement for the drug product is permitted.

DRUG PRODUCTS NOT ELIGIBLE FOR CONSIDERATION BY SPECIAL AUTHORIZATION

The following categories of drug products are **not** eligible for special authorization:

1. Drug products **deleted** from the *List*.
2. Drug products **not yet reviewed** by the Alberta Health Expert Committee on Drug Evaluation and Therapeutics. This applies to:
 - * products where a complete submission has been received from the manufacturer and the product is under review,
 - * products where an incomplete submission has been received from the manufacturer, and
 - * products where the manufacturer has not made a submission for review.

The DBL is not a prescribing or a diagnostic tool. Prescribers should refer to drug monographs and utilize professional judgment.

**ALBERTA HEALTH AND WELLNESS DRUG BENEFIT LIST REFRESHED
CRITERIA FOR RARE DISEASES DRUG PRODUCTS**

Drug products not yet reviewed may encompass new pharmaceutical products, new strengths of products already listed, reformulated products and new interchangeable (generic) products.

3. Drug products that have **completed the review** process and are **not included** on the *List*.
4. Most drugs available through Health Canada's Special Access Program.
5. Drug products when prescribed for cosmetic indications.
6. Nonprescription or over-the-counter drug products are generally not eligible.

Criteria for Coverage

Wording that appears within quotation marks (“ ”) in this section is the official special authorization criteria, as recommended by the Alberta Health Expert Committee on Drug Evaluation and Therapeutics, and approved by the Minister of Health. Wording that is not enclosed in quotation marks outlines specific information required to interpret criteria, guidelines for submitting requests and/or information regarding conditions under which coverage cannot be provided.

Products Available through Health Canada's Special Access Program

PEMOLINE

“For the treatment of attention deficit hyperactivity disorder where approval has been provided by Health Canada's Special Access Program.”

37.5 MG	ORAL TABLET
DIN N/A*	CYLERT
75 MG	ORAL TABLET
DIN N/A*	CYLERT

**As Cylert has been withdrawn from market, the DINs are no longer valid. Where authorizations for Cylert have been granted, coverage for this product will be provided under PIN 00000999917.*

Other Products

The remaining drug products in this section are listed alphabetically according to the generic ingredient name of the drug. These products can be found on the following pages.

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

ABATACEPT

Rheumatoid Arthritis:

"Special authorization coverage may be provided for use in combination with methotrexate or other DMARDS, for the reduction in signs and symptoms of severely active Rheumatoid Arthritis (RA) in adult patients (18 years of age or older) who are refractory or intolerant to:

- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- Methotrexate with other disease modifying anti-rheumatic agent(s) (minimum 4 month trial). [e.g., methotrexate with hydroxychloroquine or methotrexate with sulfasalazine]; AND
- Leflunomide (minimum 10 week trial at 20 mg daily).

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.

'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for 12 weeks as follows:
 - Abatacept intravenous infusion: five doses of up to 1000 mg/dose administered at 0, 2, 4, 8 and 12 weeks. Patients will be limited to receiving one dose of abatacept per prescription at their pharmacy.
 - Abatacept subcutaneous injection: a single IV loading dose of up to 1000 mg/dose followed by 125 mg subcutaneous injection within a day, then once-weekly 125 mg SC injections. Patients who are unable to receive an infusion may initiate weekly subcutaneous injections without an intravenous loading dose. Patients will be limited to receiving one-month supply of abatacept subcutaneous injection per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another (with the exception of anakinra) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients will not be permitted to switch from anakinra to other biologic agents except under exceptional circumstances.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond 12 weeks, the patient must meet the following criteria:

- 1) The patient must be assessed by an RA Specialist after the initial 12 weeks to determine response.
- 2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
 - ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND
 - An improvement of 0.22 in HAQ score [reported to two (2) decimal places].

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be approved for a period of 12 months. Coverage for abatacept will be provided for one intravenous dose of up to 1000 mg every 4 weeks, or one weekly 125 mg subcutaneous injection. Ongoing coverage

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may be considered only if the following criteria are met at the end of each 12-month period:

- 1) The patient has been assessed by an RA Specialist to determine response;
- 2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
 - confirmation of maintenance of ACR20, OR
 - maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.
- 3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above."

All requests (including renewal requests) for abatacept for Rheumatoid Arthritis must be completed using the Abatacept/Adalimumab/Anakinra/Certolizumab/Etanercept/Golimumab/Infliximab/Sarilumab/Tocilizumab/Tofacitinib for Rheumatoid Arthritis Special Authorization Request Form (ABC 60027).

125 MG / SYR INJECTION

00002402475 ORENCIA

BMS

\$ 373.7875

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Rheumatoid Arthritis:

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- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- Methotrexate with other disease modifying anti-rheumatic agent(s) (minimum 4 month trial). [e.g., methotrexate with hydroxychloroquine or methotrexate with sulfasalazine]; AND
- Leflunomide (minimum 10 week trial at 20 mg daily).

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.

'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for 12 weeks as follows:
 - Abatacept intravenous infusion: five doses of up to 1000 mg/dose administered at 0, 2, 4, 8 and 12 weeks. Patients will be limited to receiving one dose of abatacept per prescription at their pharmacy.
 - Abatacept subcutaneous injection: a single IV loading dose of up to 1000 mg/dose followed by 125 mg subcutaneous injection within a day, then once-weekly 125 mg SC injections. Patients who are unable to receive an infusion may initiate weekly subcutaneous injections without an intravenous loading dose. Patients will be limited to receiving one-month supply of abatacept subcutaneous injection per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another (with the exception of anakinra) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients will not be permitted to switch from anakinra to other biologic agents except under exceptional circumstances.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond 12 weeks, the patient must meet the following criteria:

- 1) The patient must be assessed by an RA Specialist after the initial 12 weeks to determine response.
- 2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
 - ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND
 - An improvement of 0.22 in HAQ score [reported to two (2) decimal places].

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be approved for a period of 12 months. Coverage for abatacept will be provided for one intravenous dose of up to 1000 mg every 4 weeks, or one weekly 125 mg subcutaneous injection. Ongoing coverage

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may be considered only if the following criteria are met at the end of each 12-month period:

- 1) The patient has been assessed by an RA Specialist to determine response;
- 2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
 - confirmation of maintenance of ACR20, OR
 - maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.
- 3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above."

All requests (including renewal requests) for abatacept for Rheumatoid Arthritis must be completed using the Abatacept/Adalimumab/Anakinra/Certolizumab/Etanercept/Golimumab/Infliximab/Sarilumab/Tocilizumab/Tofacitinib for Rheumatoid Arthritis Special Authorization Request Form (ABC 60027).

Polyarticular Juvenile Idiopathic Arthritis:

"Special authorization coverage may be provided for the reduction in signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis (pJIA) in patients 6 years of age and older who:

- Have 5 or more active joints (defined by either swelling or limitation of motion plus pain and/or tenderness), AND
- Are refractory to one or more disease modifying anti-rheumatic agents (DMARDs) conventionally used in children (minimum three month trial), AND
- Are refractory to or intolerant to etanercept and/or adalimumab (minimum 12 week trial).

'Refractory' is defined as lack of effect at the recommended doses and duration of treatments as listed above.

'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in the product monographs.

For coverage, this drug must be prescribed by a prescriber affiliated with a Pediatric Rheumatology Clinic in Edmonton or Calgary ("Pediatric Rheumatology Specialist").

- Coverage may be approved for one dose of 10 mg/kg (maximum dose 1000 mg) at 0, 2, 4, 8, 12 and 16 weeks (total of six doses).
- Patients will be limited to receiving one dose of abatacept per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another (with the exception of abatacept) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients will not be permitted to switch from abatacept to other biologic agents except under exceptional circumstances.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For potential coverage for retreatment with abatacept following a subsequent disease flare, the patient must meet the following criteria:

- 1) The patient must be assessed by a Pediatric Rheumatology Specialist after the initial 16 weeks, but no longer than 20 weeks after, treatment with this biologic agent to

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ABATACEPT

determine and document initial treatment response.

2) The Pediatric Rheumatology Specialist must confirm in writing that the patient is a responder that meets the following criteria (ACR Pedi 30):

- 30% improvement from baseline in at least three of the following six response variables, with worsening of 30% or more in no more than one of the six variables. The variables include:

i. global assessment of the severity of the disease by the Pediatric Rheumatology Specialist,

ii. global assessment of overall well-being by the patient or parent,

iii. number of active joints (joints with swelling not due to deformity or joints with limitation of motion with pain tenderness or both),

iv. number of joints with limitation of motion,

v. functional ability based on CHAQ scores,

vi. ESR or CRP

3) Data from all of the six variables comprising the ACR Pedi 30 and the CHAQ scores must be reported.

Following assessment and confirmation of initial treatment response, coverage for retreatment with abatacept may be approved for one dose of 10 mg/kg (maximum dose 1000 mg) at 0, 2*, 4, 8, 12 and 16 weeks (total of up to six doses; *the week 2 dose on retreatment is optional, to be administered at the discretion of the Pediatric Rheumatology Specialist). In order to be considered for coverage for retreatment, the patient must meet the following criteria:

1) The patient has been assessed by a Pediatric Rheumatology Specialist and the presence of disease flare confirmed. Disease flare is defined as worsening of at least 30% or greater in at least 3 of 6 ACR Pedi 30 variables for pJIA and 30% or greater improvement in no more than one variable.

2) The Pediatric Rheumatology Specialist must confirm in writing that the patient has had an initial treatment response (as assessed above) and that the patient has experienced a disease flare (as defined above)."

Please note: Coverage is provided for treatment of disease flares only. However, if a patient experiences a subsequent flare within 12 months of initiation of treatment with abatacept, they may be eligible for continuous coverage (i.e., one dose of 10 mg/kg (maximum dose 1000 mg) every 4 weeks) for a maximum period of two years, provided the patient has demonstrated a response to initial treatment."

All requests (including renewal requests) for abatacept for Polyarticular Juvenile Idiopathic Arthritis must be completed using the Abatacept for Polyarticular Juvenile Idiopathic Arthritis Special Authorization Request Form (ABC 60010).

250 MG / VIAL (BASE)	INJECTION		
00002282097	ORENCIA	BMS	\$ 500.3400

ACAMPROSATE CALCIUM

"For the treatment of alcohol use disorder in patients who have been abstinent for at least four days and as a component of an alcohol counseling program.

Initial approval period: 6 months

Renewal may be considered for an additional 6 months.

Continued coverage requests beyond 12 months may be considered on a case by case basis."

333 MG (BASE)	ORAL DELAYED-RELEASE TABLET		
00002293269	CAMPRAL	MYP	\$ 0.8184

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ACLIDINIUM BROMIDE/ FORMOTEROL FUMARATE DIHYDRATE

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD)

FIRST-LINE DRUG PRODUCT(S): LONG-ACTING BRONCHODILATOR (I.E., LONG-ACTING BETA-2 AGONIST [LABA] OR LONG-ACTING MUSCARINIC ANTAGONIST [LAMA])

"For the long-term maintenance treatment of airflow obstruction in patients with moderate to severe (i.e., FEV1 < 80% predicted) chronic obstructive pulmonary disease (COPD), who have an inadequate response to a long-acting bronchodilator (long-acting beta-2 agonist [LABA] or long-acting muscarinic antagonist [LAMA])."

"For the long-term maintenance treatment of airflow obstruction in patients with severe (i.e., FEV1 < 50% predicted) chronic obstructive pulmonary disease (COPD)."

"Special authorization may be granted for 24 months."

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

UP - First-line therapy ineffective

All requests for acclidinium bromide + formoterol fumarate dihydrate must be completed using the Long-Acting Fixed-Dose Combination Products for Asthma/COPD Special Authorization Request Form (ABC 60025).

400 MCG / DOSE * 12 MCG / DOSE	INHALATION	METERED INHALATION POWDER		
00002439530	DUAKLIR GENUAIR	AZC	\$	1.0000

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ADALIMUMAB

Ankylosing Spondylitis

"Special authorization coverage may be provided for the reduction in the signs and symptoms of severely active Ankylosing Spondylitis, as defined by the Modified New York criteria for Ankylosing Spondylitis, in adult patients (18 years of age or older) who have active disease as demonstrated by:

- a BASDAI greater than or equal to 4 units, demonstrated on 2 occasions at least 8 weeks apart AND
- a Spinal Pain VAS of greater than or equal to 4 cm (on a 0-10 cm scale), demonstrated on 2 occasions at least 8 weeks apart AND
- who are refractory or intolerant to:

at least TWO of the following

- Brenzys (etanercept)
- Cimzia (certolizumab pegol)
- Cosentyx (secukinumab)
- Erelzi (etanercept)
- Inflectra (infliximab)
- Renflexis (infliximab)
- Simponi (golimumab)

AND

- treatment with 2 or more NSAIDS each taken for a minimum of 4 weeks at maximum tolerated or recommended doses.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.

'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for 12 weeks as follows: An initial 40 mg dose, followed by additional 40 mg doses administered every two weeks for up to 12 weeks after the first dose.
- Patients will be limited to receiving a one-month supply of adalimumab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond 12 weeks, the patient must meet the following criteria:

- 1) The patient must be assessed at 12 weeks by an RA Specialist after the initial 12 weeks of therapy to determine response.
- 2) The RA Specialist must confirm, in writing, that the patient is a 'responder' that meets the following criteria:
 - Reduction of the BASDAI score by at least 50% of the pre-treatment value or by 2 or more units, AND
 - Reduction of the Spinal Pain VAS by 2 cm or more.

Following this assessment, continued coverage may be approved for one 40 mg dose every other week for a period of 12 months. Ongoing coverage may be considered if the patient is re-assessed by an RA Specialist every 12 months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above."

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All requests (including renewal requests) for adalimumab for Ankylosing Spondylitis must be completed using the Adalimumab/Certolizumab/Etanercept/Golimumab/Infliximab/Secukinumab for Ankylosing Spondylitis Special Authorization Request Form (ABC 60028).

Hidradenitis Suppurativa

"Special authorization may be provided for the treatment of adult patients with active moderate to severe Hidradenitis Suppurativa who meet all of the following criteria:

- A total abscess and nodule (AN) count of 3 or greater.
- Lesions in at least two distinct anatomical areas, one of which must be Hurley Stage II or III.
- An inadequate response to a 90-day trial of systemic antibiotics AND documented non response to conventional therapy.

For coverage, this drug must be initiated by a Specialist in Dermatology ("Dermatology Specialist").

- Initial coverage may be approved for 12 weeks as follows: an initial dose of 160 mg, followed by one 80 mg dose two weeks later, then 40 mg every week beginning four weeks after the initial dose, for a total of eleven doses.
- Patients will be limited to receiving a one-month supply of adalimumab per prescription at their pharmacy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond the initial approval period the patient must meet the following criteria:

- 1) The patient must be assessed by a Dermatology Specialist after 12 weeks of treatment to determine response.
- 2) The Dermatology Specialist must confirm, in writing, that the patient is a 'responder' that meets the following criteria:

- Greater than or equal to 50% reduction in AN count from pre-treatment baseline AND
- no increase in abscess count or draining fistula count relative to pre-treatment baseline.

Note: Treatment with adalimumab should be discontinued if there is insufficient improvement after 12 weeks of treatment.

Following this assessment, continued coverage may be considered for one 40 mg dose of adalimumab every week for an additional period of 12 months. Ongoing coverage may be considered if the patient is re-assessed by a Dermatology Specialist every 12 months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above."

All requests (including renewal requests) for adalimumab for Hidradenitis Suppurativa must be completed using the Adalimumab for Hidradenitis Suppurativa Special Authorization Request Form (ABC 60058).

Moderately to Severe Active Crohn's Disease

"Special authorization coverage may be approved for coverage of adalimumab for the reduction in signs and symptoms and induction and maintenance of clinical remission of Moderately to Severely Active Crohn's Disease in patients who meet the following criteria:

- Adalimumab must be prescribed by a Specialist in Gastroenterology or a physician appropriately trained by the University of Alberta or the University of Calgary and recognized as a prescriber by Alberta Blue Cross for adalimumab for coverage for the treatment of Moderately to Severely Active Crohn's Disease patients ('Specialist').
- Patients must be 18 years of age or older to be considered for coverage of adalimumab.
- Patients will be limited to receiving a one-month supply of adalimumab per prescription at their pharmacy.

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- Patients may be allowed to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy (both primary loss of response and secondary loss of response) or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

Prior to initiation of adalimumab therapy for New Patients:

'New Patients' are patients who have never been treated with adalimumab by any health care provider.

Moderately to Severely Active Crohn's Disease:

Prior to initiation of adalimumab therapy, New Patients must have a current Modified (without the physical exam) Harvey Bradshaw Index score of greater than or equal to 7 (New Patient's Baseline Score), AND be Refractory.

Refractory is defined as one or more of the following:

- 1) Serious adverse effects or reactions to the treatments specified below; OR
- 2) Contraindications (as defined in product monographs) to the treatments specified below; OR
- 3) Previous documented lack of effect at doses and for duration of all treatments specified below:

a) mesalamine: minimum of 3 grams/day for a minimum of 6 weeks; AND refractory to, or dependent on, glucocorticoids: following at least one tapering dosing schedule of 40 mg/day, tapering by 5 mg each week to 20 mg, then tapering by 2.5 mg each week to zero, or similar.

[Note: Patients who have used the above treatments in combination will not be required to be challenged with individual treatments as monotherapy]

AND

b) Immunosuppressive therapy as follows:

- Azathioprine: minimum of 2 mg/kg/day for a minimum of 3 months; OR
- 6-mercaptopurine: minimum of 1 mg/kg/day for a minimum of 3 months; OR
- Methotrexate: minimum or 15 mg/week for a minimum of 3 months.

OR

- Immunosuppressive therapy discontinued at less than 3 months due to serious adverse effects or reactions;

AND

c) refractory or intolerant to at least TWO of the following:

- Entyvio (vedolizumab)
- Inflectra (infliximab)
- Renflexis (infliximab).

Applications for coverage must include information regarding the dosages and duration of trial of each treatment the patient received, a description of any adverse effects, reactions, contraindications and/or lack of effect, as well as any other information requested by Alberta Blue Cross.

Coverage Criteria for Moderately to Severely Active Crohn's Disease

- New Patients must meet the criteria above prior to being considered for approval.
- All approvals are also subject to the following applicable criteria.

Induction Dosing for New Patients:

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ADALIMUMAB

- Coverage for Induction Dosing may only be approved for New Patients (those who have never been treated with adalimumab by any health care provider).
- 'Induction Dosing' means a maximum of one 160 mg dose of adalimumab per New Patient at week 0 followed by an 80 mg dose at week 2.
- New Patients are eligible to receive Induction Dosing only once, after which time the Maintenance Dosing for New Patients and Continued Coverage for Maintenance Dosing criteria will apply.
- As an interim measure, 40 mg doses of adalimumab will be provided at weeks 4, 6, 8 and 10 to allow time to determine whether the New Patient meets coverage criteria for Maintenance Dosing below.

Maintenance Dosing:

'Maintenance Dosing' means one 40 mg dose of adalimumab per patient provided no more often than every other week starting at week 4 for a period of 12 months to:

- New Patients following the completion of Induction Dosing; OR
- Existing Patients, who are patients that are being treated, or have previously been treated, with adalimumab.

Maintenance Dosing for New Patients after Completion of Induction Dosing:

- The New Patient must be assessed by a Specialist within 12 weeks after the initiation of Induction Dosing to determine response by obtaining a Modified Harvey Bradshaw Index score for patients with Moderately to Severely Active Crohn's Disease; AND
- The Specialist must confirm the Modified Harvey Bradshaw Index score shows a decrease from the New Patient's Baseline Score of greater than or equal to 3 points for patients with Moderately to Severely Active Crohn's.

Maintenance Dosing for Existing Patients:

- The patient must be assessed by a Specialist annually (within 2 months of the expiry of a patient's special authorization) at least 2 weeks after the day a dose of adalimumab was administered to the patient and prior to administration of the next dose to obtain: a Modified Harvey Bradshaw Index Score (Existing Patient's Baseline Score) for Moderately to Severely Active Crohn's Disease; AND
- these measures must be provided to Alberta Blue Cross for assessment for continued coverage for maintenance dosing.

Continued Coverage for Maintenance Dosing:

Continued coverage may be considered for one 40 mg dose of adalimumab per patient provided no more often than every other week for a period of 12 months, if the following criteria are met at the end of each 12 month period:

- The New Patient or the Existing Patient must be assessed by a Specialist annually (within 2 months of the expiry of a patient's special authorization) at least 2 weeks after the day a dose of adalimumab was administered to the patient and prior to administration of the next dose to obtain: a Modified Harvey Bradshaw Index Score for Moderately to Severely Active Crohn's Disease; AND
- For New Patients: The Specialist must confirm that the patient has maintained a greater than or equal to 3 point decrease from the New Patient's Baseline Score for Moderately to Severely Active Crohn's; OR
- For Existing Patients: The Specialist must confirm that the patient has maintained the Existing Patient's Baseline Score."

All requests (including renewal requests) for adalimumab for Moderately to Severely Active Crohn's Disease must be completed using the Adalimumab/Vedolizumab for Crohn's/Infliximab for Crohn's/Fistulizing Crohn's Special Authorization Request Form (ABC 60031).

Plaque Psoriasis

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

ADALIMUMAB

"Special authorization coverage may be provided for the reduction in signs and symptoms of severe, debilitating psoriasis in patients who:

- Have a total PASI of 10 or more and a DLQI of more than 10, OR
- Who have significant involvement of the face, palms of the hands, soles of the feet or genital region; AND
- Who are refractory or intolerant to:

at least THREE of the following:

- Cosentyx (secukinumab)
- Inflectra (infliximab)
- Renflexis (infliximab)
- Skyrizi (risankizumab)
- Taltz (ixekizumab);

AND

- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory, OR

- Cyclosporine (6 weeks treatment); AND
- Phototherapy (unless restricted by geographic location)

Patients who have a contraindication to either cyclosporine or methotrexate will be required to complete an adequate trial of the other pre-requisite medication prior to potential coverage being considered.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.

'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be prescribed by a Specialist in Dermatology ("Dermatology Specialist").

- Initial coverage may be approved for an initial dose of 80 mg, followed by one 40 mg dose every other week beginning one week after the first dose, for a total of nine doses.
- Patients will be limited to receiving a one-month supply of adalimumab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond nine doses, the patient must meet all of the following criteria:

1) The patient must be assessed by a Dermatology Specialist after the initial nine doses to determine response.

2) The Dermatology Specialist must confirm, in writing, that the patient is a 'responder' that meets the following criteria:

- Greater than or equal to 75% reduction in PASI score, OR
- Greater than or equal to 50% reduction in PASI score AND improvement of greater than or equal to 5 points in the DLQI.

Following this assessment, continued coverage may be considered for one 40 mg dose of adalimumab every other week for a period of 12 months. Ongoing coverage may be considered if the patient is re-assessed by a Dermatology Specialist every 12 months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above."

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

ADALIMUMAB

PASI and DLQI scores are required for all requests for Plaque Psoriasis including those requests for patients that have significant involvement of the face, palms, soles of feet or genital region.

All requests (including renewal requests) for adalimumab for Plaque Psoriasis must be completed using the Adalimumab/Etanercept/Infliximab/Ixekizumab/Risankizumab/Secukinumab/Ustekinumab for Plaque Psoriasis Special Authorization Request Form (ABC 60030).

Polyarticular Juvenile Idiopathic Arthritis

"Special authorization coverage may be provided for the reduction in signs and symptoms of severely active polyarticular juvenile idiopathic arthritis (pJIA) in patients 4 years of age and older who:

- Have 5 or more active joints (defined by either swelling or limitation of motion plus pain and/or tenderness), AND
- Are refractory to one or more disease modifying anti-rheumatic agents (DMARDs) conventionally used in children (minimum three month trial).

"Refractory" is defined as one or more of the following: lack of effect, serious adverse effects (e.g., leukopenia, hepatitis) or contraindications to treatments as defined in the product monographs.

For coverage, this drug must be prescribed by a prescriber affiliated with a Pediatric Rheumatology Clinic in Edmonton or Calgary (Pediatric Rheumatology Specialist).

- Coverage may be approved for 24 mg per square meter body surface area (maximum dose 40 mg) every other week for 12 weeks.
- Patients will be limited to receiving a one-month supply of adalimumab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another (with the exception of abatacept) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients will not be permitted to switch from abatacept to other biologic agents except under exceptional circumstances.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage of this agent beyond 12 weeks, the patient must meet the following criteria:

- 1) The patient must be assessed by a Pediatric Rheumatology Specialist after 12 weeks, but no longer than 16 weeks after, treatment with this biologic agent to determine response.
- 2) The Pediatric Rheumatology Specialist must confirm in writing that the patient is a responder that meets the following criteria (ACR Pedi 30):
 - 30% improvement from baseline in at least three of the following six response variables, with worsening of 30% or more in no more than one of the six variables. The variables include:
 - i. global assessment of the severity of the disease by the Pediatric Rheumatology Specialist,
 - ii. global assessment of overall well-being by the patient or parent,
 - iii. number of active joints (joints with swelling not due to deformity or joints with limitation of motion with pain tenderness or both),
 - iv. number of joints with limitation of motion,
 - v. functional ability based on CHAQ scores,
 - vi. ESR or CRP
- 3) Data from all of the six variables comprising the ACR Pedi 30 and the CHAQ scores must be reported in each request.

Following this assessment, continued coverage may be approved for 24 mg per square meter

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

ADALIMUMAB

body surface area (maximum dose 40 mg) every other week, for a maximum of twelve months. After twelve months, in order to be considered for continued coverage, the patient must be re-assessed every twelve months by a Pediatric Rheumatology Specialist and must meet the following criteria:

- 1) The patient has been assessed by a Pediatric Rheumatology Specialist to determine response, and
- 2) The Pediatric Rheumatology Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by maintenance of the ACR Pedi 30,
- 3) Data from all of the six variables comprising the ACR Pedi 30 and the CHAQ scores must be reported in each request.

Once a child with pJIA has had two disease-free years, it is common clinical practice for drug treatment to be stopped."

All requests (including renewal requests) for adalimumab for Polyarticular Juvenile Idiopathic Arthritis must be completed using the Adalimumab/Etanercept/Tocilizumab for Polyarticular Juvenile Idiopathic Arthritis Special Authorization Request Form (ABC 60011).

Psoriatic Arthritis

"Special authorization coverage may be provided for use in combination with methotrexate for reducing signs and symptoms and inhibiting the progression of structural damage of active arthritis in adult patients (18 years of age or older) with moderate to severe polyarticular psoriatic arthritis (PsA) or pauciarticular PsA with involvement of knee or hip joint who are refractory or intolerant to:

at least TWO of the following:

- Cimzia (certolizumab pegol)
- Cosentyx (secukinumab)
- Erelzi (etanercept)
- Inflectra (infliximab)
- Renflexis (infliximab)
- Simponi (golimumab)
- Taltz (ixekizumab)

AND

- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- An adequate trial of another disease modifying anti-rheumatic agent(s) (minimum 4 month trial).

Special authorization coverage of this agent may be provided for use as monotherapy in adult patients for whom methotrexate is contraindicated and/or for those patients who have experienced serious adverse effects.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.

'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for 40 mg administered every other week for 8 weeks.
- Patients will be limited to receiving a one-month supply of adalimumab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

ADALIMUMAB

contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).

- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond 8 weeks, the patient must meet the following criteria:

1) The patient must be assessed by an RA Specialist after 8 weeks, but no longer than 12 weeks after, to determine response.

2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:

- ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND
- An improvement of 0.22 in HAQ score [reported to two (2) decimal places].

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be approved for doses of 40 mg every other week, for a period of 12 months. Ongoing coverage may be considered if the following criteria are met at the end of each 12-month period:

1) The patient has been assessed by an RA Specialist to determine response;

2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:

- Confirmation of maintenance of ACR20, or
- Maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.

3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above."

All requests (including renewal requests) for adalimumab for Psoriatic Arthritis must be completed using the Adalimumab/Certolizumab/Etanercept/Golimumab/Infliximab/Ixekizumab/Secukinumab for Psoriatic Arthritis Special Authorization Request Form (ABC 60029).

Rheumatoid Arthritis

"Special authorization coverage may be provided for use in combination with methotrexate for the reduction in signs and symptoms of severely active Rheumatoid Arthritis (RA) in adult patients (18 years of age or older) who are refractory or intolerant to:

at least FOUR of the following:

- Actemra (tocilizumab)
- Brenzys (etanercept)
- Cimzia (certolizumab pegol)
- Erelzi (etanercept)
- Inflectra (infliximab)
- Kevzara (sarilumab)
- Orencia (abatacept)
- Renflexis (infliximab)
- Simponi (golimumab)
- Xeljanz (tofacitinib)

AND

- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

ADALIMUMAB

must have a trial of parenteral methotrexate before being accepted as refractory; AND

- Methotrexate with other disease modifying anti-rheumatic agent(s) (minimum 4 month trial) [e.g., methotrexate with hydroxychloroquine or methotrexate with sulfasalazine]; AND
- Leflunomide (minimum 10 week trial at 20 mg daily)

Special authorization coverage of this agent may be provided for use as monotherapy in adult patients for whom methotrexate is contraindicated and/or for those patients who have experienced serious adverse effects.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.

'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for five doses as follows: An initial 40 mg dose, followed by additional 40 mg doses at 2, 4, 6 and 8 weeks after the first dose.
- Patients will be limited to receiving a one-month supply of adalimumab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another (with the exception of anakinra) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients will not be permitted to switch from anakinra to other biologic agents except under exceptional circumstances.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond five doses, the patient must meet the following criteria:

- 1) The patient must be assessed by an RA Specialist after the initial five doses to determine response.
- 2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
 - ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND
 - An improvement of 0.22 in HAQ score [reported to two (2) decimal places].

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be approved for 40 mg every other week for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:

- 1) The patient has been assessed by an RA Specialist to determine response;
- 2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
 - confirmation of maintenance of ACR20, or
 - maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.
- 3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above."

All requests (including renewal requests) for adalimumab for Rheumatoid Arthritis must be completed using the Abatacept/Adalimumab/Anakinra/Certolizumab/Etanercept/Golimumab/Infliximab/Sarilumab/Tocilizumab/Tofacitinib for Rheumatoid Arthritis Special Authorization Request Form (ABC 60027).

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

ADALIMUMAB

Ulcerative Colitis

"Special authorization coverage may be provided for the reduction in signs and symptoms and induction and maintenance of clinical remission of Ulcerative Colitis in adult patients (18 years of age or older) with active disease (characterized by a partial Mayo score >4 prior to initiation of biologic therapy) and who are refractory or intolerant to:

- mesalamine: minimum of 4 grams/day for a minimum of 4 weeks; AND
- corticosteroids (failure to respond to prednisone 40 mg daily for 2 weeks, or; steroid dependent i.e. failure to taper off steroids without recurrence of disease or disease requiring a second dose of steroids within 12 months of previous dose).

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.

'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

Immunosuppressive therapy as follows may also be initiated if in the clinician's judgment a trial is warranted:

- i) Azathioprine: minimum of 2 mg/kg/day for a minimum of 2 months; OR
- ii) 6-mercaptopurine: minimum of 1 mg/kg/day for a minimum of 2 months

For coverage, this drug must be prescribed by a Specialist in Gastroenterology or a physician appropriately trained by the University of Alberta or the University of Calgary and recognized as a prescriber by Alberta Blue Cross ('Specialist').

Initial coverage may be approved for an initial dose of 160 mg, followed by an 80 mg dose at week 2, then one 40 mg dose at weeks 4, 6 and 8. As an interim measure, an additional 40 mg dose of adalimumab will be provided at week 10 to allow time to determine whether the New Patient meets coverage criteria for Maintenance Dosing below, for a total of six doses.

- Patients will be limited to receiving a one-month supply of adalimumab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond the initial coverage period, the patient must meet the following criteria:

- 1) The patient must be assessed by a Specialist between weeks 8 and 12 after the initiation of therapy to determine response.
- 2) The Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
 - a decrease in the partial Mayo score of greater than or equal to 2 points

Following this assessment, continued coverage may be approved for a dose of 40 mg every 2 weeks for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:

- 1) The patient has been assessed by a Specialist in Gastroenterology to determine response;
- 2) The Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
 - a decrease in the partial Mayo score of greater than or equal to 2 points from the score prior to initiation of adalimumab therapy."

All requests (including renewal requests) for adalimumab for Ulcerative Colitis must be completed using the Adalimumab/Golimumab/Infliximab/Vedolizumab for Ulcerative Colitis

ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

ADALIMUMAB

Special Authorization Request Form (ABC 60008).

40 MG / SYR INJECTION SYRINGE

00002258595 HUMIRA (40 MG/0.8 ML INJ SYR) ABV \$ 785.4500

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

ALEMTUZUMAB

Relapsing Remitting Multiple Sclerosis (RRMS):

"Special authorization coverage may be provided for the treatment of relapsing remitting multiple sclerosis (RRMS) to reduce the frequency of clinical relapses, to decrease the number and volume of active brain lesions identified on magnetic resonance imaging (MRI) scans and to delay the progression of physical disability, in adult patients (18 years of age or older) who are refractory or intolerant to:

At least ONE of the following:

- interferon beta
- glatiramer acetate
- dimethyl fumarate
- teriflunomide
- peginterferon beta.

Definition of 'intolerant'

Demonstrating serious adverse effects or contraindications to treatments as defined in the product monograph, or a persisting adverse event that is unresponsive to recommended management techniques and which is incompatible with further use of that class of MS disease modifying therapy (DMT).

Definition of 'refractory'

-Development of neutralizing antibodies to interferon beta.

-When the above MS DMTs are taken at the recommended doses for a full and adequate course of treatment, within a consecutive 12-month period while the patient was on the MS DMT, the patient has:

1) Been adherent to the MS DMT (greater than 80% of approved doses have been administered);

2) Experienced at least two relapses* of MS confirmed by the presence of neurologic deficits on examination.

i. The first qualifying clinical relapse must have begun at least one month after treatment initiation.

ii. Both qualifying relapses must be classified with a relapse severity of moderate, severe or very severe**.

*A relapse is defined as the appearance of new symptoms or worsening of old symptoms, lasting at least 48 hours in the absence of fever, not associated with withdrawal from steroids. Onset of clinical relapses must be separated by a period of at least one month. At least one definite gadolinium-enhancing T1 MRI lesion (not questionable faint enhancement) obtained at least 90 days after initiation of the DMT and at least 90 days before or after a relapse may substitute for one clinical relapse.

**Relapse severity: with moderate relapses modification or more time is required to carry out activities of daily living; with severe relapses there is inability to carry out some activities of daily living; with very severe relapses activities of daily living must be completed by others. For coverage, this drug must be prescribed by a registered MS Neurologist. A current assessment must be completed by a registered MS Neurologist.

To register to become an MS Neurologist, please complete the Registration for MS Neurologist Status Form (ABC 60002).

Coverage may be considered only if the following criteria are met:

1) The registered MS Neurologist must confirm a diagnosis of RRMS;

2) The patient must have active disease which is defined as at least two relapses* of MS during the previous two years or in the two years prior to starting an MS DMT. In most cases this will be

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

ALEMTUZUMAB

satisfied by the 'refractory' to treatment criterion but if a patient failed an MS DMT more than one year earlier, ongoing active disease must be confirmed.

3) The patient must be ambulatory with or without aid (The registered MS Neurologist must provide a current updated Expanded Disability Status Scale (EDSS) score less than or equal to 5).

Coverage will not be approved when any MS DMT or other immunosuppressive therapy is to be used in combination with alemtuzumab.

Coverage of alemtuzumab will not be approved if the patient was deemed to be refractory to alemtuzumab in the past.

Following assessment of the request, alemtuzumab may be approved for coverage at a dose of 12 mg/day administered by intravenous (IV) infusion for 2 treatment courses:

- Initial Treatment Course: 12 mg/day for 5 consecutive days (60 mg total dose)
- Second Treatment Course: 12 mg/day for 3 consecutive days (36 mg total dose) administered 12 months after the initial treatment course.

Patients will be limited to receiving one treatment course (60 mg or 36 mg) of alemtuzumab per prescription at their pharmacy.

Coverage is limited to two treatment courses (i.e., eight doses)."

All requests for alemtuzumab must be completed using the Alemtuzumab/Fingolimod/Natalizumab For Multiple Sclerosis Special Authorization Request Form (ABC 60000).

12 MG / VIAL INJECTION

00002418320 LEMTRADA

GZM

\$ 13031.1100

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

ALENDRONATE SODIUM

Osteoporosis:

"For the treatment of osteoporosis in patients with a 20% or greater 10-year fracture risk who have documented intolerance to alendronate 70 mg or risedronate 35 mg. Special authorization may be granted for 6 months."

"Requests for other osteoporosis medications covered via special authorization will not be considered until 6 months after the last dose of denosumab 60 mg/syr injection syringe."

"Requests for other osteoporosis medications covered via special authorization will not be considered until 12 months after the last dose of zoledronic acid 0.05 mg/ml injection."

Note: The fracture risk can be determined by the World Health Organization's fracture risk assessment tool, FRAX, or the most recent (2010) version of the Canadian Association of Radiologists and Osteoporosis Canada (CAROC) table.

All requests for alendronate sodium for Osteoporosis must be completed using the Alendronate/Raloxifene/Risedronate for Osteoporosis Special Authorization Request Form (ABC 60043).

The following product(s) are eligible for auto-renewal for the treatment of osteoporosis.

Paget's Disease:

"For the treatment of Paget's disease. Special Authorization for this criteria may be granted to a maximum of 6 months."

"Coverage cannot be provided for two or more medications used in the treatment of Paget's disease when these medications are intended for use in combination or when therapy with two or more medications overlap."

10 MG ORAL TABLET

00002381486	ALENDRONATE SODIUM	AHI	\$	0.4986
00002388545	AURO-ALENDRONATE	AUR	\$	0.4986

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

ALFUZOSIN HCL

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

FIRST-LINE DRUG PRODUCT(S): DOXAZOSIN OR TERAZOSIN

"For the treatment of the symptoms of benign prostatic hyperplasia (BPH) in patients who are unresponsive to a six-week trial with a non-selective alpha-blocker (e.g., terazosin) or in whom non-selective alpha-blockers are not tolerated or are contraindicated."

"Special authorization may be granted for 24 months"

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

UP - First-line therapy ineffective

UQ - First-line therapy not tolerated

10 MG ORAL SUSTAINED-RELEASE TABLET

00002447576	ALFUZOSIN	SIV	\$	0.2601
00002315866	APO-ALFUZOSIN	APX	\$	0.2601
00002443201	AURO-ALFUZOSIN	AUR	\$	0.2601
00002304678	SANDOZ ALFUZOSIN	SDZ	\$	0.2601
00002245565	XATRAL	SAV	\$	1.0404

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

ALIROCUMAB

"Special authorization coverage may be provided for the reduction of Low Density Lipoprotein Cholesterol (LDL-C) if the following clinical criteria and conditions are met:

I) Patient has a definite or probable diagnosis of Heterozygous Familial Hypercholesterolemia (HeFH) using the Simon Broome or Dutch Lipid Network criteria or genetic testing

AND

II) Patient is unable to reach LDL-C target (i.e., LDL-C < 2.0 mmol/L for secondary prevention or at least a 50% reduction in LDL-C from untreated baseline for primary prevention) despite:

a) Confirmed adherence to high dose statin (e.g., atorvastatin 80 mg or rosuvastatin 40 mg) in combination with ezetimibe for at least 3 months.

OR

b) Confirmed adherence to ezetimibe for at least 3 months.

AND

Patient is unable to tolerate high dose statin, defined as meeting all of the following:

i) Inability to tolerate at least two statins with at least one started at the lowest starting daily dose,

AND

ii) For each statin (two statins in total), dose reduction is attempted for intolerable symptom (myopathy) or biomarker abnormality (creatinine kinase (CK) > 5 times the upper limit of normal) resolution rather than discontinuation of statin altogether,

AND

iii) For each statin (two statins in total), intolerable symptoms (myopathy) or abnormal biomarkers (CK > 5 times the upper limit of normal) changes are reversible upon statin discontinuation but reproducible by re-challenge of statins where clinically appropriate,

AND

iv) One of either:

- Other known determinants of intolerable symptoms or abnormal biomarkers have been ruled out,

OR

- Patient developed confirmed and documented rhabdomyolysis.

OR

c) Confirmed adherence to ezetimibe for at least 3 months.

AND

Patient is statin contraindicated, i.e., active liver disease or unexplained persistent elevations of serum transaminases exceeding 3 times the upper limit of normal.

Initial coverage may be approved for either 75 mg once every two weeks or 300 mg once every 4 weeks for a period of 12 weeks.

- Patients prescribed alirocumab 300 mg once every 4 weeks must use the 150 mg/dose formulation.

- Patients will be limited to receiving a 4 week supply of alirocumab per prescription at their pharmacy.

For continued coverage beyond 12 weeks, the patient must meet the following criteria:

- Patient is adherent to therapy.

- Patient has achieved a reduction in LDL-C of at least 40% from baseline (4-8 weeks after initiation of alirocumab).

Continued coverage may be approved for either 75 mg once every 2 weeks or 300 mg once every 4 weeks for a period 12 months. The dosage may be adjusted to the maximum dosage of 150 mg administered every 2 weeks, depending on patient response.

- Patients are limited to 26 syringes/pens per year.

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

ALIROCUMAB

Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:

- Patient is adherent to therapy.
- Patient continues to have a significant reduction in LDL-C (with continuation of alirocumab) of at least 40% from baseline since initiation of PCSK9 inhibitor. LDL-C should be checked periodically with continued treatment with PCSK9 inhibitors (e.g., every 6 months)."

All requests (including renewal requests) for alirocumab for Heterozygous Familial Hypercholesterolemia must be completed using the Alirocumab/Evolocumab for HeFH Special Authorization Request Form (ABC 60060).

75 MG / ML INJECTION

<input checked="" type="checkbox"/>	00002453754	PRALUENT	SAV	\$	256.2100
<input checked="" type="checkbox"/>	00002453819	PRALUENT	SAV	\$	256.2100

150 MG / ML INJECTION

<input checked="" type="checkbox"/>	00002453762	PRALUENT	SAV	\$	256.2100
<input checked="" type="checkbox"/>	00002453835	PRALUENT	SAV	\$	256.2100

ALMOTRIPTAN MALATE

(Refer to 28:32.28 of the Alberta Drug Benefit List for coverage of patients 18 to 64 years of age inclusive.)

"For the treatment of acute migraine attacks in patients 65 years of age and older where other standard therapy has failed."

"For the treatment of acute migraine attacks in patients 65 years of age and older who have been using almotriptan malate prior to turning 65."

"Special authorization for both criteria may be granted for 24 months."

In order to comply with the first criteria, information is required regarding previous medications utilized and the patient's response to therapy.

The following product(s) are eligible for auto-renewal.

6.25 MG (BASE) ORAL TABLET

	00002398435	MYLAN-ALMOTRIPTAN	MYP	\$	7.0433
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12.5 MG (BASE) ORAL TABLET

	00002466821	ALMOTRIPTAN	SNS	\$	2.3478
	00002398443	MYLAN-ALMOTRIPTAN	MYP	\$	2.3478
	00002405334	SANDOZ ALMOTRIPTAN	SDZ	\$	2.3478
	00002434849	TEVA-ALMOTRIPTAN	TEV	\$	2.3478

AMPICILLIN

(Refer to Section 1 - Restricted Benefits of the Alberta Drug Benefit List for coverage of the product when prescribed by a Specialist in Infectious Diseases or a designated prescriber.)

"For the treatment of infections caused by susceptible Shigella and Salmonella."*

*Special Authorization is only required when the prescriber prescribing the medication is not a Specialist in Infectious Diseases or a designated prescriber.

250 MG ORAL CAPSULE

	00000020877	NOVO-AMPICILLIN	TEV	\$	0.4223
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500 MG ORAL CAPSULE

	00000020885	NOVO-AMPICILLIN	TEV	\$	0.8006
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**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

ANAKINRA

"Special authorization coverage may be provided for use in combination with methotrexate for the reduction in signs and symptoms of severely active Rheumatoid Arthritis (RA) in adult patients (18 years of age or older) in whom other biologics are contraindicated or in patients who have experienced serious adverse events while on other biologics and who are refractory or intolerant to:

- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- Methotrexate with other disease modifying anti-rheumatic agent(s) (minimum 4-month trial). [e.g., methotrexate with hydroxychloroquine or methotrexate with sulfasalazine]; AND
- Leflunomide (minimum 10 week trial at 20 mg daily).

Special authorization coverage of this agent may be provided for use as monotherapy in adult patients for whom methotrexate is contraindicated and/or for those patients who have experienced serious adverse effects.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.

'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for one 100 mg dose administered daily for 8 weeks.
- Patients will be limited to receiving a one-month supply of anakinra per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another (with the exception of anakinra) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients will not be permitted to switch from anakinra to other biologic agents except under exceptional circumstances.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond 8 weeks, the patient must meet the following criteria:

1) The patient must be assessed by an RA Specialist after 8 weeks but no longer than 12 weeks after treatment to determine response.

2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:

- ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND

- An improvement of 0.22 in HAQ score [reported to two (2) decimal places].

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be approved for one 100 mg dose administered once daily for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:

1) The patient has been assessed by an RA Specialist to determine response;

2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:

- Confirmation of maintenance of ACR20, or

- Maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.

3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.

ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

ANAKINRA

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above."

All requests (including renewal requests) for anakinra must be completed using the Abatacept/Adalimumab/Anakinra/Certolizumab/Etanercept/Golimumab/Infliximab/Sarilumab/Tocilizumab/Tofacitinib for Rheumatoid Arthritis Special Authorization Request Form (ABC 60027).

100 MG / SYR INJECTION SYRINGE

00002245913 KINERET

BVM

\$ 51.2275

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

APIXABAN

AT RISK PATIENTS WITH NON-VALVULAR ATRIAL FIBRILLATION

SPECIAL AUTHORIZATION (step therapy approval process)

FIRST-LINE DRUG PRODUCT(S): WARFARIN

Coverage Criteria

"Subject to the Exclusions From Coverage noted below, Members of Alberta Government Sponsored Drug Plans who are At-Risk with non-valvular atrial fibrillation (AF) who require the Drug Products for the prevention of stroke and systemic embolism AND in whom one of the following is also present:

- Inadequate Anticoagulation following at least a two month trial of warfarin; OR
- Anticoagulation using warfarin is contraindicated or not possible due to inability to regularly monitor the patient via International Normalized Ratio (INR) testing (i.e. no access to INR testing services at a laboratory, clinic, pharmacy, or at home).

Exclusions from Coverage:

- Patients with impaired renal function (creatinine clearance or estimated glomerular filtration rate <25 mL/min),
- Patients who are greater than or equal to 75 years of age and who do not have Documented Stable Renal Function,
- Patients who have hemodynamically significant rheumatic valvular heart disease, especially mitral stenosis, or,
- Patients who have a prosthetic heart valve.

Definitions:

- "At-Risk" means patients with atrial fibrillation are defined as those with a CHADS2 score of greater than or equal to 1. Prescribers may consider an antiplatelet regimen or oral anticoagulation for patients with a CHADS2 score of 1.
- "Inadequate Anticoagulation" is defined as INR testing results that are outside the desired INR range for at least 35% of the tests during the monitoring period (i.e. adequate anticoagulation is defined as INR test results that are within the desired INR range for at least 65% of the tests during the monitoring period).
- "Documented Stable Renal Function" is defined as creatinine clearance or estimated glomerular filtration rate that is maintained for at least 3 months

Notes:

- The usual recommended dose for the Drug Products is 5mg twice daily. A reduced dose of 2.5mg twice daily is recommended for patients with at least two (2) of the following three (3) characteristics:
 - an age that is equal to or greater than 80 years
 - a body weight that is equal to or lower than 60kg, and
 - serum creatinine that is equal to or greater than 133 micromole/litre.
- Since renal impairment can increase bleeding risk, renal function should be regularly monitored. Other factors that increase bleeding risk should also be assessed and monitored (see Drug Products monograph).
- Patients starting on the Drug Products should have ready access to appropriate medical services to manage a major bleeding event.
- There is currently no data to support that the Drug Products provide adequate anticoagulation in patients with rheumatic valvular disease or those with prosthetic heart valves, so the Drug Products are not recommended in these populations.

Special Authorization may be granted for up to 24 months."

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

APIXABAN

UP - First-line therapy ineffective
UQ - First-line therapy not tolerated

PROPHYLAXIS OF VENOUS THROMBOEMBOLISM

SPECIAL AUTHORIZATION

Coverage Criteria:

"For the prophylaxis of venous thromboembolism ("VTE") following elective total hip replacement surgery or elective total knee replacement surgery, where the initial post-operative doses are administered in an acute care (hospital) setting.

OTHER CRITERIA:

The dosage shall be 2.5mg twice daily.

DURATION OF COVERAGE:

Up to a total of 35 days of coverage following elective total hip replacement; or,
Up to a total of 14 days of coverage following elective total knee replacement.

Notes:

- The total duration of therapy includes the period during which doses are administered post-operatively in an acute care (hospital) setting, and the approval period is for the balance of the total duration after discharge.
- The first dose is typically administered 12 to 24 hours after surgery, assuming adequate hemostasis has been achieved.
- Due to the lack of evidence for the efficacy or safety of sequential use of a low molecular weight heparin followed by the Drug Products for the prophylaxis of VTE, coverage is not intended for this practice.
- Clinical judgment is warranted to assess the increased risk for VTE and/or adverse effects in patients with a history of previous VTE, myocardial infarction, transient ischemic attack or ischemic stroke; a history of intraocular or intracerebral bleeding; a history of gastrointestinal disease with gastrointestinal bleeding; moderate or severe renal insufficiency (estimated creatinine clearance < 30mL/min); severe liver disease; concurrent use of other anticoagulants; or age greater than 75 years.
- The Drug Products have not been studied in clinical trials in patients undergoing hip fracture surgery, and is not recommended in these patients."

VENOUS THROMBOEMBOLIC EVENTS

SPECIAL AUTHORIZATION

COVERAGE:

"For the treatment of deep vein thrombosis (DVT) or pulmonary embolism (PE).

The recommended dose of apixaban for patients initiating DVT or PE treatment is 10 mg twice daily for 7 days, followed by 5 mg taken orally twice daily.

Drug plan coverage for apixaban is an alternative to heparin/warfarin for up to 6 months. When used for greater than 6 months, apixaban is more costly than heparin/warfarin. As such, patients with an intended duration of therapy greater than 6 months should be considered for initiation on heparin/warfarin.

Special authorization may be granted for up to 6 months."

All requests for apixaban must be completed using the

ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

APIXABAN

Apixaban/Dabigatran/Edoxaban/Rivaroxaban Special Authorization Request Form (ABC 60019).

2.5 MG ORAL TABLET

00002377233 ELIQUIS

BMS

\$

1.6336

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

APIXABAN

AT RISK PATIENTS WITH NON-VALVULAR ATRIAL FIBRILLATION

SPECIAL AUTHORIZATION (step therapy approval process)

FIRST-LINE DRUG PRODUCT(S): WARFARIN

Coverage Criteria

"Subject to the Exclusions From Coverage noted below, Members of Alberta Government Sponsored Drug Plans who are At-Risk with non-valvular atrial fibrillation (AF) who require the Drug Products for the prevention of stroke and systemic embolism AND in whom one of the following is also present:

- Inadequate Anticoagulation following at least a two month trial of warfarin; OR
- Anticoagulation using warfarin is contraindicated or not possible due to inability to regularly monitor the patient via International Normalized Ratio (INR) testing (i.e. no access to INR testing services at a laboratory, clinic, pharmacy, or at home).

Exclusions from Coverage:

- Patients with impaired renal function (creatinine clearance or estimated glomerular filtration rate <25 mL/min),
- Patients who are greater than or equal to 75 years of age and who do not have Documented Stable Renal Function,
- Patients who have hemodynamically significant rheumatic valvular heart disease, especially mitral stenosis, or,
- Patients who have a prosthetic heart valve.

Definitions:

- "At-Risk" means patients with atrial fibrillation are defined as those with a CHADS2 score of greater than or equal to 1. Prescribers may consider an antiplatelet regimen or oral anticoagulation for patients with a CHADS2 score of 1.
- "Inadequate Anticoagulation" is defined as INR testing results that are outside the desired INR range for at least 35% of the tests during the monitoring period (i.e. adequate anticoagulation is defined as INR test results that are within the desired INR range for at least 65% of the tests during the monitoring period).
- "Documented Stable Renal Function" is defined as creatinine clearance or estimated glomerular filtration rate that is maintained for at least 3 months

Notes:

- The usual recommended dose for the Drug Products is 5mg twice daily. A reduced dose of 2.5mg twice daily is recommended for patients with at least two (2) of the following three (3) characteristics:
 - an age that is equal to or greater than 80 years
 - a body weight that is equal to or lower than 60kg, and
 - serum creatinine that is equal to or greater than 133 micromole/litre.
- Since renal impairment can increase bleeding risk, renal function should be regularly monitored. Other factors that increase bleeding risk should also be assessed and monitored (see Drug Products monograph).
- Patients starting on the Drug Products should have ready access to appropriate medical services to manage a major bleeding event.
- There is currently no data to support that the Drug Products provide adequate anticoagulation in patients with rheumatic valvular disease or those with prosthetic heart valves, so the Drug Products are not recommended in these populations.

Special Authorization may be granted for up to 24 months."

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

APIXABAN

UP - First-line therapy ineffective
UQ - First-line therapy not tolerated

VENOUS THROMBOEMBOLIC EVENTS

SPECIAL AUTHORIZATION

COVERAGE:

"For the treatment of deep vein thrombosis (DVT) or pulmonary embolism (PE).

The recommended dose of apixaban for patients initiating DVT or PE treatment is 10 mg twice daily for 7 days, followed by 5 mg taken orally twice daily.

Drug plan coverage for apixaban is an alternative to heparin/warfarin for up to 6 months. When used for greater than 6 months, apixaban is more costly than heparin/warfarin. As such, patients with an intended duration of therapy greater than 6 months should be considered for initiation on heparin/warfarin.

Special authorization may be granted for up to 6 months."

All requests for apixaban must be completed using the Apixaban/Dabigatran/Edoxaban/Rivaroxaban Special Authorization Request Form (ABC 60019).

5 MG ORAL TABLET				
00002397714	ELIQUIS	BMS	\$	1.6336

APOMORPHINE HCL

"For adjunctive therapy in patients with advanced Parkinson's Disease (PD) who are receiving optimized PD therapy (including levodopa and derivatives AND dopaminergic agonists) for the acute, intermittent treatment of hypomobility "off" episodes ("end-of-dose wearing off" and unpredictable "on/off" episodes)."

For coverage, this drug must be initiated in consultation with a Neurologist.

Special authorization may be granted for 6 months.

For renewals, patients must continue to demonstrate clinically significant improvement in motor function.

10 MG / ML INJECTION				
00002459132	MOVAPO	PAL	\$	14.8184

ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

ARIPIPRAZOLE

"For the maintenance treatment of schizophrenia in patients who demonstrate a pattern of significant non-compliance that compromises therapeutic success and who possess clinical evidence of previous successful treatment with aripiprazole therapy;

AND who meet at least one of the following criteria:

- Experiences extra-pyramidal symptoms with either an oral or depot first generation antipsychotic agent that precludes the use of a first generation antipsychotic depot product; OR
- Is refractory to trials of at least two other antipsychotic therapies.

Special Authorization may be granted for six months."

All requests (including renewal requests) for aripiprazole prolonged release injection must be completed using the Aripiprazole/Paliperidone/Risperidone Prolonged Release Injection Special Authorization Request Form (ABC 60024).

The following product(s) are eligible for auto-renewal.

300 MG / VIAL INJECTION			
00002420864	ABILIFY MAINTENA	OTS	\$ 456.1800
400 MG / VIAL INJECTION			
00002420872	ABILIFY MAINTENA	OTS	\$ 456.1800

ASENAPINE MALEATE

"For the acute treatment of manic or mixed episodes associated with bipolar I disorder as co-therapy with lithium or divalproex sodium."

"For the acute treatment of manic or mixed episodes associated with bipolar I disorder as monotherapy, after a trial of lithium or divalproex sodium has failed due to intolerance or lack of response, or the presence of a contraindication to lithium or divalproex sodium as defined by the product monographs."

"Special authorization coverage may be granted for 24 months."

These products are eligible for auto-renewal.

5 MG (BASE) ORAL SUBLINGUAL TABLET			
00002374803	SAPHRIS	LBC	\$ 1.5225
10 MG (BASE) ORAL SUBLINGUAL TABLET			
00002374811	SAPHRIS	LBC	\$ 1.5225

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

ASFOTASE ALFA

1. ELIGIBILITY CRITERIA FOR ASFOTASE ALFA COVERAGE

In order to maintain the integrity of the ADBL, and having regard to the financial and social implications of covering asfotase alfa for the treatment of perinatal/infantile or juvenile-onset hypophosphatasia (HPP), the following special authorization criteria must be satisfied.

In order to be eligible for asfotase alfa coverage for the treatment of HPP, a patient must have submitted a completed Application and have satisfied all of the following requirements:

The patient must:

- 1) Be diagnosed with HPP in accordance with the requirements specified in the Clinical Criteria for asfotase alfa;
 - 2) Have Alberta government-sponsored drug coverage;
 - 3) Meet the Registration Requirements;
 - 4) Satisfy the Clinical Criteria for asfotase alfa (initial or continued coverage, as appropriate);
- AND
- 5) Meet the criteria specified in Discontinuance of Coverage.

There is no guarantee that any application, whether for initial or continued coverage, will be approved. Depending on the circumstances of each case, the Minister or the Minister's delegate may:

- approve an Application;
- approve an Application with conditions;
- deny an Application;
- discontinue an approved Application; OR
- defer an Application pending the provision of further supporting information.

The process for review and approval is explained in further detail below.

2. REGISTRATION REQUIREMENTS

If the patient is a citizen or permanent resident of Canada, the patient must be continuously registered in the Alberta Health Care Insurance Plan for a minimum of one (1) year prior to an application for coverage unless:

- the patient is less than one (1) year of age at the date of the application, then the patient's parent/guardian/legal representative must be registered continuously in the Alberta Health Care Insurance Plan for a minimum of one (1) year; OR
- the patient has moved to Alberta from another province or territory in Canada (the "province of origin"), and immediately prior to moving to Alberta, was covered for asfotase alfa in the province of origin by a provincial or territorial government sponsored drug plan, (or the province of origin provided equivalent coverage for asfotase alfa as does Alberta) and the patient has been registered in the Alberta Health Care Insurance Plan (the patient must provide supporting documentation from the province of origin to prove prior coverage).

If the patient is not a citizen or permanent resident of Canada, the patient must be continuously registered in the Alberta Health Care Insurance Plan for a minimum of five (5) years prior to an application for coverage unless:

- the patient is less than five years of age at the date of the application, then the patient's parent/guardian/legal representative must be registered continuously in the Alberta Health Care Insurance Plan for a minimum of five years; OR
- the patient has moved to Alberta from another province or territory in Canada (the "province of origin"), and immediately prior to moving to Alberta, was covered for asfotase alfa in the province of origin by a provincial or territorial government sponsored drug plan, (or the province of origin provided equivalent coverage for asfotase alfa as does Alberta) and the patient has been registered in the Alberta Health Care Insurance Plan (the patient must provide supporting documentation from the province of origin to prove prior coverage).

The Minister reserves the right to modify or waive the Registration Requirements applicable to a given patient if the patient or the patient's parent/guardian/legal representative can establish to the satisfaction of the Minister that the patient has not moved to Alberta for the sole/primary

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

ASFOTASE ALFA

purpose of obtaining coverage of asfotase alfa.

3. CLINICAL CRITERIA

"For enzyme replacement therapy (ERT) in patients with a confirmed diagnosis of perinatal/infantile or juvenile -onset hypophosphatasia (HPP). These patients must have been diagnosed prior to 12 years of age and have documented onset of signs/symptoms of HPP prior to 12 years of age.

Initiation Criteria:

1. Confirmed diagnosis of perinatal/infantile or juvenile-onset hypophosphatasia (HPP) as defined below:
 - Confirmed diagnosis via genetic testing (documented tissue-nonspecific alkaline phosphatase (TNSALP) gene mutations(s) AND
 - Serum alkaline phosphatase (ALP) level below the age-adjusted normal range (these are age and gender adjusted norms developed through CALIPER which are used as reference <https://apps.sbggh.mb.ca/labmanual/test/view?seedId=3662>) ANDNOTE: Below upper limit of normal refers to 2 or lower standard deviations above the mean
 - Plasma pyridoxal-5-phosphate (PLP) above the upper limit of normal established and validated in testing laboratory AND
 - Documented history of HPP-related skeletal abnormalities confirmed radiologically:
For Infantile HPP: Full skeletal survey done at baseline - examine chest, wrist, knees, and skull. Changes to monitor include: abnormalities of skeletal mineralization including severely undermineralized and even "absence" of some or all bones; undermineralized skull; functional craniosynostosis; gracile bones; thin ribs; chest deformities; evidence of recent/ healed fractures; non-traumatic fractures, recurrent or poorly healing fractures; at the ends of long bones evaluate widening of the growth plate (physis) with irregularity of the provisional zone of calcification; metaphyseal radiolucencies, flaring and fraying at ends of metaphyses and metadiaphyseal patchy focal sclerosis

For Juvenile HPP: Similar to above however generally milder

AND

2. Assessed by a metabolic specialist who determines that the criteria noted above has been met as well as documented signs/symptoms that includes:
 - a. For Infantile HPP: Failure to thrive AND poor growth AND gross motor delay with substantial skeletal disease. May also have hypercalcemia, B6-responsive seizures and/or respiratory failure, respiratory compromise, including decreased thoracic volume and/or pulmonary hypoplasia; need for respiratory support;
 - b. For Juvenile HPP: Poor weight gain; unusual gait or running; delayed walking (>15 months); impaired mobility, need for ambulatory assistance; knock-knees; or rickets/bowed legs; muscle weakness/hypotonia; joint pain; muscle pain; bone pain sufficient to limit activity and require medication
 - c. Childhood HPP (after 6 months of age): gait disturbance, fractures, rickets and RGIC score(NOTE: RGIC score is a 7-point score of Radiographic Global Impressive of Change ie RGIC score assesses changes from baseline and is obtained on paired sequential radiographs with a score of +2 indicating substantial healing/improvement in HPP-related skeletal abnormalities), Thacher score (NOTE: Thacher score is a 10-point Rickets Severity Scale validated for Vitamin D deficiency rickets (and also valid for HPP); score of 10 = severe rickets and 0 = no rickets based on quantified growth plate abnormalities at wrists and knees), bowing of legs, short stature unexplained by other reasons and/or pain score. RGIC and Thacher scores are ideal as they are validated in HPP but a comparable radiologic assessment by an expert bone pediatric radiologist could also be considered

3. Patient is not an adult (ie > 18 years of age) at the time treatment is initiated AND

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

ASFOTASE ALFA

4. Patient does not have odontoHPP, IE premature loss of deciduous teeth alone or pseudoHPP and vitamin D deficiency to be ruled out. Patients with craniosynostosis alone who do not have other criteria noted above for the diagnosis of HPP need to be followed closely as initiation of treatment with ERT may be indicated if other systemic signs and symptoms develop including muscle weakness, fractures, rickets, pain or nephrocalcinosis and/or if bony disease develops clinically and radiologically AND

5. Patients should be initiated on treatment and followed in a specialized clinic with expertise in the diagnosis and management of HPP. Goals of therapy should be developed on a case-by-case basis prior to the initiation of therapy depending on age and signs and symptoms at presentation.

Signs and symptoms to be monitored depend on age at diagnosis and may include:

a) For perinatal/infantile would expect in addition to above parameters to be followed goals of therapy should include discontinuation or reduction of ventilatory support, increased mobility (improvement in gait vs. baseline), attainment of age-appropriate gross motor milestones. Clinical, radiological and biochemical criteria should be surveilled and these pre-specified goals met at Coverage should be reassessed following a trial of 24 weeks of therapy or more frequently depending on clinical status of patient at initiation of therapy.

b) For juvenile Healing of rickets, improvement of bone mineralization and/bony deformities, fewer fractures, less pain, need for less pain medication, improved growth, increased mobility.

If Initiation Criteria met, 24 week trial to be followed by reassessment by a metabolic specialist

Of Note: Treatment with ERT may not be recommended for newborns who are unable to be successfully ventilated and who have respiratory failure, irreversible pulmonary hypoplasia (underdeveloped lungs with reduced number of alveoli for air exchange) as assessed postnatally by established clinical and radiologic criteria (narrow chest circumference and apparent low lung volumes, evidence for increased pulmonary resistance, MRI changes consistent with lung hypoplasia), very small chest walls, very thin or absent ribs radiologically as assessed by pediatric respirologist, radiologist and treating metabolic specialist. A 6 month trial of ERT may however be recommended for such infants by the treating metabolic specialist and consultants with the consent of the parents. Discontinuation of ERT should be considered at this point and baby moved to palliative care.

Continuation Criteria:

- Assessed by a metabolic specialist who determines that the pre-specified goals have been met and includes documented signs/symptoms noted above.
- Documented compliance by patient and family with respect to follow up visits and reevaluation of laboratory and radiological parameters.
- Additional 24 week trials to be followed by reassessment by a metabolic specialist.

If Continuation Criteria are not met, the treatment should not be continued. In addition, ERT should be discontinued for lack of compliance or if patient does not come for follow up appointments, in spite of all efforts to assist patient and family in this regard, development of craniosynostosis or premature loss of deciduous teeth alone would not signify failure of treatment and ERT should be continued provided other continuation criteria are met.

Stopping Criteria:

- Consider discontinuation after growth is completed based on objective measurement of height and closure of growth plates (closure to be confirmed by Xray criteria and report from a Radiologist).
- Criteria for tapering and discontinuing treatment should be developed by expert committee and evaluated on a case-by-case basis at all age groups.
- Babies with perinatal/infantile HPP who fail treatment trials of 6 months as described above may be discontinued from ERT and moved to palliative care.

*Reference will be made re: dosing and approved vial use to minimize wastage"

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

ASFOTASE ALFA

4. PROCESS FOR ASFOTASE ALFA COVERAGE

For both initial and continued coverage the following documents (the Application) must be completed and submitted:

- An Asfotase alfa Special Authorization Request Form completed by the patient's Metabolic Specialist;
- An Asfotase alfa Consent Form completed by the patient, or a patient's parent/guardian/legal representative, and the patient's Metabolic Specialist (for any initial coverage application); AND
- Any other documentation that may be required by the Minister or the Minister's delegate.

a. Expert Review

Once the Minister or the Minister's delegate has confirmed that the patient meets the Registration Requirement or granted a waiver of the Registration Requirement, the Application will be given to one or more Expert Advisors for review.

The Application, together with the recommendation or recommendations of the Expert Advisor(s), is then forwarded to the Minister or the Minister's delegate for a decision regarding coverage.

After the Minister or Minister's delegate has rendered a decision, the patient's Metabolic Specialist and the patient or patient's parent/guardian/legal representative will be notified by letter of the Minister's decision.

5. APPROVAL OF COVERAGE

The Minister or the Minister's delegate's decision in respect of an Application will specify the effective date of asfotase alfa coverage, if coverage is approved.

Initial coverage may be approved for a period of up to 26 weeks as follows: One dose of 2 mg/kg of asfotase alfa administered three times a week or one dose of 1 mg/kg of asfotase alfa administered six times a week (total of 78 doses for the 2mg/kg dosage regimen and a total of 156 doses for the 1 mg/kg dosage regimen).

Continued coverage may be approved for up to one dose of 2 mg/kg of asfotase alfa administered three times a week or one dose of 1 mg/kg of asfotase alfa administered six times a week for a period of six (6) months (total of 78 doses for the 2mg/kg dose and a total of 156 doses for the 1 mg/kg dose).

If a patient is approved for coverage, prescriptions for asfotase alfa must be written by a Metabolic Specialist. To avoid wastage, prescription quantities are limited to a two week supply. Extended quantity and vacation supplies are not permitted. The Government is not responsible and will not pay for costs associated with wastage or improper storage of asfotase alfa.

Approval of coverage is granted for a specific period, to a maximum of 26 weeks. If continued treatment is necessary, it is the responsibility of the patient or patient's parent/guardian/legal representative and the Metabolic Specialist to submit a new Application to re-apply for asfotase alfa coverage, and receive a decision thereon, prior to the expiry date of the authorization period.

6. WITHDRAWAL

Therapy may be withdrawn at the request of the patient or the patient's parent/guardian/legal representative at any time. Notification of withdrawal from therapy must be made by the Metabolic Specialist or patient in writing.

Applications, withdrawal requests, and any other information to be provided must be sent to Clinical Drug Services, Alberta Blue Cross.

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

ASFOTASE ALFA

18 MG / VIAL INJECTION			
00002444615	STRENSIQ	APG	\$ 1358.6400
28 MG / VIAL INJECTION			
00002444623	STRENSIQ	APG	\$ 2113.4400
40 MG / VIAL INJECTION			
00002444631	STRENSIQ	APG	\$ 3019.2000
80 MG / VIAL INJECTION			
00002444658	STRENSIQ	APG	\$ 6038.4000

AZITHROMYCIN

(Refer to Section 1 - Restricted Benefits of the Alberta Drug Benefit List for coverage of the product when prescribed by a Specialist in Infectious Diseases or a designated prescriber.)

"For the prevention of disseminated Mycobacterium avium complex disease in patients with advanced HIV infection or other immunocompromised conditions.

Special authorization may be granted for 6 months."*

*Special Authorization is only required when the prescriber prescribing the medication is not a Specialist in Infectious Diseases or a designated prescriber.

The following product(s) are eligible for auto-renewal.

600 MG ORAL TABLET			
00002261642	PMS-AZITHROMYCIN	PMS	\$ 10.6652

AZTREONAM

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

FIRST-LINE DRUG PRODUCT(S): TOBRAMYCIN INHALATION SOLUTION

"For the treatment of chronic pulmonary Pseudomonas aeruginosa infections when used as cyclic treatment (28-day cycles) in patients 6 years of age and older with moderate to severe cystic fibrosis (CF) and deteriorating clinical condition despite treatment with inhaled tobramycin.

Coverage will not be considered when inhaled aztreonam and other inhaled antibiotic(s) (e.g. levofloxacin, tobramycin) are intended for use in combination.

Special authorization may be granted for 6 months."

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

UP - First-line therapy ineffective
UQ - First-line therapy not tolerated

75 MG / VIAL INHALATION POWDER FOR SOLUTION			
00002329840	CAYSTON	GIL	\$ 44.0631

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

BENRALIZUMAB

"Special authorization coverage may be provided for add-on maintenance treatment of adult patients with severe eosinophilic asthma if the following clinical criteria and conditions are met:
Patient is inadequately controlled with high-dose inhaled corticosteroids (ICS) and one or more additional asthma controller(s) (e.g., a long-acting beta-agonist [LABA]).

AND

Patient has a blood eosinophil count of greater than or equal to 300 cells/mcL AND has experienced two or more clinically significant asthma exacerbations* in the 12 months prior to treatment initiation with benralizumab;

OR

Patient has a blood eosinophil count of greater than or equal to 150 cells/mcL AND is receiving daily maintenance treatment with oral corticosteroids (OCS).

For coverage, the drug must be initiated and monitored by a respirologist or clinical immunologist or allergist.

Initial coverage may be approved for a period of 12 months at a dosage of 30 mg administered every 4 weeks for the first 3 doses and 30 mg administered every 8 weeks thereafter.

-Patients will be limited to receiving one dose of benralizumab per prescription at their pharmacy.

-Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).

-Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.

-Coverage cannot be provided for benralizumab when this medication is intended for use in combination with other biologics for the treatment of asthma.

If ALL of the following criteria are met, special authorization may be approved for 30 mg administered every 8 weeks for a further 12-month period:

- 1) An improvement in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 when compared to pre-treatment baseline or an ACQ-5 score of less than or equal to 1; AND
- 2) Maintenance or reduction in the number of clinically significant exacerbations* compared to the 12 months prior to initiation of treatment with benralizumab; AND
- 3) For patients on daily maintenance therapy with OCS prior to initiating benralizumab, a decrease in the OCS dose.

Continued coverage may be considered for 30 mg administered every 8 weeks if ALL of the following criteria are met at the end of each additional 12-month period:

- 1) The ACQ-5 score achieved during the first 12 months of therapy is at least maintained throughout treatment or the ACQ-5 score is less than or equal to 1; AND
- 2) Maintenance or reduction in the number of clinically significant exacerbations* compared to the previous 12-month period; AND
- 3) For patients on daily maintenance therapy with OCS prior to initiating benralizumab, the reduction in the OCS dose achieved after the first 12 months of therapy is at least maintained throughout treatment.

* Clinically significant asthma exacerbation is defined as worsening of asthma such that the treating physician elected to administer systemic glucocorticoids for at least 3 days or the patient visited an emergency department or was hospitalized."

All requests (including renewal requests) for benralizumab must be completed using the Benralizumab/Mepolizumab Special Authorization Request Form (ABC 60061).

30 MG / SYR INJECTION SYRINGE

00002473232

FASENRA

AZC

\$ 3876.9200

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

BRIVARACETAM

"For adjunctive therapy in patients with refractory partial-onset seizures who meet all of the following criteria:

- Are currently receiving two or more antiepileptic medications, AND
- Have failed or demonstrated intolerance to three other antiepileptic medications, AND
- Patients are not receiving concurrent therapy with levetiracetam, AND,
- Therapy must be initiated by a Neurologist.

For the purpose of administering these criteria failure is defined as inability to achieve satisfactory seizure control.

Special authorization may be granted for six months.

Coverage cannot be provided for brivaracetam, eslicarbazepine, lacosamide or perampanel when these medications are intended for use in combination."

Each of these products is eligible for auto-renewal.

10 MG ORAL TABLET				
00002452936	BRIVLERA	UCB	\$	4.3200
25 MG ORAL TABLET				
00002452944	BRIVLERA	UCB	\$	4.3200
50 MG ORAL TABLET				
00002452952	BRIVLERA	UCB	\$	4.3200
75 MG ORAL TABLET				
00002452960	BRIVLERA	UCB	\$	4.3200
100 MG ORAL TABLET				
00002452979	BRIVLERA	UCB	\$	4.3200

BUDESONIDE

"For the treatment of inflammatory bowel disease (e.g. Crohn's, ulcerative colitis, ulcerative ileitis, etc.). This drug product must be prescribed by a specialist in Gastroenterology, Internal Medicine or Pediatrics (or by a specialist in General Surgery on a case-by-case basis, in geographic areas where access to these specialties is not available).

Special authorization may be granted for 12 months."

The following product(s) are eligible for auto-renewal.

3 MG ORAL CONTROLLED-RELEASE CAPSULE				
00002229293	ENTOCORT	TPG	\$	1.7583

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

BUDESONIDE/ FORMOTEROL FUMARATE DIHYDRATE

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

ASTHMA

FIRST-LINE DRUG PRODUCT(S): INHALED CORTICOSTEROID (ICS)

"For the treatment of asthma in patients uncontrolled on inhaled steroid therapy."

CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD)

FIRST-LINE DRUG PRODUCT(S): LONG-ACTING BRONCHODILATOR (I.E., LONG-ACTING BETA-2 AGONIST [LABA] OR LONG-ACTING MUSCARINIC ANTAGONIST [LAMA])

"For the long-term maintenance treatment of airflow obstruction in patients with moderate to severe (i.e., FEV1 < 80% predicted) chronic obstructive pulmonary disease (COPD), who have an inadequate response to a long-acting bronchodilator (long-acting beta-2 agonist [LABA] or long-acting muscarinic antagonist [LAMA])."

"For the long-term maintenance treatment of airflow obstruction in patients with severe (i.e., FEV1 < 50% predicted) chronic obstructive pulmonary disease (COPD)."

"Special authorization may be granted for 24 months."

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

UP - First-line therapy ineffective

All requests for budesonide + formoterol fumarate dihydrate must be completed using the Long-Acting Fixed-Dose Combination Products for Asthma/COPD Special Authorization Request Form (ABC 60025).

100 MCG / DOSE * 6 MCG / DOSE	INHALATION	METERED INHALATION POWDER		
00002245385	SYMBICORT 100 TURBUHALER	AZC	\$	0.5700
200 MCG / DOSE * 6 MCG / DOSE	INHALATION	METERED INHALATION POWDER		
00002245386	SYMBICORT 200 TURBUHALER	AZC	\$	0.7410

BUPRENORPHINE HCL

"For the management of opioid dependence in patients clinically stabilized on no more than 8 mg of sublingual (SL) buprenorphine for the preceding 90 days in combination with counseling and psychosocial support.

The patient should be under the care of a health care provider with experience in the diagnosis and management of opioid use disorder and has been trained to implant the buprenorphine subdermal implant.

Patients will be limited to receiving one kit per prescription at their pharmacy. Special authorization may be granted for 24 months."

80 MG (BASE)	SUBDERMAL	IMPLANT		
00002474921	PROBUPHINE	KTI	\$	1495.0000

ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

BUSERELIN ACETATE

"When prescribed for non-cancer, non-cosmetic or non-fertility indications.

Special authorization may be granted for 6 months."

Information is required regarding the patient's diagnosis/indication for use of this medication.

The following product(s) are eligible for auto-renewal.

1 MG / ML (BASE)	NASAL SOLUTION			
00002225158	SUPREFACT INTRANASAL	SAV	\$	8.5530
1 MG / ML (BASE)	INJECTION			
00002225166	SUPREFACT	SAV	\$	12.1873
6.3 MG (BASE)	INJECTION IMPLANT			
00002228955	SUPREFACT DEPOT	SAV	\$	827.8500

CABERGOLINE

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

FIRST-LINE DRUG PRODUCT(S): BROMOCRIPTINE

"For the treatment of hyperprolactinemia in patients who are intolerant to or who have failed bromocriptine. Special authorization may be granted for 24 months."

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

UP - First-line therapy ineffective

UQ - First-line therapy not tolerated

0.5 MG ORAL TABLET				
00002455897	APO-CABERGOLINE	APX	\$	12.3941
00002242471	DOSTINEX	PAL	\$	15.3098

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

CANAGLIFLOZIN

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

FIRST-LINE DRUG PRODUCT(S): METFORMIN
SECOND-LINE DRUG PRODUCT(S): SULFONYLUREAS
AND WHERE INSULIN IS NOT AN OPTION

As add-on therapy for the treatment of Type 2 diabetes in patients with intolerance to and/or inadequate glycemic control on:

- a sufficient trial (i.e. a minimum of 6 months) of metformin, AND
- a sulfonylurea, AND
- for whom insulin is not an option.

Or, for whom these products are contraindicated.

Special authorization may be granted for 24 months.

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

- UP - First-line therapy ineffective
- UQ - First-line therapy not tolerated
- CA - Prior adverse reaction
- CB - Previous treatment failure
- CJ - Product is not effective

All requests for canagliflozin must be completed using the DPP-4/SGLT2 Inhibitors/GLP-1 Receptor Agonist Special Authorization Request Form (ABC 60012).

100 MG ORAL TABLET				
00002425483	INVOKANA	JAI	\$	2.8560
300 MG ORAL TABLET				
00002425491	INVOKANA	JAI	\$	2.8560

CASPOFUNGIN

(Refer to Section 1 - Restricted Benefits of the Alberta Drug Benefit List for coverage of the product when prescribed by a Specialist in Infectious Diseases or a designated prescriber.)

"For treatment of esophageal candidiasis in patients who are resistant or intolerant to fluconazole or itraconazole.

For treatment of invasive candidiasis resistant or intolerant to fluconazole.

For treatment of Invasive Aspergillosis in patients who are refractory to or intolerant of other therapies."*

*Special Authorization is only required when the prescriber prescribing the medication is not a Specialist in Infectious Diseases or a designated prescriber.

50 MG / VIAL INJECTION				
00002460947	CASPOFUNGIN	MDA	\$	188.7000
00002244265	CANCIDAS	MFC	\$	222.0000
70 MG / VIAL INJECTION				
00002460955	CASPOFUNGIN	MDA	\$	188.7000
00002244266	CANCIDAS	MFC	\$	222.0000

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

CEFADROXIL

(Refer to Section 1 - Restricted Benefits of the Alberta Drug Benefit List for coverage of the product when prescribed by a Specialist in Infectious Diseases or a designated prescriber.)

"For the treatment of skin and skin structure infections."*

*Special Authorization is only required when the prescriber prescribing the medication is not a Specialist in Infectious Diseases or a designated prescriber.

500 MG ORAL CAPSULE

00002240774	APO-CEFADROXIL	APX	\$	0.8421
00002235134	TEVA-CEFADROXIL	TEV	\$	0.8421

CEFOXITIN SODIUM

(Refer to Section 1 - Restricted Benefits of the Alberta Drug Benefit List for coverage of the product when prescribed by a Specialist in Infectious Diseases or a designated prescriber.)

"For the treatment of Mycobacterium abscessus infection."*

*Special Authorization is only required when the prescriber prescribing the medication is not a Specialist in Infectious Diseases or a designated prescriber.

1 G / VIAL (BASE) INJECTION

00002291711	CEFOXITIN	APX	\$	10.6000
00002128187	CEFOXITIN SODIUM	TEV	\$	10.6000

2 G / VIAL (BASE) INJECTION

00002291738	CEFOXITIN	APX	\$	21.2500
00002128195	CEFOXITIN SODIUM	TEV	\$	21.2500

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

CELECOXIB

"1) For patients who are at high risk of upper gastrointestinal (GI) complications due to a proven history of prior complicated GI events (e.g. GI perforation, obstruction or major bleeding) or

2) For patients who have a documented history of ulcers proven radiographically and/or endoscopically.

Special authorization for both criteria may be granted for 6 months."

All requests for celecoxib must be completed using the Celecoxib Special Authorization Request Form (ABC 60032).

The following product(s) are eligible for auto-renewal.

100 MG ORAL CAPSULE

00002420155	ACT CELECOXIB	APH	\$	0.1279
00002418932	APO-CELECOXIB	APX	\$	0.1279
00002445670	AURO-CELECOXIB	AUR	\$	0.1279
00002426382	BIO-CELECOXIB	BMD	\$	0.1279
00002429675	CELECOXIB	SIV	\$	0.1279
00002424533	JAMP-CELECOXIB	JPC	\$	0.1279
00002420058	MAR-CELECOXIB	MAR	\$	0.1279
00002412497	MINT-CELECOXIB	MPI	\$	0.1279
00002355442	PMS-CELECOXIB	PMS	\$	0.1279
00002412373	RAN-CELECOXIB	RAN	\$	0.1279
00002442639	SDZ CELECOXIB	SDZ	\$	0.1279
00002239941	CELEBREX	PFI	\$	0.7196

200 MG ORAL CAPSULE

00002420163	ACT CELECOXIB	APH	\$	0.2558
00002418940	APO-CELECOXIB	APX	\$	0.2558
00002445689	AURO-CELECOXIB	AUR	\$	0.2558
00002426390	BIO-CELECOXIB	BMD	\$	0.2558
00002429683	CELECOXIB	SIV	\$	0.2558
00002424541	JAMP-CELECOXIB	JPC	\$	0.2558
00002420066	MAR-CELECOXIB	MAR	\$	0.2558
00002412500	MINT-CELECOXIB	MPI	\$	0.2558
00002355450	PMS-CELECOXIB	PMS	\$	0.2558
00002412381	RAN-CELECOXIB	RAN	\$	0.2558
00002442647	SDZ CELECOXIB	SDZ	\$	0.2558
00002239942	CELEBREX	PFI	\$	1.4395

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

CERTOLIZUMAB PEGOL

Rheumatoid Arthritis

"Special authorization coverage may be provided for use in combination with methotrexate for the reduction in signs and symptoms of severely active Rheumatoid Arthritis (RA) in adult patients (18 years of age or older) who are refractory or intolerant to:

- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- Methotrexate with other disease modifying anti-rheumatic agent(s) (minimum 4 month trial) [e.g., methotrexate with hydroxychloroquine or methotrexate with sulfasalazine]; AND
- Leflunomide (minimum 10 week trial at 20 mg daily)

Special authorization coverage of this agent may be provided for use as monotherapy in adult patients for whom methotrexate is contraindicated and/or for those patients who have experienced serious adverse effects.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.

'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for an initial dose of 400 mg (given as 2 subcutaneous injections of 200 mg each) at Weeks 0, 2 and 4. As an interim measure, coverage will be provided for additional doses of 400 mg per 4 weeks up to week 12, to allow time to determine whether the New Patient meets coverage criteria for Maintenance Dosing below.
- Patients will be limited to receiving a one-month supply of certolizumab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another (with the exception of anakinra) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients will not be permitted to switch from anakinra to other biologic agents except under exceptional circumstances.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond 12 weeks, the patient must meet the following criteria:

1) The patient must be assessed by an RA Specialist after the initial five doses to determine response.

2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:

- ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND

- An improvement of 0.22 in HAQ score [reported to two (2) decimal places].

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be approved for 400 mg per 4 weeks, for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:

1) The patient has been assessed by an RA Specialist to determine response;

2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:

- confirmation of maintenance of ACR20, or

- maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1)

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

CERTOLIZUMAB PEGOL

decimal place] from baseline.

3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above."

All requests (including renewal requests) for certolizumab for Rheumatoid Arthritis must be completed using the Abatacept/Adalimumab/Anakinra/Certolizumab/Etanercept/Golimumab/Infliximab/Sarilumab/Tocilizumab for Rheumatoid Arthritis Special Authorization Request Form (ABC 60027).

Ankylosing Spondylitis

"Special authorization coverage may be provided for the reduction in the signs and symptoms of severely active Ankylosing Spondylitis, as defined by the Modified New York criteria for Ankylosing Spondylitis, in adult patients (18 years of age or older) who have active disease as demonstrated by:

- a BASDAI greater than or equal to 4 units, demonstrated on 2 occasions at least 8 weeks apart AND
- a Spinal Pain VAS of greater than or equal to 4 cm (on a 0-10 cm scale), demonstrated on 2 occasions at least 8 weeks apart AND
- who are refractory or intolerant to treatment with 2 or more NSAIDS each taken for a minimum of 4 weeks at maximum tolerated or recommended doses.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.

'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

Initial coverage may be approved for an initial dose of 400 mg (given as 2 subcutaneous injections of 200 mg each) at Weeks 0, 2 and 4. As an interim measure, coverage will be provided for additional doses of 400 mg per 4 weeks up to week 12, to allow time to determine whether the New Patient meets coverage criteria for Maintenance Dosing below.

- Patients will be limited to receiving a one-month supply of certolizumab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond 12 weeks, the patient must meet the following criteria:

- 1) The patient must be assessed by an RA Specialist after the initial 5 doses to determine response.
- 2) The RA Specialist must confirm, in writing, that the patient is a 'responder' that meets the following criteria:
 - Reduction of the BASDAI score by at least 50% of the pre-treatment value or by 2 or more units, AND
 - Reduction of the Spinal Pain VAS by 2 cm or more.

Following this assessment, continued coverage may be approved for 400 mg per 4 weeks, for a period of 12 months. Ongoing coverage may be considered if the patient is re-assessed by an RA Specialist every 12 months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above."

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

CERTOLIZUMAB PEGOL

All requests (including renewal requests) for certolizumab for Ankylosing Spondylitis must be completed using the Adalimumab/Certolizumab/Etanercept/Golimumab/Infliximab/Secukinumab for Ankylosing Spondylitis Special Authorization Request Form (ABC 60028).

Psoriatic Arthritis

"Special authorization coverage may be provided for use in combination with methotrexate for reducing signs and symptoms and inhibiting the progression of structural damage of active arthritis in adult patients (18 years of age or older) with moderate to severe polyarticular psoriatic arthritis (PsA) or pauciarticular PsA with involvement of knee or hip joint who are refractory or intolerant to:

- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- An adequate trial of another disease modifying anti-rheumatic agent(s) (minimum 4 month trial). Special authorization coverage of this agent may be provided for use as monotherapy in adult patients for whom methotrexate is contraindicated and/or for those patients who have experienced serious adverse effects.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.

'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for an initial dose of 400 mg (given as 2 subcutaneous injections of 200 mg each) at Weeks 0, 2 and 4. As an interim measure, coverage will be provided for additional doses of 400 mg per 4 weeks up to week 12, to allow time to determine whether the New Patient meets coverage criteria for Maintenance Dosing below.
- Patients will be limited to receiving a one-month supply of certolizumab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond 12 weeks, the patient must meet the following criteria:

- 1) The patient must be assessed by an RA Specialist after the initial 5 doses to determine response.
- 2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
 - ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND
 - An improvement of 0.22 in HAQ score [reported to two (2) decimal places].

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be approved for 400 mg per 4 weeks, for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:

- 1) The patient has been assessed by an RA Specialist to determine response;
- 2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
 - Confirmation of maintenance of ACR20, or

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

CERTOLIZUMAB PEGOL

- Maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.
3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests. It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above."

All requests (including renewal requests) for certolizumab for Psoriatic Arthritis must be completed using the Adalimumab/Certolizumab/Etanercept/Golimumab/Infliximab/Ixekizumab/Secukinumab for Psoriatic Arthritis Special Authorization Request Form (ABC 60029).

200 MG / SYR INJECTION SYRINGE

<input checked="" type="checkbox"/>	00002331675	CIMZIA	UCB	\$	664.5100
<input checked="" type="checkbox"/>	00002465574	CIMZIA AUTO-INJECTOR	UCB	\$	664.5100

CLINDAMYCIN PHOSPHATE/ BENZOYL PEROXIDE

"For the treatment of severe acne as defined by scarring acne.

Special Authorization may be granted for 6 months."

The following product(s) are eligible for auto-renewal.

1 % * 3 % TOPICAL GEL

	00002382822	CLINDOXYL ADV	GSK	\$	0.7878
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"For the treatment of severe acne as defined by scarring acne.

Special Authorization may be granted for 6 months."

The following product(s) are eligible for auto-renewal.

1 % (BASE) * 5 % TOPICAL GEL

	00002440180	TARO-CLINDAMYCIN/BENZOYL PEROXIDE TAR		\$	0.6857
	00002243158	CLINDOXYL	GSK	\$	0.9598

"For the treatment of severe acne as defined by scarring acne.

Special Authorization may be granted for 6 months."

The following product(s) are eligible for auto-renewal.

1 % (BASE) * 5 % TOPICAL GEL

	00002464519	TARO-BENZOYL PEROXIDE/CLINDAMYCIN TAR		\$	0.7422
	00002248472	KIT BENZACLIN	VCL	\$	1.0328

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

CYCLOSPORINE

"For the treatment of severe psoriasis in those patients where other standard therapy has failed. This drug product must be prescribed by a specialist in Dermatology."

"For the treatment of severe rheumatoid arthritis in patients who are unable to tolerate or have failed an adequate trial of methotrexate. This drug product must be prescribed by a specialist in Rheumatology (or by a Specialist in Internal Medicine with an interest in Rheumatology on a case-by-case basis, in geographic areas where access to this specialty is not available)."

"For the treatment of steroid dependent and steroid resistant nephrotic syndrome. Consideration will be given where cyclosporine is used for the induction and maintenance of remissions or for the maintenance of steroid induced remissions. This drug product must be prescribed by a specialist in Pediatrics or Nephrology."

"Special authorization for all criteria may be granted for 6 months."

The following product(s) are eligible for auto-renewal.

10 MG ORAL CAPSULE			
00002237671	NEORAL	NOV	\$ 0.6545
25 MG ORAL CAPSULE			
00002247073	SANDOZ CYCLOSPORINE	SDZ	\$ 1.3050
00002150689	NEORAL	NOV	\$ 1.5220
50 MG ORAL CAPSULE			
00002247074	SANDOZ CYCLOSPORINE	SDZ	\$ 2.5450
00002150662	NEORAL	NOV	\$ 2.9680
100 MG ORAL CAPSULE			
00002242821	SANDOZ CYCLOSPORINE	SDZ	\$ 5.0900
00002150670	NEORAL	NOV	\$ 5.9380
100 MG / ML ORAL SOLUTION			
00002150697	NEORAL	NOV	\$ 5.2788

CYPROTERONE ACETATE

"When prescribed for non-cancer, non-cosmetic indications.

Special authorization may be granted for 6 months."

Information is required regarding the patient's diagnosis/indication for use of this medication.

The following product(s) are eligible for auto-renewal.

50 MG ORAL TABLET			
00000704431	ANDROCUR	PMS	\$ 1.4000
00002245898	CYPROTERONE	AAP	\$ 1.4000
00002390760	MED-CYPROTERONE	GMP	\$ 1.4000
100 MG / ML INJECTION			
00000704423	ANDROCUR DEPOT	PMS	\$ 32.8000

ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

CYSTEAMINE BITARTRATE

"For use in patients with an established diagnosis of infantile nephropathic cystinosis with documented cystinosis, lysosomal cystine transporter gene mutation.

For coverage, this drug must be prescribed by or in consultation with physician with experience in the diagnosis and management of cystinosis.

Special authorization may be granted for 12 months."

This product is eligible for auto-renewal.

25 MG ORAL DELAYED-RELEASE CAPSULE

00002464705 PROCYSBI RAP \$ 10.3500

"For use in patients with an established diagnosis of infantile nephropathic cystinosis with documented cystinosis, lysosomal cystine transporter gene mutation.

For coverage, this drug must be prescribed by or in consultation with physician with experience in the diagnosis and management of cystinosis.

Special authorization may be granted for 12 months."

This product is eligible for auto-renewal.

75 MG ORAL DELAYED-RELEASE CAPSULE

00002464713 PROCYSBI RAP \$ 31.0500

CYSTEAMINE HYDROCHLORIDE

For the treatment of corneal cystine crystal deposits (CCCDs) in adults and children from 2 years of age with a diagnosis of cystinosis.

For coverage, this drug must be initiated by an ophthalmologist experienced in the management of the ocular manifestations of cystinosis.

Special authorization may be granted for 12 months.

The following product(s) are eligible for auto-renewal.

0.37 % (BASE) OPHTHALMIC SOLUTION

00002485605 CYSTADROPS RRD \$ 397.2000

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

DABIGATRAN ETEXILATE

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

FIRST-LINE DRUG PRODUCT(S): WARFARIN

For at-risk patients (CHADS2 score of greater than or equal to 1) with non-valvular atrial fibrillation (AF) for the prevention of stroke and systemic embolism AND in whom:

- a) Anticoagulation is inadequate (at least 35% of INR testing results outside the desired range) following a reasonable trial on warfarin (minimum two months of therapy); OR
- b) Anticoagulation with warfarin is contraindicated as per the product monograph or not possible due to inability to regularly monitor via International Normalized Ratio (INR) testing (i.e. no access to INR testing services at a laboratory, clinic, pharmacy, and at home).

Patients with impaired renal function (creatinine clearance or estimated glomerular filtration rate less than 30mL/min) OR hemodynamically significant rheumatic valvular heart disease, especially mitral stenosis; OR prosthetic heart valves should not receive dabigatran.

Patients 75 years of age and greater should have documented stable renal function (creatinine clearance or estimated glomerular filtration rate maintained for at least three months of 30-49 ml/min for 110mg twice daily dosing or greater than or equal to 50 ml/min for 150mg twice daily dosing).

Since renal impairment can increase bleeding risk, renal function should be regularly monitored. Other factors that increase bleeding risk should also be assessed and monitored (see Drug Product Monograph).

Patients starting the drug product should have ready access to appropriate medical services to manage a major bleeding event.

There is currently no data to support that the Drug Product provides adequate anticoagulation in patients with rheumatic valvular disease or those with prosthetic heart valves, so Drug Product is not recommended in these populations.

Special Authorization may be granted for 24 months.

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

UP - First-line therapy ineffective
UQ - First-line therapy not tolerated

All requests for dabigatran must be completed using the Apixaban/Dabigatran/Edoxaban/Rivaroxaban Special Authorization Request Form (ABC 60019).

110 MG ORAL CAPSULE

00002468905	APO-DABIGATRAN	APX	\$	1.2540
00002312441	PRADAXA	BOE	\$	1.7121

150 MG ORAL CAPSULE

00002468913	APO-DABIGATRAN	APX	\$	1.2540
00002358808	PRADAXA	BOE	\$	1.7121

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

DACLATASVIR DIHYDROCHLORIDE

"For use as combination therapy with sofosbuvir for treatment-naive or treatment-experienced (1) adult patients with chronic hepatitis C (CHC) infection who meet all of the following criteria:

I) Prescribed by or in consultation with a hepatologist, gastroenterologist or infectious disease specialist (except on a case-by-case basis, in geographic areas where access to these specialties is not available);

AND

II) Laboratory confirmed hepatitis C infection with genotype 3;

AND

III) Laboratory confirmed quantitative HCV RNA value within the last 6 months;

AND

IV) Fibrosis (2) stage of F0 or greater (Metavir scale or equivalent).

Duration of therapy reimbursed:

- Treatment-naive or treatment-experienced genotype 3, without cirrhosis: 12 weeks in combination with sofosbuvir

Exclusion criteria:

- Patients currently being treated with another HCV antiviral agent

- Retreatment for failure or re-infection in patients who have received an adequate prior course of an HCV direct-acting antiviral drug regimen may be considered on an exceptional case-by-case basis

Notes:

1. Treatment-experienced is defined as those who failed prior therapy with an interferon-based regimen, including regimens containing an HCV protease inhibitor.

2. Fibrosis score test is optional. Acceptable methods include liver biopsy, transient elastography (FibroScan), fibrotest and serum biomarker panels (such as AST-to-Platelet Ratio Index or Fibrosis-4 score) either alone or in combination.

3. Compensated cirrhosis is defined as cirrhosis with Child-Turcotte-Pugh A (i.e. score 5 to 6).

4. Health care professionals are advised to refer to the product monograph and prescribing guidelines for appropriate use of the selected drugs, including use in special populations."

All requests for daclatasvir must be completed using the Antivirals for Chronic Hepatitis C Special Authorization Request Form (ABC 60022).

30 MG (BASE)	ORAL TABLET			
00002444747	DAKLINZA	BMS	\$	428.5715
60 MG (BASE)	ORAL TABLET			
00002444755	DAKLINZA	BMS	\$	428.5715

ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

FIRST-LINE DRUG PRODUCT(S): METFORMIN OR SULFONYLUREAS
SECOND-LINE DRUG PRODUCT(S): SULFONYLUREAS OR METFORMIN
AND WHERE INSULIN IS NOT AN OPTION

As add-on therapy to metformin or a sulfonylurea for the treatment of Type 2 diabetes in patients with intolerance to and/or inadequate glycemic control on:

- a sufficient trial (i.e. a minimum of 6 months) of metformin who have a contraindication or intolerance to a sulfonylurea, OR a sulfonylurea who have a contraindication or intolerance to metformin,
- AND for whom insulin is not an option.

Special authorization may be granted for 24 months.

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

- UP - First-line therapy ineffective
- UQ - First-line therapy not tolerated
- CA - Prior adverse reaction
- CB - Previous treatment failure
- CJ - Product is not effective

All requests for dapagliflozin must be completed using the DPP-4/SGLT2 Inhibitors/GLP-1 Receptor Agonist Special Authorization Request Form (ABC 60012).

5 MG (BASE) ORAL TABLET			
00002435462 FORXIGA	AZC	\$	2.7300
10 MG (BASE) ORAL TABLET			
00002435470 FORXIGA	AZC	\$	2.7300

ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

**DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE/ METFORMIN
HCL**

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

FIRST-LINE DRUG PRODUCT(S): METFORMIN OR SULFONYLUREAS
SECOND-LINE DRUG PRODUCT(S): SULFONYLUREAS OR METFORMIN
AND WHERE INSULIN IS NOT AN OPTION

"For the treatment of Type 2 diabetes in patients with inadequate glycemic control on:
- a sufficient trial (i.e. a minimum of 6 months) of metformin who have a contraindication or intolerance to a sulfonylurea, OR
- a sulfonylurea who have failed a sufficient trial of metformin, AND
- for whom insulin is not an option.

Special authorization may be granted for 24 months."

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

UP - First-line therapy ineffective
UQ - First-line therapy not tolerated
CA - Prior adverse reaction
CB - Previous treatment failure
CJ - Product is not effective

All requests for dapagliflozin+metformin must be completed using the DPP-4/SGLT2 Inhibitors/GLP-1 Receptor Agonist Special Authorization Request Form (ABC 60012).

5 MG * 850 MG ORAL TABLET			
00002449935 XIGDUO	AZC	\$	1.2250
5 MG * 1,000 MG ORAL TABLET			
00002449943 XIGDUO	AZC	\$	1.2250

DAPTOMYCIN

For the treatment of:

- Culture confirmed gram-positive infections from sterile sites, specifically Methicillin-resistant Staphylococcus aureus (MRSA), AND
- In patients who do not respond to, or exhibit multidrug intolerance to, or allergy to vancomycin, AND
- to facilitate patient discharge from hospital where it otherwise would not be possible.

This product must be prescribed in consultation with a specialist in Infectious Diseases in all instances.

Special Authorization may be granted for 12 months.

500 MG / VIAL INJECTION			
00002465493 CUBICIN RF	CUB	\$	191.0000

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

DARBEPOETIN

"For the treatment of anemia of chronic renal failure in patients with low hemoglobin (<95 g/L and falling). Patients must be iron replete prior to initiation of therapy as indicated by transferrin saturation >20%. Special authorization will be granted for twelve months.

According to current clinical practice, hemoglobin levels should be maintained between 95 g/L to 110 g/L and the dose should be held or reduced when hemoglobin is greater than or equal to 115 g/L. Doses should not exceed 300 mcg per month."

"For the treatment of chemotherapy-induced anemia in patients with non-myeloid malignancies with low hemoglobin (<100 g/L) in whom blood transfusions are not possible due to transfusion reactions, cross-matching difficulties or iron overload. If hemoglobin is rising by more than 20 g/L per month, the dose should be reduced by about 25%. Special authorization will be granted for twelve months."

In order to comply with the first criterion information must be provided regarding the patient's hemoglobin and transferrin saturation.

In order to comply with the second criterion: if the patient has iron overload the prescriber must state this in the request or alternatively, information is required regarding the patient's transferrin saturation, along with the results of liver function tests if applicable.

For the second criterion, renewal requests may be considered if the patient's hemoglobin is < 110 g/L while on therapy.

The following product(s) are eligible for auto-renewal for the indication of the treatment of anemia of chronic renal failure.

All requests for darbepoetin must be completed using the Darbepoetin/Epoetin Special Authorization Request Form (ABC 60006).

100 MCG / SYR INJECTION SYRINGE			
00002391775	ARANESP (0.5 ML SYRINGE)	AMG	\$ 268.0000
10 MCG / SYR INJECTION SYRINGE			
00002392313	ARANESP (0.4 ML SYRINGE)	AMG	\$ 26.8000
20 MCG / SYR INJECTION SYRINGE			
00002392321	ARANESP (0.5 ML SYRINGE)	AMG	\$ 53.6000
30 MCG / SYR INJECTION SYRINGE			
00002392348	ARANESP (0.3 ML SYRINGE)	AMG	\$ 80.4000
40 MCG / SYR INJECTION SYRINGE			
00002391740	ARANESP (0.4 ML SYRINGE)	AMG	\$ 107.2000
50 MCG / SYR INJECTION SYRINGE			
00002391759	ARANESP (0.5 ML SYRINGE)	AMG	\$ 134.0000
60 MCG / SYR INJECTION SYRINGE			
00002392356	ARANESP (0.3 ML SYRINGE)	AMG	\$ 160.8000
80 MCG / SYR INJECTION SYRINGE			
00002391767	ARANESP (0.4 ML SYRINGE)	AMG	\$ 214.4000
130 MCG / SYR INJECTION SYRINGE			
00002391783	ARANESP (0.65 ML SYRINGE)	AMG	\$ 348.4000
150 MCG / SYR INJECTION SYRINGE			
00002391791	ARANESP (0.3 ML SYRINGE)	AMG	\$ 439.7550
200 MCG / SYR INJECTION SYRINGE			
00002391805	ARANESP (0.4 ML SYRINGE)	AMG	\$ 621.2500
300 MCG / SYR INJECTION SYRINGE			
00002391821	ARANESP (0.6 ML SYRINGE)	AMG	\$ 950.6900
500 MCG / SYR INJECTION SYRINGE			
00002392364	ARANESP (1.0 ML SYR)	AMG	\$ 1584.4900

ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

DARIFENACIN HYDROBROMIDE

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

FIRST-LINE DRUG PRODUCT(S): SOLIFENACIN OR TOLTERODINE LA

"For patients who have failed on or are intolerant to solifenacin or tolterodine LA."

"Special authorization may be granted for 24 months."

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

UP - First-line therapy ineffective

UQ - First-line therapy not tolerated

7.5 MG (BASE)	ORAL EXTENDED-RELEASE TABLET			
00002273217	ENABLEX	SLP	\$	1.5820
15 MG (BASE)	ORAL EXTENDED-RELEASE TABLET			
00002273225	ENABLEX	SLP	\$	1.5820

ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

DEFERASIROX

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

FIRST-LINE DRUG PRODUCT(S): DEFEROXAMINE

"For patients who require iron chelation therapy but who have an inadequate response to a sufficient trial (i.e. a minimum of 6 months) of deferoxamine, or for whom deferoxamine is contraindicated.

Contraindications may include one or more of the following: known or suspected sensitivity to deferoxamine, recurrent injection or infusion-site reactions associated with deferoxamine administration (e.g., cellulitis), inability to obtain or maintain vascular access, severe needle phobia, concomitant bleeding disorders, immunocompromised patients with a risk of infection with parenteral administration, or risk of bleeding due to anticoagulation.

According to the product monograph, Jadenu (deferasirox) is contraindicated in high risk myelodysplastic syndrome (MDS) patients, any other MDS patient with a life expectancy less than one year and patients with other hematological and nonhematological malignancies who are not expected to benefit from chelation therapy due to the rapid progression of their disease.

Special authorization may be granted for 24 months."

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

UP - First-line therapy ineffective
UQ - First-line therapy not tolerated

90 MG ORAL TABLET

00002485265	APO-DEFERASIROX (TYPE J)	APX	\$	7.8908
00002452219	JADENU	NOV	\$	10.7580

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

DEFERASIROX

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

FIRST-LINE DRUG PRODUCT(S): DEFEROXAMINE

"For patients who require iron chelation therapy but who have an inadequate response to a sufficient trial (i.e. a minimum of 6 months) of deferoxamine, or for whom deferoxamine is contraindicated.

Contraindications may include one or more of the following: known or suspected sensitivity to deferoxamine, recurrent injection or infusion-site reactions associated with deferoxamine administration (e.g., cellulitis), inability to obtain or maintain vascular access, severe needle phobia, concomitant bleeding disorders, immunocompromised patients with a risk of infection with parenteral administration, or risk of bleeding due to anticoagulation.

According to the product monograph, Jadenu (deferasirox) is contraindicated in high risk myelodysplastic syndrome (MDS) patients, any other MDS patient with a life expectancy less than one year and patients with other hematological and nonhematological malignancies who are not expected to benefit from chelation therapy due to the rapid progression of their disease.

Special authorization may be granted for 24 months."

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

UP - First-line therapy ineffective
UQ - First-line therapy not tolerated

180 MG ORAL TABLET

00002485273	APO-DEFERASIROX (TYPE J)	APX	\$	15.7830
00002452227	JADENU	NOV	\$	21.5170

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

DEFERASIROX

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

FIRST-LINE DRUG PRODUCT(S): DEFEROXAMINE

"For patients who require iron chelation therapy but who have an inadequate response to a sufficient trial (i.e. a minimum of 6 months) of deferoxamine, or for whom deferoxamine is contraindicated.

Contraindications may include one or more of the following: known or suspected sensitivity to deferoxamine, recurrent injection or infusion-site reactions associated with deferoxamine administration (e.g., cellulitis), inability to obtain or maintain vascular access, severe needle phobia, concomitant bleeding disorders, immunocompromised patients with a risk of infection with parenteral administration, or risk of bleeding due to anticoagulation.

According to the product monograph, Jadenu (deferasirox) is contraindicated in high risk myelodysplastic syndrome (MDS) patients, any other MDS patient with a life expectancy less than one year and patients with other hematological and nonhematological malignancies who are not expected to benefit from chelation therapy due to the rapid progression of their disease.

Special authorization may be granted for 24 months."

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

UP - First-line therapy ineffective
UQ - First-line therapy not tolerated

360 MG ORAL TABLET

00002485281	APO-DEFERASIROX (TYPE J)	APX	\$	31.5683
00002452235	JADENU	NOV	\$	43.2020

125 MG ORAL DISPERSIBLE TABLET FOR SUSPENSION

00002461544	APO-DEFERASIROX	APX	\$	2.6204
00002464454	SANDOZ DEFERASIROX	SDZ	\$	2.6204
00002463520	TARO-DEFERASIROX	TAR	\$	2.6204
00002287420	EXJADE	NOV	\$	10.9525

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

DEFERASIROX

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

FIRST-LINE DRUG PRODUCT(S): DEFEROXAMINE

"For patients who require iron chelation therapy but who have an inadequate response to a sufficient trial (i.e. a minimum of 6 months) of deferoxamine, or for whom deferoxamine is contraindicated.

Contraindications may include one or more of the following: known or suspected sensitivity to deferoxamine, recurrent injection or infusion-site reactions associated with deferoxamine administration (e.g., cellulitis), inability to obtain or maintain vascular access, severe needle phobia, concomitant bleeding disorders, immunocompromised patients with a risk of infection with parenteral administration, or risk of bleeding due to anticoagulation.

According to the product monograph, Exjade (deferasirox) is contraindicated in high risk myelodysplastic syndrome (MDS) patients, any other MDS patient with a life expectancy less than one year and patients with other hematological and nonhematological malignancies who are not expected to benefit from chelation therapy due to the rapid progression of their disease.

Special authorization may be granted for 24 months."

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

UP - First-line therapy ineffective
UQ - First-line therapy not tolerated

250 MG ORAL DISPERSIBLE TABLET FOR SUSPENSION

00002461552	APO-DEFERASIROX	APX	\$	5.2410
00002464462	SANDOZ DEFERASIROX	SDZ	\$	5.2410
00002463539	TARO-DEFERASIROX	TAR	\$	5.2410
00002287439	EXJADE	NOV	\$	21.9282

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

DEFERASIROX

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

FIRST-LINE DRUG PRODUCT(S): DEFEROXAMINE

"For patients who require iron chelation therapy but who have an inadequate response to a sufficient trial (i.e. a minimum of 6 months) of deferoxamine, or for whom deferoxamine is contraindicated.

Contraindications may include one or more of the following: known or suspected sensitivity to deferoxamine, recurrent injection or infusion-site reactions associated with deferoxamine administration (e.g., cellulitis), inability to obtain or maintain vascular access, severe needle phobia, concomitant bleeding disorders, immunocompromised patients with a risk of infection with parenteral administration, or risk of bleeding due to anticoagulation.

According to the product monograph, Exjade (deferasirox) is contraindicated in high risk myelodysplastic syndrome (MDS) patients, any other MDS patient with a life expectancy less than one year and patients with other hematological and nonhematological malignancies who are not expected to benefit from chelation therapy due to the rapid progression of their disease.

Special authorization may be granted for 24 months."

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

UP - First-line therapy ineffective
UQ - First-line therapy not tolerated

500 MG ORAL DISPERSIBLE TABLET FOR SUSPENSION

00002461560	APO-DEFERASIROX	APX	\$	10.4824
00002464470	SANDOZ DEFERASIROX	SDZ	\$	10.4824
00002463547	TARO-DEFERASIROX	TAR	\$	10.4824
00002287447	EXJADE	NOV	\$	43.6857

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

DEFERIPRONE

"For the treatment of transfusional iron overload due to thalassemia syndromes in patients who require iron chelation therapy but who have an inadequate response to a sufficient trial (i.e. a minimum of 6 months) of deferoxamine, or for whom deferoxamine is contraindicated.

Contraindications to deferoxamine may include one or more of the following: known or suspected sensitivity to deferoxamine, recurrent injection or infusion-site reactions associated with deferoxamine administration (e.g., cellulitis), inability to obtain or maintain vascular access, severe needle phobia, concomitant bleeding disorders, immunocompromised patients with a risk of infection with parenteral administration, or risk of bleeding due to anticoagulation.

Special authorization may be granted for 6 months."

This product is eligible for auto-renewal.

All requests (including renewal requests) for deferiprone must be completed using the Deferiprone Special Authorization Request Form (ABC 60054).

1,000 MG ORAL TABLET

00002436558	FERRIPROX	APP	\$	31.8780
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100 MG / ML ORAL SOLUTION

00002436523	FERRIPROX	APP	\$	3.1878
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ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

DENOSUMAB

"For the treatment of osteoporosis in patients who have:

A high 10-year risk (i.e., greater than 20%) of experiencing a major osteoporotic fracture,
OR

A moderate 10-year fracture risk (10-20%) and have experienced a prior fragility fracture;

AND

at least one of the following:

1) For whom oral bisphosphonates are contraindicated due to drug-induced hypersensitivity (i.e., immunologically mediated),

OR

2) For whom oral bisphosphonates are contraindicated due to an abnormality of the esophagus which delays esophageal emptying,

OR

3) For whom bisphosphonates are contraindicated due to severe renal impairment (i.e. creatinine clearance < 35 mL/min),

OR

4) Who have demonstrated persistent severe gastrointestinal intolerance to a course of therapy with either alendronate or risedronate,

OR

5) Who had an unsatisfactory response (defined as a fragility fracture despite adhering to oral alendronate or risedronate treatment fully for 1 year and evidence of a decline in BMD below pre-treatment baseline level).

Note: The fracture risk can be determined by the World Health Organization's fracture risk assessment tool, FRAX, or the most recent (2010) version of the Canadian Association of Radiologists and Osteoporosis Canada (CAROC) table.

Special authorization may be granted for 12 months.

Patients will be limited to receiving one dose of denosumab per prescription at their pharmacy.

-Coverage cannot be provided for two or more osteoporosis medications (alendronate, denosumab, raloxifene, risedronate, zoledronic acid) when these medications are intended for use as combination therapy.

-Requests for other osteoporosis medications covered via special authorization will not be considered until 6 months after the last dose of denosumab 60 mg/syr injection syringe.

-Requests for other osteoporosis medications covered via special authorization will not be considered until 12 months after the last dose of zoledronic acid 0.05 mg/ml injection."

All requests for denosumab must be completed using the Denosumab/Zoledronic Acid for Osteoporosis Special Authorization Request Form (ABC 60007).

The following product(s) are eligible for auto-renewal.

60 MG / SYR INJECTION SYRINGE

00002343541 PROLIA

AMG

\$ 378.5700

ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

DIENOGEST

"For the management of pelvic pain associated with endometriosis in patients for whom one or more less costly hormonal options are either ineffective or not tolerated."

"Special authorization may be granted for 6 months."

"This Drug Product is eligible for auto-renewal."

2 MG ORAL TABLET

00002374900 VISANNE BAI \$ 2.0461

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

DIMETHYL FUMARATE

Relapsing Remitting Multiple Sclerosis (RRMS):

"Special authorization may be provided for the reduction of the frequency and severity of clinical relapses and reduction of the number and volume of active brain lesions, identified on MRI scans, in ambulatory adult patients (18 years of age or older) with relapsing remitting multiple sclerosis.

Coverage

For coverage, this drug must be prescribed by a registered MS Neurologist. A current assessment must be completed by a registered MS Neurologist at every request.

To register to become an MS Neurologist please complete the Registration for MS Neurologist Status Form (ABC 60002).

Initial Coverage

- 1) The registered MS Neurologist must confirm a diagnosis of RRMS;
- 2) The adult patient must have active disease which is defined as at least two relapses* of MS during the previous two years or in the two years prior to starting an MS disease modifying therapy (DMT).

*A relapse is defined as the appearance of new symptoms or worsening of old symptoms, lasting at least 48 hours in the absence of fever, not associated with withdrawal from steroids. Onset of clinical relapses must be separated by a period of at least one month. At least one definite gadolinium-enhancing T1 MRI lesion (not questionable faint enhancement) obtained at least 90 days after initiation of the DMT and at least 90 days before or after a relapse may substitute for one clinical relapse.

- 3) The adult patient must be ambulatory with or without aid (The registered MS Neurologist must provide a current updated Expanded Disability Status Scale (EDSS) score less than or equal to 6.5).

Coverage may be approved for up to 12 months. Adult patients will be limited to receiving a one-month supply of dimethyl fumarate per prescription at their pharmacy for the first 12 months of coverage.

Continued Coverage

For continued coverage beyond the initial coverage period, the adult patient must meet the following criteria:

- 1) The adult patient must be assessed by a registered MS Neurologist;
- 2) The registered MS Neurologist must confirm a diagnosis of RRMS;
- 3) The registered MS Neurologist must provide a current updated EDSS score. The adult patient must not have an EDSS score of 7.0 or above sustained for one year or more.

Coverage of this drug may be considered in an adult patient with a sustained EDSS score of 7.0 or above in exceptional circumstances. For MS DMT coverage to be considered, details of the exceptional circumstance must be provided in a letter from the registered MS Neurologist and accompany the Special Authorization Request Form.

Continued coverage may be approved for up to 12 months. Adult patients may receive up to 100 days' supply of dimethyl fumarate per prescription at their pharmacy.

Restarting After an Interruption in Therapy Greater Than 12 Months

ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

DIMETHYL FUMARATE

In order to be eligible for coverage, after an interruption in therapy greater than 12 months, the adult patient must meet the following criteria:

- 1) At least one relapse* per 12 month period; or
- 2) At least two relapses* during the previous 24 month period."

All requests (including renewal requests) for dimethyl fumarate must be completed using the Dimethyl Fumarate/Glatiramer Acetate/Interferon Beta-1a/Ocrelizumab/Peginterferon Beta-1a/Teriflunomide for RRMS/Interferon Beta-1b for SPMS or RRMS Special Authorization Request Form (ABC 60001).

120 MG ORAL DELAYED-RELEASE CAPSULE

00002404508 TECFIDERA

BIO

\$ 17.3422

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

DONEPEZIL HCL

"For the treatment of Alzheimer's disease in patients with an MMSE (Mini Mental State Exam) score between 10-26 and/or an InterRAI-Cognitive Performance Scale score between 1-4.

Coverage cannot be provided for two or more medications used in the treatment of Alzheimer's disease (donepezil, galantamine, rivastigmine) when these medications are intended for use in combination.

Special authorization coverage may be granted for a maximum of 24 months per request.

For each request, an updated MMSE score or InterRAI-Cognitive Performance Scale score and the date on which the exam was administered must be provided.

Renewal requests may be considered for patients where the updated MMSE score is 10 or higher or the InterRAI-Cognitive Performance Scale is 4 or lower while on this drug."

All requests (including renewal requests) for donepezil HCl must be completed using the Donepezil/Galantamine/Rivastigmine Special Authorization Request Form (ABC 60034).

5 MG ORAL TABLET

00002362260	APO-DONEPEZIL	APX	\$	0.4586
00002400561	AURO-DONEPEZIL	AUR	\$	0.4586
00002412853	BIO-DONEPEZIL	BMD	\$	0.4586
00002420597	DONEPEZIL	SIV	\$	0.4586
00002426846	DONEPEZIL	SNS	\$	0.4586
00002402645	DONEPEZIL HYDROCHLORIDE	AHI	\$	0.4586
00002416948	JAMP-DONEPEZIL	JPC	\$	0.4586
00002402092	MAR-DONEPEZIL	MAR	\$	0.4586
00002408600	MINT-DONEPEZIL	MPI	\$	0.4586
00002439557	NAT-DONEPEZIL	NTP	\$	0.4586
00002322331	PMS-DONEPEZIL	PMS	\$	0.4586
00002381508	RAN-DONEPEZIL	RAN	\$	0.4586
00002328666	SANDOZ DONEPEZIL	SDZ	\$	0.4586
00002428482	SEPTA DONEPEZIL	SEP	\$	0.4586
00002340607	TEVA-DONEPEZIL	TEV	\$	0.4586
00002232043	ARICEPT	PFI	\$	5.0779

10 MG ORAL TABLET

00002362279	APO-DONEPEZIL	APX	\$	0.4586
00002400588	AURO-DONEPEZIL	AUR	\$	0.4586
00002412861	BIO-DONEPEZIL	BMD	\$	0.4586
00002420600	DONEPEZIL	SIV	\$	0.4586
00002426854	DONEPEZIL	SNS	\$	0.4586
00002402653	DONEPEZIL HYDROCHLORIDE	AHI	\$	0.4586
00002416956	JAMP-DONEPEZIL	JPC	\$	0.4586
00002402106	MAR-DONEPEZIL	MAR	\$	0.4586
00002408619	MINT-DONEPEZIL	MPI	\$	0.4586
00002439565	NAT-DONEPEZIL	NTP	\$	0.4586
00002322358	PMS-DONEPEZIL	PMS	\$	0.4586
00002381516	RAN-DONEPEZIL	RAN	\$	0.4586
00002328682	SANDOZ DONEPEZIL	SDZ	\$	0.4586
00002428490	SEPTA DONEPEZIL	SEP	\$	0.4586
00002340615	TEVA-DONEPEZIL	TEV	\$	0.4586
00002232044	ARICEPT	PFI	\$	5.0779

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

ECULIZUMAB

ECULIZUMAB

1. ELIGIBILITY CRITERIA FOR ECULIZUMAB COVERAGE

In order to maintain the integrity of the ADBL, and having regard to the financial and social implications of covering eculizumab for the treatment of paroxysmal nocturnal hemoglobinuria (PNH), the following special authorization criteria must be satisfied.

In order to be eligible for eculizumab coverage for the treatment of PNH, a patient must have submitted a completed Application and have satisfied all of the following requirements:

The patient must:

- 1) Be diagnosed with PNH in accordance with the requirements specified in the Clinical Criteria for eculizumab;
- 2) Have Alberta government-sponsored drug coverage;
- 3) Meet the Registration Requirements;
- 4) Satisfy the Clinical Criteria for eculizumab (initial or continued coverage, as appropriate); AND
- 5) Meet the criteria specified in Contraindications to Coverage and Discontinuance of Coverage.

There is no guarantee that any application, whether for initial or continued coverage, will be approved. Depending on the circumstances of each case, the Minister or the Minister's delegate may:

- approve an Application;
- approve an Application with conditions;
- deny an Application;
- discontinue an approved Application; OR
- defer an Application pending the provision of further supporting information.

The process for review and approval is explained in further detail below.

2. REGISTRATION REQUIREMENTS

If the patient is a citizen or permanent resident of Canada, the patient must be continuously registered in the Alberta Health Care Insurance Plan for a minimum of one (1) year prior to an application for coverage unless:

- the patient is less than one (1) year of age at the date of the application, then the patient's parent/guardian/legal representative must be registered continuously in the Alberta Health Care Insurance Plan for a minimum of one (1) year; OR
- the patient has moved to Alberta from another province or territory in Canada (the "province of origin"), and immediately prior to moving to Alberta, was covered for eculizumab in the province of origin by a provincial or territorial government sponsored drug plan, (or the province of origin provided equivalent coverage for eculizumab as does Alberta) and the patient has been registered in the Alberta Health Care Insurance Plan (the patient must provide supporting documentation from the province of origin to prove prior coverage).

If the patient is not a citizen or permanent resident of Canada, the patient must be continuously registered in the Alberta Health Care Insurance Plan for a minimum of five (5) years prior to an application for coverage unless:

- the patient is less than five years of age at the date of the application, then the patient's parent/guardian/legal representative must be registered continuously in the Alberta Health Care Insurance Plan for a minimum of five years; OR
- the patient has moved to Alberta from another province or territory in Canada (the "province of origin"), and immediately prior to moving to Alberta, was covered for eculizumab in the province of origin by a provincial or territorial government sponsored drug plan, (or the province of origin provided equivalent coverage for eculizumab as does Alberta) and the patient has been registered in the Alberta Health Care Insurance Plan (the patient must provide supporting documentation from the province of origin to prove prior coverage).

The Minister reserves the right to modify or waive the Registration Requirements applicable to a given patient if the patient or the patient's parent/guardian/legal representative can establish to

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

ECULIZUMAB

the satisfaction of the Minister that the patient has not moved to Alberta for the sole/primary purpose of obtaining coverage of eculizumab.

3. CLINICAL CRITERIA

In addition to meeting Sections 1 and Sections 2 herein, to be considered for coverage of eculizumab, a patient must be assessed by a Specialist in Hematology (i.e. a physician who holds specialty certification in Hematology from the Royal College of Physicians and Surgeons of Canada) and meet all of the following clinical criteria (initial or continued coverage, as appropriate).

a. Clinical Criteria - Initial Coverage

All of the following Clinical Criteria must be established on the basis of evidence to the satisfaction of the Minister or the Minister's delegate for initial coverage:

1) The diagnosis of PNH must have been established by flow cytometry and/or a FLAER test. The proportion of circulating cells of each type which are GPI-deficient and hence of the PNH clone is quantitated by flow cytometry. Patients must have a:

- PNH granulocyte or monocyte clone size equal to or greater than 10%, AND
- Raised LDH (value at least 1.5 times the upper limit of normal for the reporting laboratory).

2) Patients with a granulocyte or monocyte clone size equal to or greater than 10% also require AT LEAST ONE of the following:

- Thrombosis: Evidence that the patient has had a thrombotic or embolic event which required the institution of therapeutic anticoagulant therapy;
- Transfusions: Evidence that the patient has been transfused with at least four (4) units of red blood cells in the last twelve (12) months;
- Anemia: Evidence that the patient has chronic or recurrent anemia where causes other than hemolysis have been excluded and demonstrated by more than one measure of less than or equal to 70g/L or by more than one measure of less than or equal to 100 g/L with concurrent symptoms of anemia;
- Pulmonary insufficiency: Evidence that the patient has debilitating shortness of breath and/or chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded;
- Renal insufficiency: Evidence that the patient has a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60mL/min/1.73m², where causes other than PNH have been excluded; OR
- Smooth muscle spasm: Evidence that the patient has recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded.

AND

3) All patients must receive meningococcal immunization with a quadravalent vaccine (A, C, Y and W135) at least two (2) weeks prior to receiving the first dose of eculizumab. Treating physicians will be required to submit confirmation of meningococcal immunizations in order for their patients to continue to be eligible for treatment with eculizumab. Pneumococcal immunization with a 23-valent polysaccharide vaccine and a 13-valent conjugate vaccine, and a Haemophilus influenza type b (Hib) vaccine must be given according to current clinical guidelines. All patients must be monitored and reimmunized according to current clinical guidelines for vaccine use.

b. Clinical Criteria - Continued Coverage

All of the following Clinical Criteria must be established on the basis of evidence to the satisfaction of the Minister or the Minister's delegate for continued coverage:

1) Patient eligibility must be reviewed six (6) months after commencing therapy and every six (6) months thereafter;

AND

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

ECULIZUMAB

2) Continued eligibility will be subject to the assessment of evidence, in accordance with the following monitoring requirements, which demonstrates:

- Clinical improvement in the patient, OR
- Stabilization of the patient's condition;

Monitoring requirements;

The patient's Specialist in Hematology must provide the following monitoring information every six (6) months:

- Lactate dehydrogenase (LDH);
- Full blood count and reticulocytes;
- Transfusion history for previous six months;
- Iron studies;
- Urea, electrolytes and eGFR;
- Recent clinical history; AND
- Any other information requested by the Minister, the Minister's delegate, or an Expert Advisor.

The patient's Specialist in Hematology must provide the following monitoring information every twelve (12) months:

- Confirmation that the patient has been immunized or reimmunized (meningococcal, pneumococcal 23-valent, pneumococcal 13-valent and Hib) according to current clinical guidelines for vaccine use;
- Progress reports on the clinical symptoms that formed the basis of initial eligibility;
- Quality of life, through clinical narrative;
- Granulocyte or monocyte clone size (by flow cytometry): AND
- Any other information requested by the Minister, the Minister's delegate, or an Expert Advisor.

c. Contraindications to Coverage

- Small clone size - granulocyte and monocyte clone sizes below 10%;
- Aplastic anaemia with two or more of the following: neutrophil count below $0.5 \times 10^9/L$, platelet count below $20 \times 10^9/L$, reticulocytes below $25 \times 10^9/L$, or severe bone marrow hypocellularity;
- Patients with a presence of another life threatening or severe disease where the long term prognosis is unlikely to be influenced by therapy (for example acute myeloid leukaemia or high-risk myelodysplastic syndrome); OR
- The presence of another medical condition that in the opinion of the Minister or Minister's delegate might reasonably be expected to compromise a response to therapy.

d. Discontinuation of Coverage

Coverage may be discontinued where one or more of the following situations apply:

- The patient or the patient's Specialist in Hematology fails to comply adequately with treatment or measures, including monitoring requirements, taken to evaluate the effectiveness of the therapy;
- There is a failure to provide the Minister, the Minister's delegate, or an Expert Advisor with information as required or as requested;
- If in the opinion of the Minister or the Minister's delegate, therapy fails to relieve the symptoms of disease that originally resulted in the patient being approved by the Minister or the Minister's delegate;
- The patient has (or develops) a condition referred to in Contraindications to Coverage.

The patient's Specialist in Hematology will be advised if their patient is at risk of being withdrawn from treatment for failure to comply with the above requirements or other perceived "non-compliance" and given a reasonable period of time to respond prior to coverage being discontinued.

4. PROCESS FOR ECULIZUMAB COVERAGE

For both initial and continued coverage the following documents (the Application) must be

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

ECULIZUMAB

completed and submitted:

- An Eculizumab Special Authorization Request Form completed by the patient's Specialist in Hematology;
- An Eculizumab Consent Form completed by the patient, or a patient's parent/guardian/legal representative, and the patient's Specialist in Hematology (for any initial coverage application); AND
- Any other documentation that may be required by the Minister or the Minister's delegate.

a. Expert Review

Once the Minister or the Minister's delegate has confirmed that the patient meets the Registration Requirement or granted a waiver of the Registration Requirement, the Application will be given to one or more Expert Advisors for review.

The Application, together with the recommendation or recommendations of the Expert Advisor(s), is then forwarded to the Minister or the Minister's delegate for a decision regarding coverage.

After the Minister or Minister's delegate has rendered a decision, the patient's Specialist in Hematology and the patient or patient's parent/guardian/legal representative will be notified by letter of the Minister's decision.

5. APPROVAL OF COVERAGE

The Minister or the Minister's delegate's decision in respect of an Application will specify the effective date of eculizumab coverage, if coverage is approved.

Initial coverage may be approved for a period of up to six (6) months as follows: One dose of 600mg of eculizumab administered weekly for the first four (4) weeks of treatment (total of four 600mg doses), followed by one dose of 900mg of eculizumab administered every two (2) weeks from week five (5) of treatment (total of eleven 900mg doses).

Continued coverage may be approved for up to one dose of 900mg of eculizumab administered every two (2) weeks, for a period of six (6) months (total of thirteen 900mg doses). If the patient restarts treatment after a lapse in therapy, continued coverage may be approved for a period of up to six (6) months as follows: One dose of 600mg of eculizumab administered weekly for the first four (4) weeks of treatment (total of four 600mg doses), followed by one dose of 900mg of eculizumab administered every two (2) weeks from week five (5) of treatment (total of eleven 900mg doses).

If a patient is approved for coverage, prescriptions for eculizumab must be written by a Specialist in Hematology. To avoid wastage, prescription quantities are limited to a two week supply. Extended quantity and vacation supplies are not permitted. The Government is not responsible and will not pay for costs associated with wastage or improper storage of eculizumab.

Approval of coverage is granted for a specific period, to a maximum of six (6) months. If continued treatment is necessary, it is the responsibility of the patient or patient's parent/guardian/legal representative and the Specialist in Hematology to submit a new Application to re-apply for eculizumab coverage, and receive a decision thereon, prior to the expiry date of the authorization period.

6. WITHDRAWAL

Therapy may be withdrawn at the request of the patient or the patient's parent/guardian/legal representative at any time. Notification of withdrawal from therapy must be made by the Specialist in Hematology or patient in writing.

Applications, withdrawal requests, and any other information to be provided must be sent to

ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

ECULIZUMAB

Clinical Drug Services, Alberta Blue Cross.

300 MG / VIAL INJECTION

00002322285 SOLIRIS

APG

\$ 6742.0000

ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

EDOXABAN TOSYLATE MONOHYDRATE

"AT RISK PATIENTS WITH NON-VALVULAR ATRIAL FIBRILLATION

SPECIAL AUTHORIZATION (step therapy approval process)

FIRST-LINE DRUG PRODUCT(S): WARFARIN

For at-risk patients (CHADS2 score of greater than or equal to 1) with non-valvular atrial fibrillation (AF) for the prevention of stroke and systemic embolism AND in whom one of the following is also present:

- Inadequate anticoagulation (at least 35% of INR testing results outside the desired range) following a reasonable trial of warfarin (minimum two months of therapy); OR
- Anticoagulation with warfarin is contraindicated as per the product monograph or not possible due to inability to regularly monitor via International Normalized Ratio (INR) testing (i.e. no access to INR testing services at a laboratory, clinic, pharmacy, or at home).

Note: Some or all direct oral anticoagulants may have contraindications to use or precautions with use, for example: related to prosthetic heart valve disease, rheumatic valvular heart disease, renal function, or age. Refer to the product monograph for additional information.

Special Authorization may be granted for 24 months.

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

- UP - First-line therapy ineffective
- UQ - First-line therapy not tolerated

VENOUS THROMBOEMBOLIC EVENTS

SPECIAL AUTHORIZATION

For the treatment of deep vein thrombosis (DVT) or pulmonary embolism (PE).

The recommended dose of edoxaban for patients initiating DVT or PE treatment is 60 mg once daily following initial use of a parenteral anticoagulant for 5-10 days. A reduced dose of 30 mg once daily is recommended for patients with one or more of the following clinical factors:

- moderate renal impairment (creatinine clearance (CrCL) 30-50 mL/min)
- low body weight <= 60 kg (132 lbs)
- concomitant use of p-glycoprotein inhibitors except amiodarone and verapamil.

Drug plan coverage for edoxaban is an alternative to heparin/warfarin for up to 6 months. When used for greater than 6 months, edoxaban is more costly than heparin/warfarin. As such, patients with an intended duration of therapy greater than 6 months should be considered for initiation on heparin/warfarin.

Special authorization may be granted for up to 6 months."

All requests for edoxaban must be completed using the Apixaban/Dabigatran/Edoxaban/Rivaroxaban Special Authorization Request Form (ABC 60019).

15 MG (BASE)	ORAL TABLET			
00002458640	LIXIANA	SEV	\$	2.9053
30 MG (BASE)	ORAL TABLET			
00002458659	LIXIANA	SEV	\$	2.9053
60 MG (BASE)	ORAL TABLET			
00002458667	LIXIANA	SEV	\$	2.9053

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

ELBASVIR/ GRAZOPRE VIR

"For treatment-naive or treatment-experienced (1) adult patients with chronic hepatitis C (CHC) infection who meet all of the following criteria:

I) Prescribed by or in consultation with a hepatologist, gastroenterologist or infectious disease specialist (except on a case-by-case basis, in geographic areas where access to these specialties is not available);

AND

II) Laboratory confirmed hepatitis C genotype 1 or genotype 4;

AND

III) Laboratory confirmed quantitative HCV RNA value within the last 6 months;

AND

IV) Fibrosis (2) stage of F0 or greater (Metavir scale or equivalent).

Duration of therapy reimbursed:

- Treatment-naive, without cirrhosis or with compensated cirrhosis (3): 12 weeks*

- Treatment-experienced relapsers, without cirrhosis or with compensated cirrhosis (3): 12 weeks

- Treatment-experienced genotype 1b who have had on-treatment virologic failures (4), without cirrhosis or with compensated cirrhosis (3): 12 weeks

- Treatment-experienced genotype 1a or genotype 4 who have had on-treatment virologic failures (4), without cirrhosis or with compensated cirrhosis (3): 16 weeks in combination with ribavirin

*Note: As approved by Health Canada, 8 weeks may be considered in treatment-naive genotype 1b patients without significant fibrosis or cirrhosis as determined by liver biopsy (i.e., Metavir F0-F2) or by non-invasive tests.

Exclusion criteria:

- Patients currently being treated with another HCV antiviral agent

- Retreatment for failure or re-infection in patients who have received an adequate prior course of an HCV direct-acting antiviral drug regimen may be considered on an exceptional case-by-case basis

- Combination therapy with sofosbuvir will not be considered for any genotypes

Notes:

1. Treatment experienced for patients with genotype 1 is defined as patients who have been previously treated with a pegylated interferon + ribavirin regimen or a protease inhibitor + pegylated interferon + ribavirin regimen and have not experienced adequate response.

Treatment experienced for patients with genotype 4 is defined as patients who have been previously treated with a pegylated interferon + ribavirin regimen and have not experienced adequate response.

2. Fibrosis score test is optional. Acceptable methods include liver biopsy, transient elastography (FibroScan), fibrotest and serum biomarker panels (such as AST-to-Platelet Ratio Index or Fibrosis-4 score) either alone or in combination.

3. Compensated cirrhosis is defined as cirrhosis with Child-Turcotte-Pugh A (i.e. score 5 to 6).

4. On-treatment virologic failures are patients who have not experienced adequate response to prior treatment, including a null response, partial response or virologic breakthrough or rebound.

5. Health care professionals are advised to refer to the product monograph and prescribing guidelines for appropriate use of the selected drug, including use in special populations."

All requests for elbasvir/grazoprevir must be completed using the Antivirals for Chronic Hepatitis C Special Authorization Request Form (ABC 60022).

50 MG * 100 MG ORAL TABLET

00002451131 ZEPATIER

MFC

\$ 666.9400

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

EMPAGLIFLOZIN

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

"FIRST-LINE DRUG PRODUCT(S): METFORMIN

As add-on therapy for the treatment of Type 2 diabetes in patients with intolerance to and/or inadequate glycemic control on:

- a sufficient trial (i.e. a minimum of 6 months) of metformin, AND
- a sulfonylurea, AND
- for whom insulin is not an option.

Or, for whom these products are contraindicated.

As an adjunct to diet, exercise, and standard care therapy to reduce the incidence of cardiovascular (CV) death in patients with Type 2 diabetes and established cardiovascular diseases who have an inadequate glycemic control, if the following criteria are met:

- a sufficient trial (i.e. a minimum of 6 months) of metformin, AND
- established cardiovascular disease* as defined in the EMPA-REG OUTCOME trial

* Established cardiovascular disease is defined on the basis of one of the following:

- 1) History of myocardial infarction (MI)
- 2) Multi-vessel coronary artery disease in two or more major coronary arteries (irrespective of revascularization status)
- 3) Single-vessel coronary artery disease with significant stenosis and either a positive non-invasive stress test or discharged from hospital with a documented diagnosis of unstable angina within the last 12 months
- 4) Last episode of unstable angina greater than 2 months prior with confirmed evidence of coronary multi-vessel or single-vessel disease
- 5) History of ischemic or hemorrhagic stroke
- 6) Occlusive peripheral artery disease

Special authorization may be granted for 24 months.

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

- UP - First-line therapy ineffective
- UQ - First-line therapy not tolerated
- CA - Prior adverse reaction
- CB - Previous treatment failure
- CJ - Product is not effective"

All requests for empagliflozin must be completed using the DPP-4/SGLT2 Inhibitors/GLP-1 Receptor Agonist Special Authorization Request Form (ABC 60012).

10 MG ORAL TABLET

00002443937	JARDIANCE	BOE	\$	2.7276
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25 MG ORAL TABLET

00002443945	JARDIANCE	BOE	\$	2.7276
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**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

EMPAGLIFLOZIN/ METFORMIN HCL

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

"FIRST-LINE DRUG PRODUCT(S): METFORMIN

As add-on therapy for the treatment of Type 2 diabetes in patients with intolerance to and/or inadequate glycemic control on:

- a sufficient trial (i.e. a minimum of 6 months) of metformin, AND
- a sulfonylurea, AND
- for whom insulin is not an option.

Or, for whom these products are contraindicated.

As an adjunct to diet, exercise, and standard care therapy to reduce the incidence of cardiovascular (CV) death in patients with Type 2 diabetes and established cardiovascular diseases who have an inadequate glycemic control, if the following criteria are met:

- a sufficient trial (i.e. a minimum of 6 months) of metformin, AND
- established cardiovascular disease* as defined in the EMPA-REG OUTCOME trial

* Established cardiovascular disease is defined on the basis of one of the following:

- 1) History of myocardial infarction (MI)
- 2) Multi-vessel coronary artery disease in two or more major coronary arteries (irrespective of revascularization status)
- 3) Single-vessel coronary artery disease with significant stenosis and either a positive non-invasive stress test or discharged from hospital with a documented diagnosis of unstable angina within the last 12 months
- 4) Last episode of unstable angina greater than 2 months prior with confirmed evidence of coronary multi-vessel or single-vessel disease
- 5) History of ischemic or hemorrhagic stroke
- 6) Occlusive peripheral artery disease

Special authorization may be granted for 24 months.

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

- UP - First-line therapy ineffective
- UQ - First-line therapy not tolerated
- CA - Prior adverse reaction
- CB - Previous treatment failure
- CJ - Product is not effective"

All requests for empagliflozin+metformin must be completed using the DPP-4/SGLT2 Inhibitors/GLP-1 Receptor Agonist Special Authorization Request Form (ABC 60012).

5 MG * 500 MG ORAL TABLET			
00002456575 SYNJARDY	BOE	\$	1.3783
5 MG * 850 MG ORAL TABLET			
00002456583 SYNJARDY	BOE	\$	1.3783
5 MG * 1,000 MG ORAL TABLET			
00002456591 SYNJARDY	BOE	\$	1.3783
12.5 MG * 500 MG ORAL TABLET			
00002456605 SYNJARDY	BOE	\$	1.3783
12.5 MG * 850 MG ORAL TABLET			
00002456613 SYNJARDY	BOE	\$	1.3783
12.5 MG * 1,000 MG ORAL TABLET			
00002456621 SYNJARDY	BOE	\$	1.3783

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

EPLERENONE

"For persons suffering from New York Heart Association (NYHA) class II chronic heart failure with left ventricular systolic dysfunction with ejection fraction less than or equal to 35 per cent, as a complement to standard therapy."

Special authorization will be granted for 12 months.

This product is eligible for auto-renewal.

All requests (including renewal requests) for eplerenone must be completed using the Eplerenone/Ivabradine/Sacubitril+Valstartan Special Authorization Request Form (ABC 60050).

25 MG ORAL TABLET

00002471442	MINT-EPLERENONE	MPI	\$	2.0595
00002323052	INSPRA	PFI	\$	2.8457

50 MG ORAL TABLET

00002471450	MINT-EPLERENONE	MPI	\$	2.0595
00002323060	INSPRA	PFI	\$	2.8457

EPOETIN ALFA

"For the treatment of anemia of chronic renal failure in patients with low hemoglobin (< 95 g/L and falling). Patients must be iron replete prior to initiation of therapy as indicated by transferrin saturation >20%. Special authorization will be granted for twelve months.

According to current clinical practice, hemoglobin levels should be maintained between 95 g/L to 110 g/L and the dose should be held or reduced when hemoglobin is greater than or equal to 115 g/L. Doses should not exceed 60,000 units per month."

"For the treatment of anemia in AZT-treated/HIV infected patients. Special authorization will be granted for twelve months."

"For the treatment of chemotherapy-induced anemia in patients with non-myeloid malignancies with low hemoglobin (<100 g/L) in whom blood transfusions are not possible due to transfusion reactions, cross-matching difficulties or iron overload. If hemoglobin is rising by more than 20 g/L per month, the dose should be reduced by about 25%. Special authorization will be granted for twelve months."

In order to comply with the first criterion information must be provided regarding the patient's hemoglobin and transferrin saturation.

In order to comply with the third criterion: if the patient has iron overload the prescriber must state this in the request or alternatively, information is required regarding the patient's transferrin saturation, along with the results of liver function tests if applicable.

For the third criterion, renewal requests may be considered if the patient's hemoglobin is < 110 g/L while on therapy.

The following product(s) are eligible for auto-renewal for the indication of treatment of anemia of chronic renal failure.

All requests for epoetin alfa must be completed using the Darbepoetin/Epoetin Special Authorization Request Form (ABC 60006).

1,000 UNIT / SYR INJECTION SYRINGE

00002231583	EPREX (0.5 ML SYRINGE)	JAI	\$	14.2500
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2,000 UNIT / SYR INJECTION SYRINGE

00002231584	EPREX (0.5 ML SYRINGE)	JAI	\$	28.5000
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3,000 UNIT / SYR INJECTION SYRINGE

00002231585	EPREX (0.3 ML SYRINGE)	JAI	\$	42.7500
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**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

EPOETIN ALFA

4,000 UNIT / SYR	INJECTION	SYRINGE		
00002231586	EPREX (0.4 ML SYRINGE)		JAI	\$ 57.0000
5,000 UNIT / SYR	INJECTION	SYRINGE		
00002243400	EPREX (0.5 ML SYRINGE)		JAI	\$ 71.2500
6,000 UNIT / SYR	INJECTION	SYRINGE		
00002243401	EPREX (0.6 ML SYRINGE)		JAI	\$ 85.5000
8,000 UNIT / SYR	INJECTION	SYRINGE		
00002243403	EPREX (0.8 ML SYRINGE)		JAI	\$ 114.0000
10,000 UNIT / SYR	INJECTION	SYRINGE		
00002231587	EPREX (1 ML SYRINGE)		JAI	\$ 142.5000
20,000 UNIT / SYR	INJECTION	SYRINGE		
00002243239	EPREX (0.5 ML SYRINGE)		JAI	\$ 313.3200

EPOETIN ALFA

"For the treatment of chemotherapy-induced anemia in patients with non-myeloid malignancies with low hemoglobin (<100 g/L) in whom blood transfusions are not possible due to transfusion reactions, cross-matching difficulties or iron overload. If hemoglobin is rising by more than 20 g/L per month, the dose should be reduced by about 25%. Patients may be granted a maximum allowable dose of 40,000 IU per week. Special authorization will be granted for twelve months."

In order to comply with this criterion, if the patient has iron overload the prescriber must state this in the request, or alternatively, information is required regarding the patient's transferrin saturation, along with the results of liver function tests, if applicable.

Renewal requests may be considered if the patient's hemoglobin is <110 g/L while on therapy.

All requests for epoetin alfa must be completed using the Darbepoetin/Epoetin Special Authorization Request Form (ABC 60006).

30,000 UNIT / SYR	INJECTION	SYRINGE		
00002288680	EPREX		JAI	\$ 360.8300
40,000 UNIT / SYR	INJECTION	SYRINGE		
00002240722	EPREX		JAI	\$ 470.0200

ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

ERTAPENEM

(Refer to Section 1 - Restricted Benefits of the Alberta Drug Benefit List for coverage of the product when prescribed by a Specialist in Infectious Diseases or a designated prescriber.)

"For therapy of complicated polymicrobial skin and skin structure infections."*

"For the therapy of community-acquired intra-abdominal infections."*

"For culture & susceptibility directed therapy against infections with Enterobacteriaceae producing AmpC or extended-spectrum beta-lactamases (ESBLs) where there is resistance to first line agents."*

"For use in other Health Canada approved indications, in consultation with a specialist in Infectious Diseases."*

*Special Authorization is only required when the prescriber prescribing the medication is not a Specialist in Infectious Diseases or a designated prescriber.

In order to comply with all of the above criteria, information is required regarding the type of infection and organisms involved. Also, where the criteria restrict coverage of the requested drug to non-first line therapy, information is required regarding previous first-line antibiotic therapy that has been utilized, the patient's response to therapy, and the first line agents the organism is resistant to or why other first-line therapies cannot be used in this patient. Also, where applicable, the specialist in Infectious Diseases that recommended this drug is required.

1 G / VIAL INJECTION

00002247437 INVANZ MFC \$ 55.8246

ESLICARBAZEPINE ACETATE

"For adjunctive therapy in patients with refractory partial-onset seizures who meet all of the following criteria:

- Are currently receiving two or more antiepileptic medications, AND
- Have failed or demonstrated intolerance to three other antiepileptic medications, AND
- Therapy must be initiated by a Neurologist.

For the purpose of administering these criteria failure is defined as inability to achieve satisfactory seizure control.

Special authorization may be granted for six months.

Coverage cannot be provided for brivaracetam, eslicarbazepine, lacosamide or perampanel when these medications are intended for use in combination."

Each of these products is eligible for auto-renewal.

200 MG ORAL TABLET

00002426862 APTIOM SUN \$ 9.8700

400 MG ORAL TABLET

00002426870 APTIOM SUN \$ 9.8700

600 MG ORAL TABLET

00002426889 APTIOM SUN \$ 9.8700

800 MG ORAL TABLET

00002426897 APTIOM SUN \$ 9.8700

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

ETANERCEPT

25 MG / VIAL INJECTION

00002242903 ENBREL AMG \$ 200.7100

Ankylosing Spondylitis

***Effective March 1, 2018, all new Special Authorization requests for the treatment of Rheumatoid Arthritis or Ankylosing Spondylitis for etanercept-naïve patients will be assessed for coverage with Brenzys or Erelzi. Effective June 1, 2019, all new Special Authorization requests for the treatment of Psoriatic Arthritis for etanercept-naïve patients will be assessed for coverage with Erelzi. Enbrel will not be approved for new etanercept starts for patients with the indications stated above; however, coverage for Enbrel will continue for patients who are currently well maintained on Enbrel and are considered a 'responder' as defined in criteria.

In addition, all new Special Authorization requests for the treatment of Polyarticular Juvenile Idiopathic Arthritis for etanercept-naïve patients weighing 63 kg (138 pounds) or more will be assessed for coverage with Erelzi. Enbrel will be approved for new etanercept starts for pediatric patients with Polyarticular Juvenile Idiopathic Arthritis weighing less than 63 kg, and coverage for Enbrel will continue for patients who are currently well maintained on Enbrel and are considered a 'responder' as defined in criteria.

Additionally, patients will not be permitted to switch between etanercept products, if the patient has been previously trialed on any etanercept product and deemed unresponsive to therapy.***

"Special authorization coverage may be provided for the reduction in the signs and symptoms of severely active Ankylosing Spondylitis, as defined by the Modified New York criteria for Ankylosing Spondylitis, in adult patients (18 years of age or older) who have active disease as demonstrated by:

- a BASDAI greater than or equal to 4 units, demonstrated on 2 occasions at least 8 weeks apart AND
- a Spinal Pain VAS of greater than or equal to 4 cm (on a 0-10 cm scale), demonstrated on 2 occasions at least 8 weeks apart AND
- who are refractory or intolerant to treatment with 2 or more NSAIDS each taken for a minimum of 4 weeks at maximum tolerated or recommended doses.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.

'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for 50 mg per week for 12 weeks.
- Patients will be limited to receiving a one-month supply of etanercept per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond 12 weeks, the patient must meet the following criteria:

- 1) The patient must be assessed at week 12 by an RA Specialist after the initial twelve weeks of therapy to determine response.
- 2) The RA Specialist must confirm, in writing, that the patient is a 'responder' that meets the following criteria:

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

ETANERCEPT

- Reduction of the BASDAI score by at least 50% of the pre-treatment value or by 2 or more units, AND
- Reduction of the Spinal Pain VAS by 2 cm or more.

Following this assessment, continued coverage may be approved for 50 mg per week for a period of 12 months. Ongoing coverage may be considered if the patient is re-assessed by an RA Specialist every 12 months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above."

All requests (including renewal requests) for etanercept for Ankylosing Spondylitis must be completed using the Adalimumab/Certolizumab/Etanercept/Golimumab/Infliximab/Secukinumab for Ankylosing Spondylitis Special Authorization Request Form (ABC 60028).

Plaque Psoriasis

***Effective March 1, 2018, all new Special Authorization requests for the treatment of Rheumatoid Arthritis or Ankylosing Spondylitis for etanercept-naïve patients will be assessed for coverage with Brenzys or Erelzi. Effective June 1, 2019, all new Special Authorization requests for the treatment of Psoriatic Arthritis for etanercept-naïve patients will be assessed for coverage with Erelzi. Enbrel will not be approved for new etanercept starts for patients with the indications stated above; however, coverage for Enbrel will continue for patients who are currently well maintained on Enbrel and are considered a 'responder' as defined in criteria.

In addition, all new Special Authorization requests for the treatment of Polyarticular Juvenile Idiopathic Arthritis for etanercept-naïve patients weighing 63 kg (138 pounds) or more will be assessed for coverage with Erelzi. Enbrel will be approved for new etanercept starts for pediatric patients with Polyarticular Juvenile Idiopathic Arthritis weighing less than 63 kg, and coverage for Enbrel will continue for patients who are currently well maintained on Enbrel and are considered a 'responder' as defined in criteria.

Additionally, patients will not be permitted to switch between etanercept products, if the patient has been previously trialed on any etanercept product and deemed unresponsive to therapy.***

"Special authorization coverage may be provided for the reduction in signs and symptoms of severe, debilitating plaque psoriasis in patients who:

- Have a total PASI of 10 or more and a DLQI of more than 10, OR
- Who have significant involvement of the face, palms of the hands, soles of the feet or genital region; AND
- Who are refractory or intolerant to:

at least THREE of the following:

- Cosentyx (secukinumab)
 - Inflectra (infliximab)
 - Renflexis (infliximab)
 - Skyrizi (risankizumab)
 - Taltz (ixekizumab);
- AND

- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory, OR

- Cyclosporine (6 weeks treatment); AND
- Phototherapy (unless restricted by geographic location)

Patients who have a contraindication to either cyclosporine or methotrexate will be required to complete an adequate trial of the other pre-requisite medication prior to potential coverage being considered.

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

ETANERCEPT

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.

'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be prescribed by a Specialist in Dermatology ("Dermatology Specialist").

-Initial coverage may be approved for up to 100 mg per week for 12 weeks.

-Patients will be limited to receiving a one-month supply of etanercept per prescription at their pharmacy.

- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).

- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.

- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond 12 weeks, the patient must meet all of the following criteria:

1) The patient must be assessed by a Dermatology Specialist after the initial 12 weeks of therapy to determine response.

2) The Dermatology Specialist must confirm, in writing, that the patient is a 'responder' that meets the following criteria:

- Greater than or equal to 75% reduction in PASI score, OR

- Greater than or equal to 50% reduction in PASI score AND improvement of greater than or equal to 5 points in the DLQI

Following this assessment, continued coverage may be considered for 50 mg per week for a period of 12 months. Ongoing coverage may be considered if the patient is re-assessed by a Dermatology Specialist every 12 months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above."

PASI and DLQI scores are required for all requests for Plaque Psoriasis including those requests for patients that have significant involvement of the face, palms, soles of feet or genital region.

All requests (including renewal requests) for etanercept for Plaque Psoriasis must be completed using the Adalimumab/Etanercept/Infliximab/Ixekizumab/Risankizumab/Secukinumab/Ustekinumab for Plaque Psoriasis Special Authorization Request Form (ABC 60030).

Polyarticular Juvenile Idiopathic Arthritis

***Effective March 1, 2018, all new Special Authorization requests for the treatment of Rheumatoid Arthritis or Ankylosing Spondylitis for etanercept-naïve patients will be assessed for coverage with Brenzys or Erelzi. Effective June 1, 2019, all new Special Authorization requests for the treatment of Psoriatic Arthritis for etanercept-naïve patients will be assessed for coverage with Erelzi. Enbrel will not be approved for new etanercept starts for patients with the indications stated above; however, coverage for Enbrel will continue for patients who are currently well maintained on Enbrel and are considered a 'responder' as defined in criteria.

In addition, all new Special Authorization requests for the treatment of Polyarticular Juvenile Idiopathic Arthritis for etanercept-naïve patients weighing 63 kg (138 pounds) or more will be assessed for coverage with Erelzi. Enbrel will be approved for new etanercept starts for pediatric patients with Polyarticular Juvenile Idiopathic Arthritis weighing less than 63 kg, and coverage for Enbrel will continue for patients who are currently well maintained on Enbrel and are considered a 'responder' as defined in criteria.

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

ETANERCEPT

Additionally, patients will not be permitted to switch between etanercept products, if the patient has been previously trialed on any etanercept product and deemed unresponsive to therapy.***

"Special authorization coverage may be provided for the reduction in signs and symptoms of severely active polyarticular juvenile idiopathic arthritis (pJIA) in patients 4 years of age and older who:

- Have 5 or more active joints (defined by either swelling or limitation of motion plus pain and/or tenderness), AND
- Are refractory to one or more disease modifying anti-rheumatic agents (DMARDs) conventionally used in children (minimum three month trial).

"Refractory" is defined as one or more of the following: lack of effect, serious adverse effects (e.g., leukopenia, hepatitis) or contraindications to treatments as defined in the product monographs.

For coverage, this drug must be prescribed by a prescriber affiliated with a Pediatric Rheumatology Clinic in Edmonton or Calgary (Pediatric Rheumatology Specialist).

- Coverage may be approved for 0.8 mg/kg/dose (maximum dose 50 mg) weekly for 12 weeks.
- Patients will be limited to receiving a one-month supply of etanercept per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another (with the exception of abatacept) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients will not be permitted to switch from abatacept to other biologic agents except under exceptional circumstances.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage of this agent beyond 12 weeks, the patient must meet the following criteria:

- 1) The patient must be assessed by a Pediatric Rheumatology Specialist after 12 weeks, but no longer than 16 weeks after, treatment with this biologic agent to determine response.
- 2) The Pediatric Rheumatology Specialist must confirm in writing that the patient is a responder that meets the following criteria (ACR Pedi 30):
 - 30% improvement from baseline in at least three of the following six response variables, with worsening of 30% or more in no more than one of the six variables. The variables include:
 - i. global assessment of the severity of the disease by the Pediatric Rheumatology Specialist,
 - ii. global assessment of overall well-being by the patient or parent,
 - iii. number of active joints (joints with swelling not due to deformity or joints with limitation of motion with pain tenderness or both),
 - iv. number of joints with limitation of motion,
 - v. functional ability based on CHAQ scores,
 - vi. ESR or CRP
- 3) Data from all of the six variables comprising the ACR Pedi 30 and the CHAQ scores must be reported in each request

Following this assessment, continued coverage may be approved for 0.8 mg/kg/dose (maximum dose 50 mg) weekly, for a maximum of twelve months. After twelve months, in order to be considered for continued coverage, the patient must be re-assessed every twelve months by a Pediatric Rheumatology Specialist and must meet the following criteria:

- 1) The patient has been assessed by a Pediatric Rheumatology Specialist to determine response, and
- 2) The Pediatric RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by maintenance of the ACR Pedi 30,
- 3) Data from all of the six variables comprising the ACR Pedi 30 and the CHAQ scores must be reported in each request.

Once a child with pJIA has had two disease-free years, it is common clinical practice for drug treatment to be stopped."

All requests (including renewal requests) for etanercept for Polyarticular Juvenile Idiopathic Arthritis must be completed using the Adalimumab/Etanercept/Tocilizumab for Polyarticular Juvenile Idiopathic Arthritis Special Authorization Request Form (ABC 60011).

Psoriatic Arthritis

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

ETANERCEPT

***Effective March 1, 2018, all new Special Authorization requests for the treatment of Rheumatoid Arthritis or Ankylosing Spondylitis for etanercept-naïve patients will be assessed for coverage with Brenzys or Erelzi. Effective June 1, 2019, all new Special Authorization requests for the treatment of Psoriatic Arthritis for etanercept-naïve patients will be assessed for coverage with Erelzi. Enbrel will not be approved for new etanercept starts for patients with the indications stated above; however, coverage for Enbrel will continue for patients who are currently well maintained on Enbrel and are considered a 'responder' as defined in criteria.

In addition, all new Special Authorization requests for the treatment of Polyarticular Juvenile Idiopathic Arthritis for etanercept-naïve patients weighing 63 kg (138 pounds) or more will be assessed for coverage with Erelzi. Enbrel will be approved for new etanercept starts for pediatric patients with Polyarticular Juvenile Idiopathic Arthritis weighing less than 63 kg, and coverage for Enbrel will continue for patients who are currently well maintained on Enbrel and are considered a 'responder' as defined in criteria.

Additionally, patients will not be permitted to switch between etanercept products, if the patient has been previously trialed on any etanercept product and deemed unresponsive to therapy.***

"Special authorization coverage may be provided for use in combination with methotrexate for reducing signs and symptoms and inhibiting the progression of structural damage of active arthritis in adult patients (18 years of age or older) with moderate to severe polyarticular psoriatic arthritis (PsA) or pauciarticular PsA with involvement of knee or hip joint who are refractory or intolerant to:

- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- An adequate trial of another disease modifying anti-rheumatic agent(s) (minimum 4 month trial).

Special authorization coverage of this agent may be provided for use as monotherapy in adult patients for whom methotrexate is contraindicated and/or for those patients who have experienced serious adverse effects.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.

'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for 50 mg per week for 8 weeks.
- Patients will be limited to receiving a one-month supply of etanercept per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond 8 weeks, the patient must meet the following criteria:

- 1) The patient must be assessed by an RA Specialist after 8 weeks, but no longer than 12 weeks after treatment to determine response.
- 2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
 - ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND
 - An improvement of 0.22 in HAQ score [reported to two (2) decimal places].

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be approved for 50 mg per week, for a period of 12 months. Ongoing coverage may be considered if the following criteria are met at the end of each 12-month period:

- 1) The patient has been assessed by an RA Specialist to determine response;
- 2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

ETANERCEPT

as indicated by:

- Confirmation of maintenance of ACR20, or
- Maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.
- 3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above."

All requests (including renewal requests) for etanercept for Psoriatic Arthritis must be completed using the Adalimumab/Certolizumab/Etanercept/Golimumab/Infliximab/Ixekizumab/Secukinumab for Psoriatic Arthritis Special Authorization Request Form (ABC 60029).

Rheumatoid Arthritis

***Effective March 1, 2018, all new Special Authorization requests for the treatment of Rheumatoid Arthritis or Ankylosing Spondylitis for etanercept-naïve patients will be assessed for coverage with Brenzys or Erelzi. Effective June 1, 2019, all new Special Authorization requests for the treatment of Psoriatic Arthritis for etanercept-naïve patients will be assessed for coverage with Erelzi. Enbrel will not be approved for new etanercept starts for patients with the indications stated above; however, coverage for Enbrel will continue for patients who are currently well maintained on Enbrel and are considered a 'responder' as defined in criteria.

In addition, all new Special Authorization requests for the treatment of Polyarticular Juvenile Idiopathic Arthritis for etanercept-naïve patients weighing 63 kg (138 pounds) or more will be assessed for coverage with Erelzi. Enbrel will be approved for new etanercept starts for pediatric patients with Polyarticular Juvenile Idiopathic Arthritis weighing less than 63 kg, and coverage for Enbrel will continue for patients who are currently well maintained on Enbrel and are considered a 'responder' as defined in criteria.

Additionally, patients will not be permitted to switch between etanercept products, if the patient has been previously trialed on any etanercept product and deemed unresponsive to therapy.***

"Special authorization coverage may be provided for use in combination with methotrexate for the reduction in signs and symptoms of severely active Rheumatoid Arthritis (RA) in adult patients (18 years of age or older) who are refractory or intolerant to:

- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- Methotrexate with other disease modifying anti-rheumatic agent(s) (minimum 4-month trial). [e.g., methotrexate with hydroxychloroquine or methotrexate with sulfasalazine]; AND
- Leflunomide (minimum 10 week trial at 20 mg daily).

Special authorization coverage of this agent may be provided for use as monotherapy in adult patients for whom methotrexate is contraindicated and/or for those patients who have experienced serious adverse effects.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.

'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for 50 mg per week for 8 weeks.
- Patients will be limited to receiving a one-month supply of etanercept per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another (with the exception of anakinra) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

ETANERCEPT

completion of induction dosing (e.g. initial coverage period).

- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients will not be permitted to switch from anakinra to other biologic agents except under exceptional circumstances.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond 8 weeks, the patient must meet the following criteria:

1) The patient must be assessed by an RA Specialist after 8 weeks, but no longer than 12 weeks after treatment to determine response.

2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:

- ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place];
AND

- An improvement of 0.22 in HAQ score [reported to two (2) decimal places].

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be approved for 50 mg per week, for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:

1) The patient has been assessed by an RA Specialist to determine response;

2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:

- Confirmation of maintenance of ACR20, or

- Maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.

3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above."

All requests (including renewal requests) for etanercept for Rheumatoid Arthritis must be completed using the

Abatacept/Adalimumab/Anakinra/Certolizumab/Etanercept/Golimumab/Infliximab/Sarilumab/Tocilizumab/Tofacitinib for Rheumatoid Arthritis Special Authorization Request Form (ABC 60027).

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

ETANERCEPT

25 MG / SYR INJECTION SYRINGE

00002462877 ERELZI SDZ \$ 120.5000

Rheumatoid Arthritis:

***Effective March 1, 2018, all new Special Authorization requests for the treatment of Rheumatoid Arthritis or Ankylosing Spondylitis for etanercept-naïve patients will be assessed for coverage with Brenzys or Erelzi. Effective June 1, 2019, all new Special Authorization requests for the treatment of Psoriatic Arthritis for etanercept-naïve patients will be assessed for coverage with Erelzi. Enbrel will not be approved for new etanercept starts for patients with the indications stated above; however, coverage for Enbrel will continue for patients who are currently well maintained on Enbrel and are considered a 'responder' as defined in criteria.

In addition, all new Special Authorization requests for the treatment of Polyarticular Juvenile Idiopathic Arthritis for etanercept-naïve patients weighing 63 kg (138 pounds) or more will be assessed for coverage with Erelzi. Enbrel will be approved for new etanercept starts for pediatric patients with Polyarticular Juvenile Idiopathic Arthritis weighing less than 63 kg, and coverage for Enbrel will continue for patients who are currently well maintained on Enbrel and are considered a 'responder' as defined in criteria.

Additionally, patients will not be permitted to switch between etanercept products, if the patient has been previously trialed on any etanercept product and deemed unresponsive to therapy.***

"Special authorization coverage may be provided for use in combination with methotrexate for the reduction in signs and symptoms of severely active Rheumatoid Arthritis (RA) in adult patients (18 years of age or older) who are refractory or intolerant to:

- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- Methotrexate with other disease modifying anti-rheumatic agent(s) (minimum 4-month trial). [e.g., methotrexate with hydroxychloroquine or methotrexate with sulfasalazine]; AND
- Leflunomide (minimum 10 week trial at 20 mg daily).

Special authorization coverage of this agent may be provided for use as monotherapy in adult patients for whom methotrexate is contraindicated and/or for those patients who have experienced serious adverse effects.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.

'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for 50 mg per week for 8 weeks.
- Patients will be limited to receiving a one-month supply of etanercept per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another (with the exception of anakinra) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients will not be permitted to switch from anakinra to other biologic agents except under exceptional circumstances.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond 8 weeks, the patient must meet the following criteria:

- 1) The patient must be assessed by an RA Specialist after 8 weeks, but no longer than 12 weeks after treatment to determine response.
- 2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
 - ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND
 - An improvement of 0.22 in HAQ score [reported to two (2) decimal places].

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CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

ETANERCEPT

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be approved for 50 mg per week, for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:

- 1) The patient has been assessed by an RA Specialist to determine response;
- 2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
 - Confirmation of maintenance of ACR20, or
 - Maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.
- 3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above."

All requests (including renewal requests) for etanercept for Rheumatoid Arthritis must be completed using the Abatacept/Adalimumab/Anakinra/Certolizumab/Etanercept/Golimumab/Infliximab/Sarilumab/Tocilizumab/Tofacitinib for Rheumatoid Arthritis Special Authorization Request Form (ABC 60027).

Polyarticular Juvenile Idiopathic Arthritis:

***Effective March 1, 2018, all new Special Authorization requests for the treatment of Rheumatoid Arthritis or Ankylosing Spondylitis for etanercept-naïve patients will be assessed for coverage with Brenzys or Erelzi. Effective June 1, 2019, all new Special Authorization requests for the treatment of Psoriatic Arthritis for etanercept-naïve patients will be assessed for coverage with Erelzi. Enbrel will not be approved for new etanercept starts for patients with the indications stated above; however, coverage for Enbrel will continue for patients who are currently well maintained on Enbrel and are considered a 'responder' as defined in criteria.

In addition, all new Special Authorization requests for the treatment of Polyarticular Juvenile Idiopathic Arthritis for etanercept-naïve patients weighing 63 kg (138 pounds) or more will be assessed for coverage with Erelzi. Enbrel will be approved for new etanercept starts for pediatric patients with Polyarticular Juvenile Idiopathic Arthritis weighing less than 63 kg, and coverage for Enbrel will continue for patients who are currently well maintained on Enbrel and are considered a 'responder' as defined in criteria.

Additionally, patients will not be permitted to switch between etanercept products, if the patient has been previously trialed on any etanercept product and deemed unresponsive to therapy.***

"Special authorization coverage may be provided for the reduction in signs and symptoms of severely active polyarticular juvenile idiopathic arthritis (pJIA) in patients 4 years of age and older who:

- Have 5 or more active joints (defined by either swelling or limitation of motion plus pain and/or tenderness), AND
- Are refractory to one or more disease modifying anti-rheumatic agents (DMARDs) conventionally used in children (minimum three month trial).

"Refractory" is defined as one or more of the following: lack of effect, serious adverse effects (e.g., leukopenia, hepatitis) or contraindications to treatments as defined in the product monographs.

For coverage, this drug must be prescribed by a prescriber affiliated with a Pediatric Rheumatology Clinic in Edmonton or Calgary (Pediatric Rheumatology Specialist).

- Coverage may be approved for 0.8 mg/kg/dose (maximum dose 50 mg) weekly for 12 weeks.
- Patients will be limited to receiving a one-month supply of etanercept per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another (with the exception of abatacept) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients will not be permitted to switch from abatacept to other biologic agents except under exceptional circumstances.

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ETANERCEPT

- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage of this agent beyond 12 weeks, the patient must meet the following criteria:

1) The patient must be assessed by a Pediatric Rheumatology Specialist after 12 weeks, but no longer than 16 weeks after, treatment with this biologic agent to determine response.

2) The Pediatric Rheumatology Specialist must confirm in writing that the patient is a responder that meets the following criteria (ACR Pedi 30):

- 30% improvement from baseline in at least three of the following six response variables, with worsening of 30% or more in no more than one of the six variables. The variables include:

- i. global assessment of the severity of the disease by the Pediatric Rheumatology Specialist,
- ii. global assessment of overall well-being by the patient or parent,
- iii. number of active joints (joints with swelling not due to deformity or joints with limitation of motion with pain tenderness or both),
- iv. number of joints with limitation of motion,
- v. functional ability based on CHAQ scores,
- vi. ESR or CRP

3) Data from all of the six variables comprising the ACR Pedi 30 and the CHAQ scores must be reported in each request

Following this assessment, continued coverage may be approved for 0.8 mg/kg/dose (maximum dose 50 mg) weekly, for a maximum of twelve months. After twelve months, in order to be considered for continued coverage, the patient must be re-assessed every twelve months by a Pediatric Rheumatology Specialist and must meet the following criteria:

- 1) The patient has been assessed by a Pediatric Rheumatology Specialist to determine response, and
- 2) The Pediatric RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by maintenance of the ACR Pedi 30,
- 3) Data from all of the six variables comprising the ACR Pedi 30 and the CHAQ scores must be reported in each request.

Once a child with pJIA has had two disease-free years, it is common clinical practice for drug treatment to be stopped."

All requests (including renewal requests) for etanercept for Polyarticular Juvenile Idiopathic Arthritis must be completed using the Adalimumab/Etanercept/Tocilizumab for Polyarticular Juvenile Idiopathic Arthritis Special Authorization Request Form (ABC 60011).

Ankylosing Spondylitis:

***Effective March 1, 2018, all new Special Authorization requests for the treatment of Rheumatoid Arthritis or Ankylosing Spondylitis for etanercept-naïve patients will be assessed for coverage with Brenzys or Erelzi. Effective June 1, 2019, all new Special Authorization requests for the treatment of Psoriatic Arthritis for etanercept-naïve patients will be assessed for coverage with Erelzi. Enbrel will not be approved for new etanercept starts for patients with the indications stated above; however, coverage for Enbrel will continue for patients who are currently well maintained on Enbrel and are considered a 'responder' as defined in criteria.

In addition, all new Special Authorization requests for the treatment of Polyarticular Juvenile Idiopathic Arthritis for etanercept-naïve patients weighing 63 kg (138 pounds) or more will be assessed for coverage with Erelzi. Enbrel will be approved for new etanercept starts for pediatric patients with Polyarticular Juvenile Idiopathic Arthritis weighing less than 63 kg, and coverage for Enbrel will continue for patients who are currently well maintained on Enbrel and are considered a 'responder' as defined in criteria.

Additionally, patients will not be permitted to switch between etanercept products, if the patient has been previously trialed on any etanercept product and deemed unresponsive to therapy.***

"Special authorization coverage may be provided for the reduction in the signs and symptoms of severely active Ankylosing Spondylitis, as defined by the Modified New York criteria for Ankylosing Spondylitis, in adult patients (18 years of age or older) who have active disease as demonstrated by:

- a BASDAI greater than or equal to 4 units, demonstrated on 2 occasions at least 8 weeks apart AND
- a Spinal Pain VAS of greater than or equal to 4 cm (on a 0-10 cm scale), demonstrated on 2 occasions at least 8 weeks apart AND

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

ETANERCEPT

- who are refractory or intolerant to treatment with 2 or more NSAIDS each taken for a minimum of 4 weeks at maximum tolerated or recommended doses.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.

'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for 50 mg per week for 12 weeks.
- Patients will be limited to receiving a one-month supply of etanercept per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond 12 weeks, the patient must meet the following criteria:

1) The patient must be assessed at week 12 by an RA Specialist after the initial twelve weeks of therapy to determine response.

2) The RA Specialist must confirm, in writing, that the patient is a 'responder' that meets the following criteria:

- Reduction of the BASDAI score by at least 50% of the pre-treatment value or by 2 or more units, AND
- Reduction of the Spinal Pain VAS by 2 cm or more.

Following this assessment, continued coverage may be approved for 50 mg per week for a period of 12 months. Ongoing coverage may be considered if the patient is re-assessed by an RA Specialist every 12 months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above."

All requests (including renewal requests) for etanercept for Ankylosing Spondylitis must be completed using the Adalimumab/Certolizumab/Etanercept/Golimumab/Infliximab/Secukinumab for Ankylosing Spondylitis Special Authorization Request Form (ABC 60028).

Psoriatic Arthritis

***Effective March 1, 2018, all new Special Authorization requests for the treatment of Rheumatoid Arthritis or Ankylosing Spondylitis for etanercept-naïve patients will be assessed for coverage with Brenzys or Erelzi. Effective June 1, 2019, all new Special Authorization requests for the treatment of Psoriatic Arthritis for etanercept-naïve patients will be assessed for coverage with Erelzi. Enbrel will not be approved for new etanercept starts for patients with the indications stated above; however, coverage for Enbrel will continue for patients who are currently well maintained on Enbrel and are considered a 'responder' as defined in criteria.

In addition, all new Special Authorization requests for the treatment of Polyarticular Juvenile Idiopathic Arthritis for etanercept-naïve patients weighing 63 kg (138 pounds) or more will be assessed for coverage with Erelzi. Enbrel will be approved for new etanercept starts for pediatric patients with Polyarticular Juvenile Idiopathic Arthritis weighing less than 63 kg, and coverage for Enbrel will continue for patients who are currently well maintained on Enbrel and are considered a 'responder' as defined in criteria.

Additionally, patients will not be permitted to switch between etanercept products, if the patient has been previously trialed on any etanercept product and deemed unresponsive to therapy.***

"Special authorization coverage may be provided for use in combination with methotrexate for reducing signs and symptoms and inhibiting the progression of structural damage of active arthritis in adult patients (18 years of age or older) with moderate to severe polyarticular psoriatic arthritis (PsA) or pauciarticular PsA with involvement of knee or hip joint who are refractory or intolerant to:
- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

ETANERCEPT

of parenteral methotrexate before being accepted as refractory; AND
- An adequate trial of another disease modifying anti-rheumatic agent(s) (minimum 4 month trial).

Special authorization coverage of this agent may be provided for use as monotherapy in adult patients for whom methotrexate is contraindicated and/or for those patients who have experienced serious adverse effects.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.

'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for 50 mg per week for 8 weeks.
- Patients will be limited to receiving a one-month supply of etanercept per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond 8 weeks, the patient must meet the following criteria:

1) The patient must be assessed by an RA Specialist after 8 weeks, but no longer than 12 weeks after treatment to determine response.

2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:

- ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND

- An improvement of 0.22 in HAQ score [reported to two (2) decimal places].

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be approved for 50 mg per week, for a period of 12 months. Ongoing coverage may be considered if the following criteria are met at the end of each 12-month period:

1) The patient has been assessed by an RA Specialist to determine response;

2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:

- Confirmation of maintenance of ACR20, or

- Maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.

3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above."

All requests (including renewal requests) for etanercept for Psoriatic Arthritis must be completed using the Adalimumab/Certolizumab/Etanercept/Golimumab/Infliximab/Ixekizumab/Secukinumab for Psoriatic Arthritis Special Authorization Request Form (ABC 60029).

ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

ETANERCEPT

50 MG / SYR INJECTION SYRINGE

☒ 00002455323 BRENZYS SSB \$ 241.0000

Rheumatoid Arthritis

***Effective March 1, 2018, all new Special Authorization requests for the treatment of Rheumatoid Arthritis or Ankylosing Spondylitis for etanercept-naïve patients will be assessed for coverage with Brenzys or Erelzi. Enbrel will not be approved for new etanercept starts for patients with the indications stated above; however, coverage for Enbrel will continue for patients who are currently well maintained on Enbrel and are considered a 'responder' as defined in criteria.

Additionally, patients will not be permitted to switch between etanercept products, if the patient has been previously trialed on any etanercept product and deemed unresponsive to therapy.***

"Special authorization coverage may be provided for use in combination with methotrexate for the reduction in signs and symptoms of severely active Rheumatoid Arthritis (RA) in adult patients (18 years of age or older) who are refractory or intolerant to:

- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- Methotrexate with other disease modifying anti-rheumatic agent(s) (minimum 4-month trial). [e.g., methotrexate with hydroxychloroquine or methotrexate with sulfasalazine]; AND
- Leflunomide (minimum 10 week trial at 20 mg daily).

Special authorization coverage of this agent may be provided for use as monotherapy in adult patients for whom methotrexate is contraindicated and/or for those patients who have experienced serious adverse effects.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.

'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for 50 mg per week for 8 weeks.
- Patients will be limited to receiving a one-month supply of etanercept per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another (with the exception of anakinra) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients will not be permitted to switch from anakinra to other biologic agents except under exceptional circumstances.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond 8 weeks, the patient must meet the following criteria:

- 1) The patient must be assessed by an RA Specialist after 8 weeks, but no longer than 12 weeks after treatment to determine response.
- 2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
 - ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND
 - An improvement of 0.22 in HAQ score [reported to two (2) decimal places].

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be approved for 50 mg per week, for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:

- 1) The patient has been assessed by an RA Specialist to determine response;
- 2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:

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ETANERCEPT

- Confirmation of maintenance of ACR20, or
 - Maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.
 - 3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.
- It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above."

All requests (including renewal requests) for etanercept for Rheumatoid Arthritis must be completed using the Abatacept/Adalimumab/Anakinra/Certolizumab/Etanercept/Golimumab/Infliximab/Sarilumab/Tocilizumab/Tofacitinib for Rheumatoid Arthritis Special Authorization Request Form (ABC 60027).

Ankylosing Spondylitis

***Effective March 1, 2018, all new Special Authorization requests for the treatment of Rheumatoid Arthritis or Ankylosing Spondylitis for etanercept-naïve patients will be assessed for coverage with Brenzys or Erelzi. Enbrel will not be approved for new etanercept starts for patients with the indications stated above; however, coverage for Enbrel will continue for patients who are currently well maintained on Enbrel and are considered a 'responder' as defined in criteria.

Additionally, patients will not be permitted to switch between etanercept products, if the patient has been previously trialed on any etanercept product and deemed unresponsive to therapy.***

"Special authorization coverage may be provided for the reduction in the signs and symptoms of severely active Ankylosing Spondylitis, as defined by the Modified New York criteria for Ankylosing Spondylitis, in adult patients (18 years of age or older) who have active disease as demonstrated by:

- a BASDAI greater than or equal to 4 units, demonstrated on 2 occasions at least 8 weeks apart AND
- a Spinal Pain VAS of greater than or equal to 4 cm (on a 0-10 cm scale), demonstrated on 2 occasions at least 8 weeks apart AND
- who are refractory or intolerant to treatment with 2 or more NSAIDs each taken for a minimum of 4 weeks at maximum tolerated or recommended doses.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.

'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for 50 mg per week for 12 weeks.
- Patients will be limited to receiving a one-month supply of etanercept per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond 12 weeks, the patient must meet the following criteria:

- 1) The patient must be assessed at week 12 by an RA Specialist after the initial twelve weeks of therapy to determine response.
- 2) The RA Specialist must confirm, in writing, that the patient is a 'responder' that meets the following criteria:
 - Reduction of the BASDAI score by at least 50% of the pre-treatment value or by 2 or more units, AND
 - Reduction of the Spinal Pain VAS by 2 cm or more.

Following this assessment, continued coverage may be approved for 50 mg per week for a period of 12 months. Ongoing coverage may be considered if the patient is re-assessed by an RA Specialist every 12 months and is confirmed to be continuing to respond to therapy by meeting

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criteria as outlined in (2) above."

All requests (including renewal requests) for etanercept for Ankylosing Spondylitis must be completed using the Adalimumab/Certolizumab/Etanercept/Golimumab/Infliximab/Secukinumab for Ankylosing Spondylitis Special Authorization Request Form (ABC 60028).

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Rheumatoid Arthritis

***Effective March 1, 2018, all new Special Authorization requests for the treatment of Rheumatoid Arthritis or Ankylosing Spondylitis for etanercept-naïve patients will be assessed for coverage with Brenzys or Erelzi. Enbrel will not be approved for new etanercept starts for patients with the indications stated above; however, coverage for Enbrel will continue for patients who are currently well maintained on Enbrel and are considered a 'responder' as defined in criteria.

Additionally, patients will not be permitted to switch between etanercept products, if the patient has been previously trialed on any etanercept product and deemed unresponsive to therapy.***

"Special authorization coverage may be provided for use in combination with methotrexate for the reduction in signs and symptoms of severely active Rheumatoid Arthritis (RA) in adult patients (18 years of age or older) who are refractory or intolerant to:

- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- Methotrexate with other disease modifying anti-rheumatic agent(s) (minimum 4-month trial). [e.g., methotrexate with hydroxychloroquine or methotrexate with sulfasalazine]; AND
- Leflunomide (minimum 10 week trial at 20 mg daily).

Special authorization coverage of this agent may be provided for use as monotherapy in adult patients for whom methotrexate is contraindicated and/or for those patients who have experienced serious adverse effects.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.

'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for 50 mg per week for 8 weeks.
- Patients will be limited to receiving a one-month supply of etanercept per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another (with the exception of anakinra) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients will not be permitted to switch from anakinra to other biologic agents except under exceptional circumstances.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond 8 weeks, the patient must meet the following criteria:

- 1) The patient must be assessed by an RA Specialist after 8 weeks, but no longer than 12 weeks after treatment to determine response.
 - 2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
 - ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND
 - An improvement of 0.22 in HAQ score [reported to two (2) decimal places].
- It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

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Following this assessment, continued coverage may be approved for 50 mg per week, for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:

- 1) The patient has been assessed by an RA Specialist to determine response;
 - 2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
 - Confirmation of maintenance of ACR20, or
 - Maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.
 - 3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.
- It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above."

All requests (including renewal requests) for etanercept for Rheumatoid Arthritis must be completed using the Abatacept/Adalimumab/Anakinra/Certolizumab/Etanercept/Golimumab/Infliximab/Sarilumab/Tocilizumab/Tofacitinib for Rheumatoid Arthritis Special Authorization Request Form (ABC 60027).

Ankylosing Spondylitis

***Effective March 1, 2018, all new Special Authorization requests for the treatment of Rheumatoid Arthritis or Ankylosing Spondylitis for etanercept-naïve patients will be assessed for coverage with Brenzys or Erelzi. Enbrel will not be approved for new etanercept starts for patients with the indications stated above; however, coverage for Enbrel will continue for patients who are currently well maintained on Enbrel and are considered a 'responder' as defined in criteria.

Additionally, patients will not be permitted to switch between etanercept products, if the patient has been previously trialed on any etanercept product and deemed unresponsive to therapy.***

"Special authorization coverage may be provided for the reduction in the signs and symptoms of severely active Ankylosing Spondylitis, as defined by the Modified New York criteria for Ankylosing Spondylitis, in adult patients (18 years of age or older) who have active disease as demonstrated by:

- a BASDAI greater than or equal to 4 units, demonstrated on 2 occasions at least 8 weeks apart AND
- a Spinal Pain VAS of greater than or equal to 4 cm (on a 0-10 cm scale), demonstrated on 2 occasions at least 8 weeks apart AND
- who are refractory or intolerant to treatment with 2 or more NSAIDs each taken for a minimum of 4 weeks at maximum tolerated or recommended doses.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.

'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for 50 mg per week for 12 weeks.
- Patients will be limited to receiving a one-month supply of etanercept per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond 12 weeks, the patient must meet the following criteria:

- 1) The patient must be assessed at week 12 by an RA Specialist after the initial twelve weeks of therapy to determine response.
- 2) The RA Specialist must confirm, in writing, that the patient is a 'responder' that meets the following criteria:
 - Reduction of the BASDAI score by at least 50% of the pre-treatment value or by 2 or more units,

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AND

- Reduction of the Spinal Pain VAS by 2 cm or more.

Following this assessment, continued coverage may be approved for 50 mg per week for a period of 12 months. Ongoing coverage may be considered if the patient is re-assessed by an RA Specialist every 12 months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above."

All requests (including renewal requests) for etanercept for Ankylosing Spondylitis must be completed using the Adalimumab/Certolizumab/Etanercept/Golimumab/Infliximab/Secukinumab for Ankylosing Spondylitis Special Authorization Request Form (ABC 60028).

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Rheumatoid Arthritis:

***Effective March 1, 2018, all new Special Authorization requests for the treatment of Rheumatoid Arthritis or Ankylosing Spondylitis for etanercept-naïve patients will be assessed for coverage with Brenzys or Erelzi. Effective June 1, 2019, all new Special Authorization requests for the treatment of Psoriatic Arthritis for etanercept-naïve patients will be assessed for coverage with Erelzi. Enbrel will not be approved for new etanercept starts for patients with the indications stated above; however, coverage for Enbrel will continue for patients who are currently well maintained on Enbrel and are considered a 'responder' as defined in criteria.

In addition, all new Special Authorization requests for the treatment of Polyarticular Juvenile Idiopathic Arthritis for etanercept-naïve patients weighing 63 kg (138 pounds) or more will be assessed for coverage with Erelzi. Enbrel will be approved for new etanercept starts for pediatric patients with Polyarticular Juvenile Idiopathic Arthritis weighing less than 63 kg, and coverage for Enbrel will continue for patients who are currently well maintained on Enbrel and are considered a 'responder' as defined in criteria.

Additionally, patients will not be permitted to switch between etanercept products, if the patient has been previously trialed on any etanercept product and deemed unresponsive to therapy.***

"Special authorization coverage may be provided for use in combination with methotrexate for the reduction in signs and symptoms of severely active Rheumatoid Arthritis (RA) in adult patients (18 years of age or older) who are refractory or intolerant to:

- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- Methotrexate with other disease modifying anti-rheumatic agent(s) (minimum 4-month trial). [e.g., methotrexate with hydroxychloroquine or methotrexate with sulfasalazine]; AND
- Leflunomide (minimum 10 week trial at 20 mg daily).

Special authorization coverage of this agent may be provided for use as monotherapy in adult patients for whom methotrexate is contraindicated and/or for those patients who have experienced serious adverse effects.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.

'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for 50 mg per week for 8 weeks.
- Patients will be limited to receiving a one-month supply of etanercept per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another (with the exception of anakinra) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients will not be permitted to switch from anakinra to other biologic agents except under

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exceptional circumstances.

- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond 8 weeks, the patient must meet the following criteria:

1) The patient must be assessed by an RA Specialist after 8 weeks, but no longer than 12 weeks after treatment to determine response.

2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:

- ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place];
AND

- An improvement of 0.22 in HAQ score [reported to two (2) decimal places].

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be approved for 50 mg per week, for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:

1) The patient has been assessed by an RA Specialist to determine response;

2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:

- Confirmation of maintenance of ACR20, or

- Maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.

3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above."

All requests (including renewal requests) for etanercept for Rheumatoid Arthritis must be completed using the

Abatacept/Adalimumab/Anakinra/Certolizumab/Etanercept/Golimumab/Infliximab/Sarilumab/Tocilizumab/Tofacitinib for Rheumatoid Arthritis Special Authorization Request Form (ABC 60027).

Polyarticular Juvenile Idiopathic Arthritis:

***Effective March 1, 2018, all new Special Authorization requests for the treatment of Rheumatoid Arthritis or Ankylosing Spondylitis for etanercept-naïve patients will be assessed for coverage with Brenzys or Erelzi. Effective June 1, 2019, all new Special Authorization requests for the treatment of Psoriatic Arthritis for etanercept-naïve patients will be assessed for coverage with Erelzi. Enbrel will not be approved for new etanercept starts for patients with the indications stated above; however, coverage for Enbrel will continue for patients who are currently well maintained on Enbrel and are considered a 'responder' as defined in criteria.

In addition, all new Special Authorization requests for the treatment of Polyarticular Juvenile Idiopathic Arthritis for etanercept-naïve patients weighing 63 kg (138 pounds) or more will be assessed for coverage with Erelzi. Enbrel will be approved for new etanercept starts for pediatric patients with Polyarticular Juvenile Idiopathic Arthritis weighing less than 63 kg, and coverage for Enbrel will continue for patients who are currently well maintained on Enbrel and are considered a 'responder' as defined in criteria.

Additionally, patients will not be permitted to switch between etanercept products, if the patient has been previously trialed on any etanercept product and deemed unresponsive to therapy.***

"Special authorization coverage may be provided for the reduction in signs and symptoms of severely active polyarticular juvenile idiopathic arthritis (pJIA) in patients 4 years of age and older who:

- Have 5 or more active joints (defined by either swelling or limitation of motion plus pain and/or tenderness), AND

- Are refractory to one or more disease modifying anti-rheumatic agents (DMARDs) conventionally used in children (minimum three month trial).

"Refractory" is defined as one or more of the following: lack of effect, serious adverse effects (e.g., leukopenia, hepatitis) or contraindications to treatments as defined in the product monographs.

For coverage, this drug must be prescribed by a prescriber affiliated with a Pediatric Rheumatology Clinic in Edmonton or Calgary (Pediatric Rheumatology Specialist).

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- Coverage may be approved for 0.8 mg/kg/dose (maximum dose 50 mg) weekly for 12 weeks.
- Patients will be limited to receiving a one-month supply of etanercept per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another (with the exception of abatacept) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients will not be permitted to switch from abatacept to other biologic agents except under exceptional circumstances.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage of this agent beyond 12 weeks, the patient must meet the following criteria:

- 1) The patient must be assessed by a Pediatric Rheumatology Specialist after 12 weeks, but no longer than 16 weeks after, treatment with this biologic agent to determine response.
- 2) The Pediatric Rheumatology Specialist must confirm in writing that the patient is a responder that meets the following criteria (ACR Pedi 30):
 - 30% improvement from baseline in at least three of the following six response variables, with worsening of 30% or more in no more than one of the six variables. The variables include:
 - i. global assessment of the severity of the disease by the Pediatric Rheumatology Specialist,
 - ii. global assessment of overall well-being by the patient or parent,
 - iii. number of active joints (joints with swelling not due to deformity or joints with limitation of motion with pain tenderness or both),
 - iv. number of joints with limitation of motion,
 - v. functional ability based on CHAQ scores,
 - vi. ESR or CRP
- 3) Data from all of the six variables comprising the ACR Pedi 30 and the CHAQ scores must be reported in each request

Following this assessment, continued coverage may be approved for 0.8 mg/kg/dose (maximum dose 50 mg) weekly, for a maximum of twelve months. After twelve months, in order to be considered for continued coverage, the patient must be re-assessed every twelve months by a Pediatric Rheumatology Specialist and must meet the following criteria:

- 1) The patient has been assessed by a Pediatric Rheumatology Specialist to determine response, and
- 2) The Pediatric RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by maintenance of the ACR Pedi 30,
- 3) Data from all of the six variables comprising the ACR Pedi 30 and the CHAQ scores must be reported in each request.

Once a child with pJIA has had two disease-free years, it is common clinical practice for drug treatment to be stopped."

All requests (including renewal requests) for etanercept for Polyarticular Juvenile Idiopathic Arthritis must be completed using the Adalimumab/Etanercept/Tocilizumab for Polyarticular Juvenile Idiopathic Arthritis Special Authorization Request Form (ABC 60011).

Ankylosing Spondylitis:

***Effective March 1, 2018, all new Special Authorization requests for the treatment of Rheumatoid Arthritis or Ankylosing Spondylitis for etanercept-naïve patients will be assessed for coverage with Brenzys or Erelzi. Effective June 1, 2019, all new Special Authorization requests for the treatment of Psoriatic Arthritis for etanercept-naïve patients will be assessed for coverage with Erelzi. Enbrel will not be approved for new etanercept starts for patients with the indications stated above; however, coverage for Enbrel will continue for patients who are currently well maintained on Enbrel and are considered a 'responder' as defined in criteria.

In addition, all new Special Authorization requests for the treatment of Polyarticular Juvenile Idiopathic Arthritis for etanercept-naïve patients weighing 63 kg (138 pounds) or more will be assessed for coverage with Erelzi. Enbrel will be approved for new etanercept starts for pediatric patients with Polyarticular Juvenile Idiopathic Arthritis weighing less than 63 kg, and coverage for Enbrel will continue for patients who are currently well maintained on Enbrel and are considered a 'responder' as defined in criteria.

Additionally, patients will not be permitted to switch between etanercept products, if the patient has

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been previously trialed on any etanercept product and deemed unresponsive to therapy.***

"Special authorization coverage may be provided for the reduction in the signs and symptoms of severely active Ankylosing Spondylitis, as defined by the Modified New York criteria for Ankylosing Spondylitis, in adult patients (18 years of age or older) who have active disease as demonstrated by:

- a BASDAI greater than or equal to 4 units, demonstrated on 2 occasions at least 8 weeks apart AND
- a Spinal Pain VAS of greater than or equal to 4 cm (on a 0-10 cm scale), demonstrated on 2 occasions at least 8 weeks apart AND
- who are refractory or intolerant to treatment with 2 or more NSAIDS each taken for a minimum of 4 weeks at maximum tolerated or recommended doses.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.

'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for 50 mg per week for 12 weeks.
- Patients will be limited to receiving a one-month supply of etanercept per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond 12 weeks, the patient must meet the following criteria:

- 1) The patient must be assessed at week 12 by an RA Specialist after the initial twelve weeks of therapy to determine response.
- 2) The RA Specialist must confirm, in writing, that the patient is a 'responder' that meets the following criteria:
 - Reduction of the BASDAI score by at least 50% of the pre-treatment value or by 2 or more units, AND
 - Reduction of the Spinal Pain VAS by 2 cm or more.

Following this assessment, continued coverage may be approved for 50 mg per week for a period of 12 months. Ongoing coverage may be considered if the patient is re-assessed by an RA Specialist every 12 months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above."

All requests (including renewal requests) for etanercept for Ankylosing Spondylitis must be completed using the Adalimumab/Certolizumab/Etanercept/Golimumab/Infliximab/Secukinumab for Ankylosing Spondylitis Special Authorization Request Form (ABC 60028).

Psoriatic Arthritis

***Effective March 1, 2018, all new Special Authorization requests for the treatment of Rheumatoid Arthritis or Ankylosing Spondylitis for etanercept-naive patients will be assessed for coverage with Brenzys or Erelzi. Effective June 1, 2019, all new Special Authorization requests for the treatment of Psoriatic Arthritis for etanercept-naive patients will be assessed for coverage with Erelzi. Enbrel will not be approved for new etanercept starts for patients with the indications stated above; however, coverage for Enbrel will continue for patients who are currently well maintained on Enbrel and are considered a 'responder' as defined in criteria.

In addition, all new Special Authorization requests for the treatment of Polyarticular Juvenile Idiopathic Arthritis for etanercept-naive patients weighing 63 kg (138 pounds) or more will be assessed for coverage with Erelzi. Enbrel will be approved for new etanercept starts for pediatric patients with Polyarticular Juvenile Idiopathic Arthritis weighing less than 63 kg, and coverage for Enbrel will continue for patients who are currently well maintained on Enbrel and are considered a 'responder' as defined in criteria.

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Additionally, patients will not be permitted to switch between etanercept products, if the patient has been previously trialed on any etanercept product and deemed unresponsive to therapy.***

"Special authorization coverage may be provided for use in combination with methotrexate for reducing signs and symptoms and inhibiting the progression of structural damage of active arthritis in adult patients (18 years of age or older) with moderate to severe polyarticular psoriatic arthritis (PsA) or pauciarticular PsA with involvement of knee or hip joint who are refractory or intolerant to:

- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- An adequate trial of another disease modifying anti-rheumatic agent(s) (minimum 4 month trial).

Special authorization coverage of this agent may be provided for use as monotherapy in adult patients for whom methotrexate is contraindicated and/or for those patients who have experienced serious adverse effects.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.

'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for 50 mg per week for 8 weeks.
- Patients will be limited to receiving a one-month supply of etanercept per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond 8 weeks, the patient must meet the following criteria:

- 1) The patient must be assessed by an RA Specialist after 8 weeks, but no longer than 12 weeks after treatment to determine response.
- 2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
 - ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND
 - An improvement of 0.22 in HAQ score [reported to two (2) decimal places].

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be approved for 50 mg per week, for a period of 12 months. Ongoing coverage may be considered if the following criteria are met at the end of each 12-month period:

- 1) The patient has been assessed by an RA Specialist to determine response;
- 2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
 - Confirmation of maintenance of ACR20, or
 - Maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.
- 3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above."

All requests (including renewal requests) for etanercept for Psoriatic Arthritis must be completed using the Adalimumab/Certolizumab/Etanercept/Golimumab/Infliximab/Ixekizumab/Secukinumab for Psoriatic Arthritis Special Authorization Request Form (ABC 60029).

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Rheumatoid Arthritis:

***Effective March 1, 2018, all new Special Authorization requests for the treatment of Rheumatoid Arthritis or Ankylosing Spondylitis for etanercept-naïve patients will be assessed for coverage with Brenzys or Erelzi. Effective June 1, 2019, all new Special Authorization requests for the treatment of Psoriatic Arthritis for etanercept-naïve patients will be assessed for coverage with Erelzi. Enbrel will not be approved for new etanercept starts for patients with the indications stated above; however, coverage for Enbrel will continue for patients who are currently well maintained on Enbrel and are considered a 'responder' as defined in criteria.

In addition, all new Special Authorization requests for the treatment of Polyarticular Juvenile Idiopathic Arthritis for etanercept-naïve patients weighing 63 kg (138 pounds) or more will be assessed for coverage with Erelzi. Enbrel will be approved for new etanercept starts for pediatric patients with Polyarticular Juvenile Idiopathic Arthritis weighing less than 63 kg, and coverage for Enbrel will continue for patients who are currently well maintained on Enbrel and are considered a 'responder' as defined in criteria.

Additionally, patients will not be permitted to switch between etanercept products, if the patient has been previously trialed on any etanercept product and deemed unresponsive to therapy.***

"Special authorization coverage may be provided for use in combination with methotrexate for the reduction in signs and symptoms of severely active Rheumatoid Arthritis (RA) in adult patients (18 years of age or older) who are refractory or intolerant to:

- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- Methotrexate with other disease modifying anti-rheumatic agent(s) (minimum 4-month trial). [e.g., methotrexate with hydroxychloroquine or methotrexate with sulfasalazine]; AND
- Leflunomide (minimum 10 week trial at 20 mg daily).

Special authorization coverage of this agent may be provided for use as monotherapy in adult patients for whom methotrexate is contraindicated and/or for those patients who have experienced serious adverse effects.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.

'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for 50 mg per week for 8 weeks.
- Patients will be limited to receiving a one-month supply of etanercept per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another (with the exception of anakinra) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients will not be permitted to switch from anakinra to other biologic agents except under exceptional circumstances.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond 8 weeks, the patient must meet the following criteria:

1) The patient must be assessed by an RA Specialist after 8 weeks, but no longer than 12 weeks after treatment to determine response.

2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:

- ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND
- An improvement of 0.22 in HAQ score [reported to two (2) decimal places].

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

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CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

ETANERCEPT

Following this assessment, continued coverage may be approved for 50 mg per week, for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:

- 1) The patient has been assessed by an RA Specialist to determine response;
 - 2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
 - Confirmation of maintenance of ACR20, or
 - Maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.
 - 3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.
- It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above."

All requests (including renewal requests) for etanercept for Rheumatoid Arthritis must be completed using the Abatacept/Adalimumab/Anakinra/Certolizumab/Etanercept/Golimumab/Infliximab/Sarilumab/Tocilizumab/Tofacitinib for Rheumatoid Arthritis Special Authorization Request Form (ABC 60027).

Polyarticular Juvenile Idiopathic Arthritis:

***Effective March 1, 2018, all new Special Authorization requests for the treatment of Rheumatoid Arthritis or Ankylosing Spondylitis for etanercept-naïve patients will be assessed for coverage with Brenzys or Erelzi. Effective June 1, 2019, all new Special Authorization requests for the treatment of Psoriatic Arthritis for etanercept-naïve patients will be assessed for coverage with Erelzi. Enbrel will not be approved for new etanercept starts for patients with the indications stated above; however, coverage for Enbrel will continue for patients who are currently well maintained on Enbrel and are considered a 'responder' as defined in criteria.

In addition, all new Special Authorization requests for the treatment of Polyarticular Juvenile Idiopathic Arthritis for etanercept-naïve patients weighing 63 kg (138 pounds) or more will be assessed for coverage with Erelzi. Enbrel will be approved for new etanercept starts for pediatric patients with Polyarticular Juvenile Idiopathic Arthritis weighing less than 63 kg, and coverage for Enbrel will continue for patients who are currently well maintained on Enbrel and are considered a 'responder' as defined in criteria.

Additionally, patients will not be permitted to switch between etanercept products, if the patient has been previously trialed on any etanercept product and deemed unresponsive to therapy.***

"Special authorization coverage may be provided for the reduction in signs and symptoms of severely active polyarticular juvenile idiopathic arthritis (pJIA) in patients 4 years of age and older who:

- Have 5 or more active joints (defined by either swelling or limitation of motion plus pain and/or tenderness), AND
- Are refractory to one or more disease modifying anti-rheumatic agents (DMARDs) conventionally used in children (minimum three month trial).

"Refractory" is defined as one or more of the following: lack of effect, serious adverse effects (e.g., leukopenia, hepatitis) or contraindications to treatments as defined in the product monographs.

For coverage, this drug must be prescribed by a prescriber affiliated with a Pediatric Rheumatology Clinic in Edmonton or Calgary (Pediatric Rheumatology Specialist).

- Coverage may be approved for 0.8 mg/kg/dose (maximum dose 50 mg) weekly for 12 weeks.
- Patients will be limited to receiving a one-month supply of etanercept per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another (with the exception of abatacept) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients will not be permitted to switch from abatacept to other biologic agents except under exceptional circumstances.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

ETANERCEPT

For continued coverage of this agent beyond 12 weeks, the patient must meet the following criteria:

- 1) The patient must be assessed by a Pediatric Rheumatology Specialist after 12 weeks, but no longer than 16 weeks after, treatment with this biologic agent to determine response.
- 2) The Pediatric Rheumatology Specialist must confirm in writing that the patient is a responder that meets the following criteria (ACR Pedi 30):
 - 30% improvement from baseline in at least three of the following six response variables, with worsening of 30% or more in no more than one of the six variables. The variables include:
 - i. global assessment of the severity of the disease by the Pediatric Rheumatology Specialist,
 - ii. global assessment of overall well-being by the patient or parent,
 - iii. number of active joints (joints with swelling not due to deformity or joints with limitation of motion with pain tenderness or both),
 - iv. number of joints with limitation of motion,
 - v. functional ability based on CHAQ scores,
 - vi. ESR or CRP
- 3) Data from all of the six variables comprising the ACR Pedi 30 and the CHAQ scores must be reported in each request

Following this assessment, continued coverage may be approved for 0.8 mg/kg/dose (maximum dose 50 mg) weekly, for a maximum of twelve months. After twelve months, in order to be considered for continued coverage, the patient must be re-assessed every twelve months by a Pediatric Rheumatology Specialist and must meet the following criteria:

- 1) The patient has been assessed by a Pediatric Rheumatology Specialist to determine response, and
- 2) The Pediatric RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by maintenance of the ACR Pedi 30,
- 3) Data from all of the six variables comprising the ACR Pedi 30 and the CHAQ scores must be reported in each request.

Once a child with pJIA has had two disease-free years, it is common clinical practice for drug treatment to be stopped."

All requests (including renewal requests) for etanercept for Polyarticular Juvenile Idiopathic Arthritis must be completed using the Adalimumab/Etanercept/Tocilizumab for Polyarticular Juvenile Idiopathic Arthritis Special Authorization Request Form (ABC 60011).

Ankylosing Spondylitis:

***Effective March 1, 2018, all new Special Authorization requests for the treatment of Rheumatoid Arthritis or Ankylosing Spondylitis for etanercept-naïve patients will be assessed for coverage with Brenzys or Erelzi. Effective June 1, 2019, all new Special Authorization requests for the treatment of Psoriatic Arthritis for etanercept-naïve patients will be assessed for coverage with Erelzi. Enbrel will not be approved for new etanercept starts for patients with the indications stated above; however, coverage for Enbrel will continue for patients who are currently well maintained on Enbrel and are considered a 'responder' as defined in criteria.

In addition, all new Special Authorization requests for the treatment of Polyarticular Juvenile Idiopathic Arthritis for etanercept-naïve patients weighing 63 kg (138 pounds) or more will be assessed for coverage with Erelzi. Enbrel will be approved for new etanercept starts for pediatric patients with Polyarticular Juvenile Idiopathic Arthritis weighing less than 63 kg, and coverage for Enbrel will continue for patients who are currently well maintained on Enbrel and are considered a 'responder' as defined in criteria.

Additionally, patients will not be permitted to switch between etanercept products, if the patient has been previously trialed on any etanercept product and deemed unresponsive to therapy.***

"Special authorization coverage may be provided for the reduction in the signs and symptoms of severely active Ankylosing Spondylitis, as defined by the Modified New York criteria for Ankylosing Spondylitis, in adult patients (18 years of age or older) who have active disease as demonstrated by:

- a BASDAI greater than or equal to 4 units, demonstrated on 2 occasions at least 8 weeks apart
- AND
- a Spinal Pain VAS of greater than or equal to 4 cm (on a 0-10 cm scale), demonstrated on 2 occasions at least 8 weeks apart
- AND
- who are refractory or intolerant to treatment with 2 or more NSAIDs each taken for a minimum of 4 weeks at maximum tolerated or recommended doses.

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

ETANERCEPT

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.

'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for 50 mg per week for 12 weeks.
- Patients will be limited to receiving a one-month supply of etanercept per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond 12 weeks, the patient must meet the following criteria:

- 1) The patient must be assessed at week 12 by an RA Specialist after the initial twelve weeks of therapy to determine response.
- 2) The RA Specialist must confirm, in writing, that the patient is a 'responder' that meets the following criteria:
 - Reduction of the BASDAI score by at least 50% of the pre-treatment value or by 2 or more units, AND
 - Reduction of the Spinal Pain VAS by 2 cm or more.

Following this assessment, continued coverage may be approved for 50 mg per week for a period of 12 months. Ongoing coverage may be considered if the patient is re-assessed by an RA Specialist every 12 months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above."

All requests (including renewal requests) for etanercept for Ankylosing Spondylitis must be completed using the Adalimumab/Certolizumab/Etanercept/Golimumab/Infliximab/Secukinumab for Ankylosing Spondylitis Special Authorization Request Form (ABC 60028).

Psoriatic Arthritis

***Effective March 1, 2018, all new Special Authorization requests for the treatment of Rheumatoid Arthritis or Ankylosing Spondylitis for etanercept-naïve patients will be assessed for coverage with Brenzys or Erelzi. Effective June 1, 2019, all new Special Authorization requests for the treatment of Psoriatic Arthritis for etanercept-naïve patients will be assessed for coverage with Erelzi. Enbrel will not be approved for new etanercept starts for patients with the indications stated above; however, coverage for Enbrel will continue for patients who are currently well maintained on Enbrel and are considered a 'responder' as defined in criteria.

In addition, all new Special Authorization requests for the treatment of Polyarticular Juvenile Idiopathic Arthritis for etanercept-naïve patients weighing 63 kg (138 pounds) or more will be assessed for coverage with Erelzi. Enbrel will be approved for new etanercept starts for pediatric patients with Polyarticular Juvenile Idiopathic Arthritis weighing less than 63 kg, and coverage for Enbrel will continue for patients who are currently well maintained on Enbrel and are considered a 'responder' as defined in criteria.

Additionally, patients will not be permitted to switch between etanercept products, if the patient has been previously trialed on any etanercept product and deemed unresponsive to therapy.***

"Special authorization coverage may be provided for use in combination with methotrexate for reducing signs and symptoms and inhibiting the progression of structural damage of active arthritis in adult patients (18 years of age or older) with moderate to severe polyarticular psoriatic arthritis (PsA) or pauciarticular PsA with involvement of knee or hip joint who are refractory or intolerant to:
- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- An adequate trial of another disease modifying anti-rheumatic agent(s) (minimum 4 month trial).

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CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

ETANERCEPT

Special authorization coverage of this agent may be provided for use as monotherapy in adult patients for whom methotrexate is contraindicated and/or for those patients who have experienced serious adverse effects.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.

'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for 50 mg per week for 8 weeks.
- Patients will be limited to receiving a one-month supply of etanercept per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond 8 weeks, the patient must meet the following criteria:

1) The patient must be assessed by an RA Specialist after 8 weeks, but no longer than 12 weeks after treatment to determine response.

2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:

- ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place];
AND

- An improvement of 0.22 in HAQ score [reported to two (2) decimal places].

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be approved for 50 mg per week, for a period of 12 months. Ongoing coverage may be considered if the following criteria are met at the end of each 12-month period:

1) The patient has been assessed by an RA Specialist to determine response;

2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:

- Confirmation of maintenance of ACR20, or

- Maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.

3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above."

All requests (including renewal requests) for etanercept for Psoriatic Arthritis must be completed using the Adalimumab/Certolizumab/Etanercept/Golimumab/Infliximab/Ixekizumab/Secukinumab for Psoriatic Arthritis Special Authorization Request Form (ABC 60029).

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Ankylosing Spondylitis

***Effective March 1, 2018, all new Special Authorization requests for the treatment of Rheumatoid Arthritis or Ankylosing Spondylitis for etanercept-naïve patients will be assessed for coverage with Brenzys or Erelzi. Effective June 1, 2019, all new Special Authorization requests for the treatment of Psoriatic Arthritis for etanercept-naïve patients will be assessed for coverage with Erelzi. Enbrel will not be approved for new etanercept starts for patients with the indications stated above; however, coverage for Enbrel will continue for patients who are currently well maintained on Enbrel and are considered a 'responder' as defined in criteria.

In addition, all new Special Authorization requests for the treatment of Polyarticular Juvenile Idiopathic Arthritis for etanercept-naïve patients weighing 63 kg (138 pounds) or more will be assessed for coverage with Erelzi. Enbrel will be approved for new etanercept starts for pediatric

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ETANERCEPT

patients with Polyarticular Juvenile Idiopathic Arthritis weighing less than 63 kg, and coverage for Enbrel will continue for patients who are currently well maintained on Enbrel and are considered a 'responder' as defined in criteria.

Additionally, patients will not be permitted to switch between etanercept products, if the patient has been previously trialed on any etanercept product and deemed unresponsive to therapy.***

"Special authorization coverage may be provided for the reduction in the signs and symptoms of severely active Ankylosing Spondylitis, as defined by the Modified New York criteria for Ankylosing Spondylitis, in adult patients (18 years of age or older) who have active disease as demonstrated by:

- a BASDAI greater than or equal to 4 units, demonstrated on 2 occasions at least 8 weeks apart
AND

- a Spinal Pain VAS of greater than or equal to 4 cm (on a 0-10 cm scale), demonstrated on 2 occasions at least 8 weeks apart AND

- who are refractory or intolerant to treatment with 2 or more NSAIDS each taken for a minimum of 4 weeks at maximum tolerated or recommended doses.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.

'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for 50 mg per week for 12 weeks.

- Patients will be limited to receiving a one-month supply of etanercept per prescription at their pharmacy.

- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).

- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.

- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond 12 weeks, the patient must meet the following criteria:

1) The patient must be assessed at week 12 by an RA Specialist after the initial twelve weeks of therapy to determine response.

2) The RA Specialist must confirm, in writing, that the patient is a 'responder' that meets the following criteria:

- Reduction of the BASDAI score by at least 50% of the pre-treatment value or by 2 or more units,
AND

- Reduction of the Spinal Pain VAS by 2 cm or more.

Following this assessment, continued coverage may be approved for 50 mg per week for a period of 12 months. Ongoing coverage may be considered if the patient is re-assessed by an RA Specialist every 12 months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above."

All requests (including renewal requests) for etanercept for Ankylosing Spondylitis must be completed using the Adalimumab/Certolizumab/Etanercept/Golimumab/Infliximab/Secukinumab for Ankylosing Spondylitis Special Authorization Request Form (ABC 60028).

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ETANERCEPT

Plaque Psoriasis

***Effective March 1, 2018, all new Special Authorization requests for the treatment of Rheumatoid Arthritis or Ankylosing Spondylitis for etanercept-naïve patients will be assessed for coverage with Brenzys or Erelzi. Effective June 1, 2019, all new Special Authorization requests for the treatment of Psoriatic Arthritis for etanercept-naïve patients will be assessed for coverage with Erelzi. Enbrel will not be approved for new etanercept starts for patients with the indications stated above; however, coverage for Enbrel will continue for patients who are currently well maintained on Enbrel and are considered a 'responder' as defined in criteria.

In addition, all new Special Authorization requests for the treatment of Polyarticular Juvenile Idiopathic Arthritis for etanercept-naïve patients weighing 63 kg (138 pounds) or more will be assessed for coverage with Erelzi. Enbrel will be approved for new etanercept starts for pediatric patients with Polyarticular Juvenile Idiopathic Arthritis weighing less than 63 kg, and coverage for Enbrel will continue for patients who are currently well maintained on Enbrel and are considered a 'responder' as defined in criteria.

Additionally, patients will not be permitted to switch between etanercept products, if the patient has been previously trialed on any etanercept product and deemed unresponsive to therapy.***

"Special authorization coverage may be provided for the reduction in signs and symptoms of severe, debilitating plaque psoriasis in patients who:

- Have a total PASI of 10 or more and a DLQI of more than 10, OR
- Who have significant involvement of the face, palms of the hands, soles of the feet or genital region; AND
- Who are refractory or intolerant to:

at least THREE of the following:

- Cosentyx (secukinumab)
 - Inflectra (infliximab)
 - Renflexis (infliximab)
 - Skyrizi (risankizumab)
 - Taltz (ixekizumab);
- AND

- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory, OR

- Cyclosporine (6 weeks treatment); AND
- Phototherapy (unless restricted by geographic location)

Patients who have a contraindication to either cyclosporine or methotrexate will be required to complete an adequate trial of the other pre-requisite medication prior to potential coverage being considered.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.

'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be prescribed by a Specialist in Dermatology ("Dermatology Specialist").

-Initial coverage may be approved for up to 100 mg per week for 12 weeks.

-Patients will be limited to receiving a one-month supply of etanercept per prescription at their pharmacy.

- Patients will be permitted to switch from one biologic agent to another following an adequate trial

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ETANERCEPT

of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).

- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.

- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond 12 weeks, the patient must meet all of the following criteria:

1) The patient must be assessed by a Dermatology Specialist after the initial 12 weeks of therapy to determine response.

2) The Dermatology Specialist must confirm, in writing, that the patient is a 'responder' that meets the following criteria:

- Greater than or equal to 75% reduction in PASI score, OR

- Greater than or equal to 50% reduction in PASI score AND improvement of greater than or equal to 5 points in the DLQI

Following this assessment, continued coverage may be considered for 50 mg per week for a period of 12 months. Ongoing coverage may be considered if the patient is re-assessed by a Dermatology Specialist every 12 months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above."

PASI and DLQI scores are required for all requests for Plaque Psoriasis including those requests for patients that have significant involvement of the face, palms, soles of feet or genital region.

All requests (including renewal requests) for etanercept for Plaque Psoriasis must be completed using the Adalimumab/Etanercept/Infliximab/Ixekizumab/Risankizumab/Secukinumab/Ustekinumab for Plaque Psoriasis Special Authorization Request Form (ABC 60030).

Polyarticular Juvenile Idiopathic Arthritis

***Effective March 1, 2018, all new Special Authorization requests for the treatment of Rheumatoid Arthritis or Ankylosing Spondylitis for etanercept-naïve patients will be assessed for coverage with Brenzys or Erelzi. Effective June 1, 2019, all new Special Authorization requests for the treatment of Psoriatic Arthritis for etanercept-naïve patients will be assessed for coverage with Erelzi. Enbrel will not be approved for new etanercept starts for patients with the indications stated above; however, coverage for Enbrel will continue for patients who are currently well maintained on Enbrel and are considered a 'responder' as defined in criteria.

In addition, all new Special Authorization requests for the treatment of Polyarticular Juvenile Idiopathic Arthritis for etanercept-naïve patients weighing 63 kg (138 pounds) or more will be assessed for coverage with Erelzi. Enbrel will be approved for new etanercept starts for pediatric patients with Polyarticular Juvenile Idiopathic Arthritis weighing less than 63 kg, and coverage for Enbrel will continue for patients who are currently well maintained on Enbrel and are considered a 'responder' as defined in criteria.

Additionally, patients will not be permitted to switch between etanercept products, if the patient has been previously trialed on any etanercept product and deemed unresponsive to therapy.***

"Special authorization coverage may be provided for the reduction in signs and symptoms of severely active polyarticular juvenile idiopathic arthritis (pJIA) in patients 4 years of age and older who:

- Have 5 or more active joints (defined by either swelling or limitation of motion plus pain and/or tenderness), AND

- Are refractory to one or more disease modifying anti-rheumatic agents (DMARDs) conventionally used in children (minimum three month trial).

"Refractory" is defined as one or more of the following: lack of effect, serious adverse effects (e.g., leukopenia, hepatitis) or contraindications to treatments as defined in the product monographs.

For coverage, this drug must be prescribed by a prescriber affiliated with a Pediatric Rheumatology

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ETANERCEPT

Clinic in Edmonton or Calgary (Pediatric Rheumatology Specialist).

- Coverage may be approved for 0.8 mg/kg/dose (maximum dose 50 mg) weekly for 12 weeks.
- Patients will be limited to receiving a one-month supply of etanercept per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another (with the exception of abatacept) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients will not be permitted to switch from abatacept to other biologic agents except under exceptional circumstances.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage of this agent beyond 12 weeks, the patient must meet the following criteria:

- 1) The patient must be assessed by a Pediatric Rheumatology Specialist after 12 weeks, but no longer than 16 weeks after, treatment with this biologic agent to determine response.
- 2) The Pediatric Rheumatology Specialist must confirm in writing that the patient is a responder that meets the following criteria (ACR Pedi 30):
 - 30% improvement from baseline in at least three of the following six response variables, with worsening of 30% or more in no more than one of the six variables. The variables include:
 - i. global assessment of the severity of the disease by the Pediatric Rheumatology Specialist,
 - ii. global assessment of overall well-being by the patient or parent,
 - iii. number of active joints (joints with swelling not due to deformity or joints with limitation of motion with pain tenderness or both),
 - iv. number of joints with limitation of motion,
 - v. functional ability based on CHAQ scores,
 - vi. ESR or CRP
- 3) Data from all of the six variables comprising the ACR Pedi 30 and the CHAQ scores must be reported in each request

Following this assessment, continued coverage may be approved for 0.8 mg/kg/dose (maximum dose 50 mg) weekly, for a maximum of twelve months. After twelve months, in order to be considered for continued coverage, the patient must be re-assessed every twelve months by a Pediatric Rheumatology Specialist and must meet the following criteria:

- 1) The patient has been assessed by a Pediatric Rheumatology Specialist to determine response, and
- 2) The Pediatric RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by maintenance of the ACR Pedi 30,
- 3) Data from all of the six variables comprising the ACR Pedi 30 and the CHAQ scores must be reported in each request.

Once a child with pJIA has had two disease-free years, it is common clinical practice for drug treatment to be stopped."

All requests (including renewal requests) for etanercept for Polyarticular Juvenile Idiopathic Arthritis must be completed using the Adalimumab/Etanercept/Tocilizumab for Polyarticular Juvenile Idiopathic Arthritis Special Authorization Request Form (ABC 60011).

Psoriatic Arthritis

***Effective March 1, 2018, all new Special Authorization requests for the treatment of Rheumatoid Arthritis or Ankylosing Spondylitis for etanercept-naive patients will be assessed for coverage with Brenzys or Erelzi. Effective June 1, 2019, all new Special Authorization requests for the treatment of Psoriatic Arthritis for etanercept-naive patients will be assessed for coverage with Erelzi. Enbrel will not be approved for new etanercept starts for patients with the indications stated above; however, coverage for Enbrel will continue for patients who are currently well maintained on Enbrel and are considered a 'responder' as defined in criteria.

In addition, all new Special Authorization requests for the treatment of Polyarticular Juvenile Idiopathic Arthritis for etanercept-naive patients weighing 63 kg (138 pounds) or more will be assessed for coverage with Erelzi. Enbrel will be approved for new etanercept starts for pediatric patients with Polyarticular Juvenile Idiopathic Arthritis weighing less than 63 kg, and coverage for Enbrel will continue for patients who are currently well maintained on Enbrel and are considered a 'responder' as defined in criteria.

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CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

ETANERCEPT

Additionally, patients will not be permitted to switch between etanercept products, if the patient has been previously trialed on any etanercept product and deemed unresponsive to therapy.***

"Special authorization coverage may be provided for use in combination with methotrexate for reducing signs and symptoms and inhibiting the progression of structural damage of active arthritis in adult patients (18 years of age or older) with moderate to severe polyarticular psoriatic arthritis (PsA) or pauciarticular PsA with involvement of knee or hip joint who are refractory or intolerant to:

- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- An adequate trial of another disease modifying anti-rheumatic agent(s) (minimum 4 month trial).

Special authorization coverage of this agent may be provided for use as monotherapy in adult patients for whom methotrexate is contraindicated and/or for those patients who have experienced serious adverse effects.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.

'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for 50 mg per week for 8 weeks.
- Patients will be limited to receiving a one-month supply of etanercept per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond 8 weeks, the patient must meet the following criteria:

- 1) The patient must be assessed by an RA Specialist after 8 weeks, but no longer than 12 weeks after treatment to determine response.
- 2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
 - ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND
 - An improvement of 0.22 in HAQ score [reported to two (2) decimal places].

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be approved for 50 mg per week, for a period of 12 months. Ongoing coverage may be considered if the following criteria are met at the end of each 12-month period:

- 1) The patient has been assessed by an RA Specialist to determine response;
- 2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
 - Confirmation of maintenance of ACR20, or
 - Maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.
- 3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above."

All requests (including renewal requests) for etanercept for Psoriatic Arthritis must be completed using the Adalimumab/Certolizumab/Etanercept/Golimumab/Infliximab/Ixekizumab/Secukinumab for Psoriatic Arthritis Special Authorization Request Form (ABC 60029).

Rheumatoid Arthritis

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

ETANERCEPT

***Effective March 1, 2018, all new Special Authorization requests for the treatment of Rheumatoid Arthritis or Ankylosing Spondylitis for etanercept-naïve patients will be assessed for coverage with Brenzys or Erelzi. Effective June 1, 2019, all new Special Authorization requests for the treatment of Psoriatic Arthritis for etanercept-naïve patients will be assessed for coverage with Erelzi. Enbrel will not be approved for new etanercept starts for patients with the indications stated above; however, coverage for Enbrel will continue for patients who are currently well maintained on Enbrel and are considered a 'responder' as defined in criteria.

In addition, all new Special Authorization requests for the treatment of Polyarticular Juvenile Idiopathic Arthritis for etanercept-naïve patients weighing 63 kg (138 pounds) or more will be assessed for coverage with Erelzi. Enbrel will be approved for new etanercept starts for pediatric patients with Polyarticular Juvenile Idiopathic Arthritis weighing less than 63 kg, and coverage for Enbrel will continue for patients who are currently well maintained on Enbrel and are considered a 'responder' as defined in criteria.

Additionally, patients will not be permitted to switch between etanercept products, if the patient has been previously trialed on any etanercept product and deemed unresponsive to therapy.***

"Special authorization coverage may be provided for use in combination with methotrexate for the reduction in signs and symptoms of severely active Rheumatoid Arthritis (RA) in adult patients (18 years of age or older) who are refractory or intolerant to:

- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND

- Methotrexate with other disease modifying anti-rheumatic agent(s) (minimum 4-month trial). [e.g., methotrexate with hydroxychloroquine or methotrexate with sulfasalazine]; AND

- Leflunomide (minimum 10 week trial at 20 mg daily).

Special authorization coverage of this agent may be provided for use as monotherapy in adult patients for whom methotrexate is contraindicated and/or for those patients who have experienced serious adverse effects.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.

'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for 50 mg per week for 8 weeks.

- Patients will be limited to receiving a one-month supply of etanercept per prescription at their pharmacy.

- Patients will be permitted to switch from one biologic agent to another (with the exception of anakinra) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).

- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.

- Patients will not be permitted to switch from anakinra to other biologic agents except under exceptional circumstances.

- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond 8 weeks, the patient must meet the following criteria:

- 1) The patient must be assessed by an RA Specialist after 8 weeks, but no longer than 12 weeks after treatment to determine response.

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

ETANERCEPT

2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:

- ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place];
AND

- An improvement of 0.22 in HAQ score [reported to two (2) decimal places].

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be approved for 50 mg per week, for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:

1) The patient has been assessed by an RA Specialist to determine response;

2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:

- Confirmation of maintenance of ACR20, or

- Maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.

3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above."

All requests (including renewal requests) for etanercept for Rheumatoid Arthritis must be completed using the Abatacept/Adalimumab/Anakinra/Certolizumab/Etanercept/Golimumab/Infliximab/Sarilumab/Tocilizumab/Tofacitinib for Rheumatoid Arthritis Special Authorization Request Form (ABC 60027).

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

EVOLOCUMAB

"Special authorization coverage may be provided for the reduction of Low Density Lipoprotein Cholesterol (LDL-C) if the following clinical criteria and conditions are met:

I) Patient has a definite or probable diagnosis of Heterozygous Familial Hypercholesterolemia (HeFH) using the Simon Broome or Dutch Lipid Network criteria or genetic testing.

AND

II) Patient is unable to reach LDL-C target (i.e., LDL-C < 2.0 mmol/L for secondary prevention or at least a 50% reduction in LDL-C from untreated baseline for primary prevention) despite:

a) Confirmed adherence to high dose statin (e.g., atorvastatin 80 mg or rosuvastatin 40 mg) in combination with ezetimibe for at least 3 months.

OR

b) Confirmed adherence to ezetimibe for at least 3 months.

AND

Patient is unable to tolerate high dose statin, defined as meeting all of the following:

i) Inability to tolerate at least two statins with at least one started at the lowest starting daily dose,

AND

ii) For each statin (two statins in total), dose reduction is attempted for intolerable symptom (myopathy) or biomarker abnormality (creatinine kinase (CK) > 5 times the upper limit of normal) resolution rather than discontinuation of statin altogether,

AND

iii) For each statin (two statins in total), intolerable symptoms (myopathy) or abnormal biomarkers (CK > 5 times the upper limit of normal) changes are reversible upon statin discontinuation but reproducible by re-challenge of statins where clinically appropriate,

AND

iv) One of either:

- Other known determinants of intolerable symptoms or abnormal biomarkers have been ruled out,

OR

- Patient developed confirmed and documented rhabdomyolysis.

OR

c) Confirmed adherence to ezetimibe for at least 3 months.

AND

Patient is statin contraindicated, i.e., active liver disease or unexplained persistent elevations of serum transaminases exceeding 3 times the upper limit of normal.

- Initial coverage may be approved for either 140 mg every two weeks or 420 mg every month for a period of 3 months.

- Patients prescribed evolocumab 420 mg every month must use the 420 mg/dose formulation.

- Patients will be limited to receiving a one-month supply of evolocumab per prescription at their pharmacy.

For continued coverage beyond 3 months, the patient must meet the following criteria:

- Patient is adherent to therapy.

- Patient has achieved a reduction in LDL-C of at least 40% from baseline (4-8 weeks after initiation of evolocumab).

Continued coverage may be approved for 140 mg every 2 weeks or 420 mg every month for a period 12 months. Patients prescribed evolocumab 140 mg every 2 weeks are limited to 26 doses per year. Patients prescribed evolocumab 420 mg every month are limited to 12 doses per year.

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

EVOLOCUMAB

Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:

- Patient is adherent to therapy.
- Patient continues to have a significant reduction in LDL-C (with continuation of evolocumab) of at least 40% from baseline since initiation of PCSK9 inhibitor. LDL-C should be checked periodically with continued treatment with PCSK9 inhibitors (e.g., every 6 months)."

All requests (including renewal requests) for evolocumab for Heterozygous Familial Hypercholesterolemia must be completed using the Alirocumab/Evolocumab for HeFH Special Authorization Request Form (ABC 60060).

420 MG INJECTION CARTRIDGE			
00002459779	REPATHA	AMG	\$ 555.1200
140 MG / SYR INJECTION SYRINGE			
00002446057	REPATHA AUTOINJECTOR	AMG	\$ 256.2100

EZETIMIBE

"For the treatment of hypercholesterolemia in patients who are intolerant to statins or in whom a statin is contraindicated and who are at high cardiovascular risk*; or

For the treatment of hypercholesterolemia when used in combination with a statin in patients failing to achieve target LDL with a statin at maximum tolerable dose or maximum recommended dose as per respective product monograph and who are at high cardiovascular risk*:

* High cardiovascular risk is defined as possessing one of the following:

- 1) Pre-existing cardiovascular disease and/or cerebrovascular disease, or
- 2) Diabetes, or
- 3) Familial hypercholesterolemia, or
- 4) Greater than or equal to 20% risk as defined by the Framingham Risk Assessment Tool, or
- 5) Three or more of the following risk factors:
 - Family history of premature cardiovascular disease
 - Smoking
 - Hypertension
 - Obesity
 - Glucose intolerance
 - Renal disease.

Special authorization for these criteria may be granted for 6 months."

All requests for ezetimibe must be completed using the Ezetimibe Special Authorization Request Form (ABC 60036).

The following product(s) are eligible for auto-renewal.

10 MG ORAL TABLET			
00002425610	ACH-EZETIMIBE	AHI	\$ 0.1811
00002427826	APO-EZETIMIBE	APX	\$ 0.1811
00002469286	AURO-EZETIMIBE	AUR	\$ 0.1811
00002429659	EZETIMIBE	SIV	\$ 0.1811
00002431300	EZETIMIBE	SNS	\$ 0.1811
00002423235	JAMP-EZETIMIBE	JPC	\$ 0.1811
00002422662	MAR-EZETIMIBE	MAR	\$ 0.1811
00002423243	MINT-EZETIMIBE	MPI	\$ 0.1811
00002416409	PMS-EZETIMIBE	PMS	\$ 0.1811
00002419548	RAN-EZETIMIBE	RAN	\$ 0.1811
00002416778	SANDOZ EZETIMIBE	SDZ	\$ 0.1811
00002354101	TEVA-EZETIMIBE	TEV	\$ 0.1811
00002247521	EZETROL	MFC	\$ 1.9180

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

FEBUXOSTAT

"For the treatment of symptomatic gout in patients with a documented hypersensitivity to allopurinol.

Special authorization may be granted for 6 months."

Please note: Hypersensitivity to allopurinol is a rare condition that is characterized by a major skin manifestation, fever, multi-organ involvement, lymphadenopathy and hematological abnormalities (eosinophilia, atypical lymphocytes). Intolerance or lack of response to allopurinol will not be covered by this criteria.

All requests for febuxostat must be completed using the Febuxostat Special Authorization Request Form (ABC 60037).

The following product(s) are eligible for auto-renewal.

80 MG ORAL TABLET

00002473607	MAR-FEBUXOSTAT	MAR	\$	1.1925
00002357380	ULORIC	TAK	\$	1.5900

FENTANYL

"For the treatment of persistent, severe chronic pain in those patients who require continuous around-the-clock analgesia for an extended period of time in those patients who cannot swallow. Special authorization may be granted for 6 months."

"For the treatment of persistent, severe chronic pain in those patients who require continuous around-the-clock analgesia for an extended period of time in those patients who require opioid therapy at a total daily dose of at least 60 mg/day oral morphine equivalents. Patients must have tried and not been able to tolerate at least two discrete courses of therapy with two of the following agents: morphine, hydromorphone and oxycodone, if not contraindicated. Special authorization may be granted for 6 months."

Information is required regarding previous medications utilized and the patient's response to therapy. Also, information regarding the number of discrete (separate) courses of these medications is required. A discrete course is defined as a separate treatment course, which may involve more than 1 agent, used at one time to manage the patient's condition.

All requests for fentanyl must be completed using the Fentanyl Special Authorization Request Form (ABC 60005).

(Please note: The following fentanyl products are benefits not requiring special authorization for individuals approved by Alberta Health for Palliative Coverage. Refer to the Palliative Coverage Drug Benefit Supplement for additional information on this coverage.)

The following product(s) are eligible for auto-renewal.

12 MCG/HR TRANSDERMAL PATCH

00002341379	PMS-FENTANYL MTX	PMS	\$	2.2280
00002327112	SANDOZ FENTANYL PATCH	SDZ	\$	2.2280
00002311925	TEVA-FENTANYL	TEV	\$	2.2280

25 MCG/HR TRANSDERMAL PATCH

00002341387	PMS-FENTANYL MTX	PMS	\$	3.6560
00002327120	SANDOZ FENTANYL PATCH	SDZ	\$	3.6560
00002282941	TEVA-FENTANYL	TEV	\$	3.6560

50 MCG/HR TRANSDERMAL PATCH

00002341395	PMS-FENTANYL MTX	PMS	\$	6.8820
00002327147	SANDOZ FENTANYL PATCH	SDZ	\$	6.8820
00002282968	TEVA-FENTANYL	TEV	\$	6.8820

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

FENTANYL

75 MCG/HR TRANSDERMAL PATCH

00002341409	PMS-FENTANYL MTX	PMS	\$	9.6800
00002327155	SANDOZ FENTANYL PATCH	SDZ	\$	9.6800
00002282976	TEVA-FENTANYL	TEV	\$	9.6800

100 MCG/HR TRANSDERMAL PATCH

00002341417	PMS-FENTANYL MTX	PMS	\$	12.0500
00002327163	SANDOZ FENTANYL PATCH	SDZ	\$	12.0500
00002282984	TEVA-FENTANYL	TEV	\$	12.0500

FENTANYL CITRATE

"For the treatment of persistent, severe chronic pain in those patients who cannot swallow, or who are intolerant of morphine and/or hydromorphone, if not contraindicated. Special authorization may be granted for 6 months."

All requests for fentanyl must be completed using the Fentanyl Special Authorization Request Form (ABC 60005).

(Please note: The following fentanyl products are benefits not requiring special authorization for individuals approved by Alberta Health for Palliative Coverage. Refer to the Palliative Coverage Drug Benefit Supplement for additional information on this coverage.)

This product is eligible for auto-renewal.

0.05 MG / ML (BASE)	INJECTION			
00002240434	FENTANYL CITRATE	SDZ	\$	2.7290

FESOTERODINE FUMARATE

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

FIRST-LINE DRUG PRODUCT(S): SOLIFENACIN OR TOLTERODINE LA

"For patients who have failed on or are intolerant to solifenacin or tolterodine LA."

"Special authorization may be granted for 24 months."

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

UP - First-line therapy ineffective

UQ - First-line therapy not tolerated

4 MG ORAL EXTENDED-RELEASE TABLET				
00002380021	TOVIAZ	PFI	\$	1.5000
8 MG ORAL EXTENDED-RELEASE TABLET				
00002380048	TOVIAZ	PFI	\$	1.5000

ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

FIDAXOMICIN

For the treatment of:

- 1) C. difficile infection (CDI) where the patient has failed, or is intolerant of oral vancomycin; or
- 2) Patients with third or greater recurrence of CDI (i.e. 4th or greater episode of CDI)

Note:

- Fidaxomicin should not be used as an add-on to existing therapy (metronidazole or vancomycin).
- Not studied in multiple recurrences or those with life-threatening or fulminant CDI, toxic megacolon, or inflammatory bowel disease.

Special authorization coverage for fidaxomicin will be provided for one treatment course (10 days) plus one additional treatment course for an early relapse occurring within 8 weeks of the start of the most recent fidaxomicin course.

New episode of CDI after 8 weeks will require treatment with first line therapy before fidaxomicin coverage may be considered.

All requests (including renewal requests) for fidaxomicin must be completed using the Fidaxomicin Special Authorization Request Form (ABC 60014).

200 MG ORAL TABLET

00002387174	DIFICID	MFC	\$	94.6000
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FILGRASTIM

Effective April 1, 2017, all Special Authorization requests for filgrastim will be assessed for coverage with Grastofil. Neupogen will not be approved for new filgrastim starts or repeat treatments (e.g. new course of chemotherapy); however, coverage for Neupogen will continue for pediatric patients and patients with congenital, cyclic or idiopathic neutropenia who are currently maintained on Neupogen.

"In patients with non-myeloid malignancies, receiving myelosuppressive anti-neoplastic drugs with curative intent, to decrease the incidence of infection, as manifested by febrile neutropenia."

"Following induction and consolidation treatment for acute myeloid leukemia, for the reduction in the duration of neutropenia, fever, antibiotic use and hospitalization."

"In patients with a diagnosis of congenital, cyclic or idiopathic neutropenia, to increase neutrophil counts and to reduce the incidence and duration of infection."

Please note for the first criterion: Coverage cannot be considered for palliative patients.

All requests for filgrastim must be completed using the Filgrastim/Pegfilgrastim/Plerixafor Special Authorization Request Form (ABC 60013).

0.3 MG / ML INJECTION

00001968017	NEUPOGEN	AMG	\$	176.1330
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0.3 MG / SYR INJECTION SYRINGE

00002441489	GRASTOFIL	APX	\$	144.3135
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0.48 MG / SYR INJECTION SYRINGE

00002454548	GRASTOFIL	APX	\$	230.9017
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ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

FINGOLIMOD HYDROCHLORIDE

Relapsing Remitting Multiple Sclerosis (RRMS):

Special authorization coverage may be provided for the treatment of relapsing remitting multiple sclerosis (RRMS) to reduce the frequency of clinical relapses and to delay the progression of physical disability in adult patients (18 years of age or older) who are refractory or intolerant to at least ONE of the following:

- interferon beta
- glatiramer acetate
- dimethyl fumarate
- teriflunomide
- peginterferon beta.

Definition of 'intolerant'

Demonstrating serious adverse effects or contraindications to treatments as defined in the product monograph, or a persisting adverse event that is unresponsive to recommended management techniques and which is incompatible with further use of that class of MS disease modifying therapy (DMT).

Definition of 'refractory'

-Development of neutralizing antibodies to interferon beta.

-When the above MS DMTs are taken at the recommended doses for a full and adequate course of treatment, within a consecutive 12-month period while the patient was on the MS DMT, the patient has:

- 1) Been adherent to the MS DMT (greater than 80% of approved doses have been administered);
- 2) Experienced at least two relapses* of MS confirmed by the presence of neurologic deficits on examination.
 - i. The first qualifying clinical relapse must have begun at least one month after treatment initiation.
 - ii. Both qualifying relapses must be classified with a relapse severity of moderate, severe or very severe**.

* A relapse is defined as the appearance of new symptoms or worsening of old symptoms, lasting at least 48 hours in the absence of fever, not associated with withdrawal from steroids. Onset of clinical relapses must be separated by a period of at least one month. At least one definite gadolinium-enhancing T1 MRI lesion (not questionable faint enhancement) obtained at least 90 days after initiation of the DMT and at least 90 days before or after a relapse may substitute for one clinical relapse.

**Relapse Severity: with moderate relapses modification or more time is required to carry out activities of daily living; with severe relapses there is inability to carry out some activities of daily living; with very severe relapses activities of daily living must be completed by others.

Coverage

For coverage, this drug must be prescribed by a registered MS Neurologist. A current assessment must be completed by a registered MS Neurologist at every request.

To register to become an MS Neurologist please complete the Registration for MS Neurologist Status Form (ABC 60002).

Initial Coverage

- 1) The registered MS Neurologist must confirm a diagnosis of RRMS;
- 2) The patient must have active disease which is defined as at least two relapses* of MS during

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

FINGOLIMOD HYDROCHLORIDE

the previous two years or in the two years prior to starting an MS DMT. In most cases this will be satisfied by the refractory to treatment criterion but if a patient failed an MS DMT more than one year earlier, ongoing active disease must be confirmed.

3) The patient must be ambulatory with or without aid (The registered MS Neurologist must provide a current updated Expanded Disability Status Scale (EDSS) score less than or equal to 6.5).

Coverage will not be approved when any MS DMT or other immunosuppressive therapy is to be used in combination with fingolimod.

Coverage of fingolimod will not be approved if the patient was deemed to be refractory to fingolimod in the past, i.e., has not met the 'responder' criteria below in 'Continued Coverage'.

Following assessment of the request, coverage may be approved for up to 12 months. Patients will be limited to receiving a one-month supply of fingolimod per prescription at their pharmacy for the first 12 months of coverage.

Continued Coverage

For continued coverage beyond the initial coverage period, the patient must meet the following criteria:

- 1) The patient must be assessed by a registered MS Neurologist;
- 2) The registered MS Neurologist must confirm a diagnosis of RRMS;
- 3) The registered MS Neurologist must provide a current updated EDSS score. The patient must not have an EDSS score of 7.0 or above sustained for one year or more;

Coverage of this drug may be considered in a patient with a sustained EDSS score of 7.0 or above in exceptional circumstances. For MS DMT coverage to be considered, details of the exceptional circumstance must be provided in a letter from the registered MS Neurologist and accompany the Special Authorization Request Form.

4) The registered MS Neurologist must confirm in writing that the patient is a 'responder' who has experienced no more than one inflammatory event in the last year (defined as either a clinical relapse or gadolinium-enhancing lesion). In instances where a patient has had four or more clinical relapses in the year prior to starting treatment, there must be at least a 50% reduction in relapse rate over the entire treatment period.

Following assessment of the request, continued coverage may be approved for maintenance therapy for up to 12 months. Patients may receive up to 100 days' supply of fingolimod per prescription at their pharmacy.

Restarting After an Interruption in Therapy Greater Than 12 Months

In order to be eligible for coverage, after an interruption of therapy greater than 12 months, the patient must meet the following criteria:

- 1) At least one relapse* per 12 month period; or
- 2) At least two relapses* during the previous 24 month period.

All requests (including renewal requests) for fingolimod must be completed using the Alemtuzumab/Fingolimod/Natalizumab For Multiple Sclerosis Special Authorization Request Form (ABC 60000).

0.5 MG (BASE) ORAL CAPSULE

00002469936	APO-FINGOLIMOD	APX	\$	21.7381
00002487772	JAMP FINGOLIMOD	JPC	\$	21.7381

ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

FINGOLIMOD HYDROCHLORIDE

00002474743	MAR-FINGOLIMOD	MAR	\$	21.7381
00002469715	MYLAN-FINGOLIMOD	MYP	\$	21.7381
00002469782	PMS-FINGOLIMOD	PMS	\$	21.7381
00002482606	SANDOZ FINGOLIMOD	SDZ	\$	21.7381
00002469618	TARO-FINGOLIMOD	TAR	\$	21.7381
00002469561	TEVA-FINGOLIMOD	TEV	\$	21.7381
00002365480	GILENYA	NOV	\$	86.9525

FLUCONAZOLE

(Refer to Section 1 - Restricted Benefits of the Alberta Drug Benefit List for coverage of the product when prescribed by a Specialist in Infectious Diseases or a designated prescriber.)

"For susceptible infections in patients who cannot swallow tablets."*

*Special Authorization is only required when the prescriber prescribing the medication is not a Specialist in Infectious Diseases or a designated prescriber.

10 MG / ML ORAL SUSPENSION				
00002024152	DIFLUCAN	PFI	\$	1.1854

FLUTAMIDE

"When prescribed for non-cancer, non-cosmetic indications.

Special authorization may be granted for 6 months."

Information is required regarding the patient's diagnosis/indication for use of this medication.

The following product(s) are eligible for auto-renewal.

250 MG ORAL TABLET				
00002238560	FLUTAMIDE	AAP	\$	1.8894

ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

**FLUTICASONE FUROATE/ UMECLIDINIUM BROMIDE/
VILANTEROL TRIFENATATE**

CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD)

FIRST-LINE DRUG PRODUCT(S):

LONG-ACTING BRONCHODILATOR (I.E., LONG-ACTING BETA-2 AGONIST [LABA] OR
LONG-ACTING MUSCARINIC ANTAGONIST [LAMA])

SECOND-LINE DRUG PRODUCT(S):

LONG-ACTING BRONCHODILATOR DUAL THERAPY (I.E., LONG-ACTING BETA-2
AGONIST [LABA] AND LONG-ACTING MUSCARINIC ANTAGONIST [LAMA]) OR
DUAL THERAPY OF INHALED CORTICOSTEROID [ICS] AND LONG-ACTING BETA-2
AGONIST [LABA])

"For the long-term maintenance treatment of chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema, in patients who are not controlled on optimal dual inhaled therapy (i.e., long-acting beta-2 agonist [LABA]/long-acting muscarinic antagonist [LAMA] OR inhaled corticosteroid [ICS]/long-acting beta-2 agonist [LABA])."

"Special authorization may be granted for 24 months."

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the third-line therapy drug.

UP - First-line therapy ineffective

All requests for fluticasone furoate + umeclidinium + vilanterol must be completed using the Long-Acting Fixed-Dose Combination Products for Asthma/COPD Special Authorization Request Form (ABC 60025).

100 MCG / DOSE * 62.5 MCG / DOSE (BASE) * 25 MCG / DOSE (BASE)	INHALATION	METERED	
00002474522 TRELEGY ELLIPTA	GSK	\$	4.4067

ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

FLUTICASONE FUROATE/ VILANTEROL TRIFENATATE

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

ASTHMA

FIRST-LINE DRUG PRODUCT(S): INHALED CORTICOSTEROID (ICS)

"For the treatment of asthma in patients uncontrolled on inhaled steroid therapy."

CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD)

FIRST-LINE DRUG PRODUCT(S): LONG-ACTING BRONCHODILATOR (I.E., LONG-ACTING BETA-2 AGONIST [LABA] OR LONG-ACTING MUSCARINIC ANTAGONIST [LAMA])

"For the long-term maintenance treatment of airflow obstruction in patients with moderate to severe (i.e., FEV1 < 80% predicted) chronic obstructive pulmonary disease (COPD), who have an inadequate response to a long-acting bronchodilator (long-acting beta-2 agonist [LABA] or long-acting muscarinic antagonist [LAMA])."

"For the long-term maintenance treatment of airflow obstruction in patients with severe (i.e., FEV1 < 50% predicted) chronic obstructive pulmonary disease (COPD)."

"Special authorization may be granted for 24 months."

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

UP - First-line therapy ineffective

All requests for fluticasone furoate + vilanterol trifenate must be completed using the Long-Acting Fixed-Dose Combination Products for Asthma/COPD Special Authorization Request Form (ABC 60025).

100 MCG / DOSE * 25 MCG / DOSE (BASE)	INHALATION	METERED INHALATION POWDER		
00002408872	BREO ELLIPTA	GSK	\$	2.8770

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

FLUTICASONE FUROATE/ VILANTEROL TRIFENATATE

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

ASTHMA

FIRST-LINE DRUG PRODUCT(S): INHALED CORTICOSTEROID (ICS)

"For the treatment of asthma in patients uncontrolled on inhaled steroid therapy."

"Special authorization may be granted for 24 months."

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

UP - First-line therapy ineffective

All requests for fluticasone furoate + vilanterol trifenate must be completed using the Long-Acting Fixed-Dose Combination Products for Asthma/COPD Special Authorization Request Form (ABC 60025).

200 MCG / DOSE * 25 MCG / DOSE	INHALATION	METERED INHALATION POWDER		
00002444186	BREO ELLIPTA	GSK	\$	4.5059

GALANTAMINE HYDROBROMIDE

"For the treatment of Alzheimer's disease in patients with an MMSE (Mini Mental State Exam) score between 10-26 and/or an InterRAI-Cognitive Performance Scale score between 1-4.

Coverage cannot be provided for two or more medications used in the treatment of Alzheimer's disease (donepezil, galantamine, rivastigmine) when these medications are intended for use in combination.

Special authorization coverage may be granted for a maximum of 24 months per request.

For each request, an updated MMSE score or InterRAI-Cognitive Performance Scale score and the date on which the exam was administered must be provided.

Renewal requests may be considered for patients where the updated MMSE score is 10 or higher or the InterRAI-Cognitive Performance Scale is 4 or lower while on this drug."

All requests (including renewal requests) for galantamine hydrobromide must be completed using the Donepezil/Galantamine/Rivastigmine Special Authorization Request Form (ABC 60034).

8 MG (BASE)	ORAL	EXTENDED-RELEASE CAPSULE		
00002425157	AURO-GALANTAMINE ER	AUR	\$	1.2463
00002443015	GALANTAMINE ER	SNS	\$	1.2463
00002339439	MYLAN-GALANTAMINE ER	MYP	\$	1.2463
00002398370	PMS-GALANTAMINE ER	PMS	\$	1.2463
16 MG (BASE)	ORAL	EXTENDED-RELEASE CAPSULE		
00002425165	AURO-GALANTAMINE ER	AUR	\$	1.2463
00002443023	GALANTAMINE ER	SNS	\$	1.2463
00002339447	MYLAN-GALANTAMINE ER	MYP	\$	1.2463
00002398389	PMS-GALANTAMINE ER	PMS	\$	1.2463

ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

GALANTAMINE HYDROBROMIDE

24 MG (BASE) ORAL EXTENDED-RELEASE CAPSULE

00002425173	AURO-GALANTAMINE ER	AUR	\$	1.2463
00002443031	GALANTAMINE ER	SNS	\$	1.2463
00002339455	MYLAN-GALANTAMINE ER	MYP	\$	1.2463
00002398397	PMS-GALANTAMINE ER	PMS	\$	1.2463

ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

GLATIRAMER ACETATE

20 MG / SYR INJECTION SYRINGE

00002460661 GLATECT PMS \$ 32.4000

Relapsing Remitting Multiple Sclerosis (RRMS):

Effective July 1, 2018, all new Special Authorization requests for the treatment of Relapsing Remitting Multiple Sclerosis (RRMS) for glatiramer-naive patients will be assessed for coverage with Glatect. Copaxone will not be approved for new glatiramer acetate starts for patients with the indication stated above; however, coverage for Copaxone will continue for patients who are currently well maintained on Copaxone as per maintenance coverage criteria. Additionally, patients will not be permitted to switch from Glatect to Copaxone.

"Special authorization coverage may be provided for the reduction of the frequency and severity of clinical relapses and reduction of the number and volume of active brain lesions, identified on MRI scans, in ambulatory patients with relapsing remitting multiple sclerosis.

Coverage

For coverage, this drug must be prescribed by a registered MS Neurologist. A current assessment must be completed by a registered MS Neurologist at every request.

To register to become an MS Neurologist please complete the Registration for MS Neurologist Status Form (ABC 60002).

Initial Coverage

- 1) The registered MS Neurologist must confirm a diagnosis of RRMS;
- 2) The patient must have active disease which is defined as at least two relapses* of MS during the previous two years or in the two years prior to starting an MS disease modifying therapy (DMT).

*A relapse is defined as the appearance of new symptoms or worsening of old symptoms, lasting at least 48 hours in the absence of fever, not associated with withdrawal from steroids. Onset of clinical relapses must be separated by a period of at least one month. At least one definite gadolinium-enhancing T1 MRI lesion (not questionable faint enhancement) obtained at least 90 days after initiation of the DMT and at least 90 days before or after a relapse may substitute for one clinical relapse.

- 3) The patient must be ambulatory with or without aid (The registered MS Neurologist must provide a current updated Expanded Disability Status Scale (EDSS) score less than or equal to 6.5).

Coverage may be approved for up to 12 months. Patients will be limited to receiving a one-month supply of glatiramer acetate per prescription at their pharmacy for the first 12 months of coverage.

Continued Coverage

For continued coverage beyond the initial coverage period, the patient must meet the following criteria:

- 1) The patient must be assessed by a registered MS Neurologist;
- 2) The registered MS Neurologist must confirm a diagnosis of RRMS;
- 3) The registered MS Neurologist must provide a current updated EDSS score. The patient must not have an EDSS score of 7.0 or above sustained for one year or more.

Coverage of this drug may be considered in a patient with a sustained EDSS score of 7.0 or above in exceptional circumstances. For MS DMT coverage to be considered, details of the exceptional circumstance must be provided in a letter from the registered MS Neurologist and accompany the Special Authorization Request Form.

Continued coverage may be approved for up to 12 months. Patients may receive up to 100 days' supply of glatiramer acetate per prescription at their pharmacy.

Restarting After an Interruption in Therapy Greater Than 12 Months

In order to be eligible for coverage, after an interruption in therapy greater than 12 months, the patient must meet the following criteria:

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

GLATIRAMER ACETATE

- 1) At least one relapse* per 12 month period; or
- 2) At least two relapses* during the previous 24 month period."

All requests (including renewal requests) for glatiramer acetate must be completed using the Dimethyl Fumarate/Glatiramer Acetate/Interferon Beta-1a/Ocrelizumab/Peginterferon Beta-1a/Teriflunomide for RRMS/Interferon Beta-1b for SPMS or RRMS Special Authorization Request Form (ABC 60001).

00002245619 COPAXONE TMP \$ 48.8051

Relapsing Remitting Multiple Sclerosis (RRMS):

Effective July 1, 2018, all new Special Authorization requests for the treatment of Relapsing Remitting Multiple Sclerosis (RRMS) for glatiramer-naive patients will be assessed for coverage with Glatect. Copaxone will not be approved for new glatiramer acetate starts for patients with the indication stated above; however, coverage for Copaxone will continue for patients who are currently well maintained on Copaxone as per maintenance coverage criteria. Additionally, patients will not be permitted to switch from Glatect to Copaxone.

"Special authorization coverage may be provided for the reduction of the frequency and severity of clinical relapses and reduction of the number and volume of active brain lesions, identified on MRI scans, in ambulatory patients with relapsing remitting multiple sclerosis.

Coverage

For coverage, this drug must be prescribed by a registered MS Neurologist. A current assessment must be completed by a registered MS Neurologist at every request.

To register to become an MS Neurologist please complete the Registration for MS Neurologist Status Form (ABC 60002).

Initial Coverage

- 1) The registered MS Neurologist must confirm a diagnosis of RRMS;
- 2) The patient must have active disease which is defined as at least two relapses* of MS during the previous two years or in the two years prior to starting an MS disease modifying therapy (DMT).

*A relapse is defined as the appearance of new symptoms or worsening of old symptoms, lasting at least 48 hours in the absence of fever, not associated with withdrawal from steroids. Onset of clinical relapses must be separated by a period of at least one month. At least one definite gadolinium-enhancing T1 MRI lesion (not questionable faint enhancement) obtained at least 90 days after initiation of the DMT and at least 90 days before or after a relapse may substitute for one clinical relapse.

- 3) The patient must be ambulatory with or without aid (The registered MS Neurologist must provide a current updated Expanded Disability Status Scale (EDSS) score less than or equal to 6.5).

Coverage may be approved for up to 12 months. Patients will be limited to receiving a one-month supply of glatiramer acetate per prescription at their pharmacy for the first 12 months of coverage.

Continued Coverage

For continued coverage beyond the initial coverage period, the patient must meet the following criteria:

- 1) The patient must be assessed by a registered MS Neurologist;
- 2) The registered MS Neurologist must confirm a diagnosis of RRMS;
- 3) The registered MS Neurologist must provide a current updated EDSS score. The patient must not have an EDSS score of 7.0 or above sustained for one year or more.

Coverage of this drug may be considered in a patient with a sustained EDSS score of 7.0 or above in exceptional circumstances. For MS DMT coverage to be considered, details of the exceptional circumstance must be provided in a letter from the registered MS Neurologist and accompany the Special Authorization Request Form.

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

GLATIRAMER ACETATE

Continued coverage may be approved for up to 12 months. Patients may receive up to 100 days' supply of glatiramer acetate per prescription at their pharmacy.

Restarting After an Interruption in Therapy Greater Than 12 Months

In order to be eligible for coverage, after an interruption in therapy greater than 12 months, the patient must meet the following criteria:

- 1) At least one relapse* per 12 month period; or
- 2) At least two relapses* during the previous 24 month period."

All requests (including renewal requests) for glatiramer acetate must be completed using the Dimethyl Fumarate/Glatiramer Acetate/Interferon Beta-1a/Ocrelizumab/Peginterferon Beta-1a/Teriflunomide for RRMS/Interferon Beta-1b for SPMS or RRMS Special Authorization Request Form (ABC 60001).

GLYCEROL PHENYLBUTYRATE

"For chronic management of patients with urea cycle disorders (UCDs) who cannot be managed by dietary protein restriction and/or amino acid supplementation alone.

For coverage, this drug must be prescribed by or in consultation with a metabolic or genetic physician. The diagnosis must be confirmed by blood, enzymatic, biochemical, or genetic testing.

Special authorization may be granted for 12 months."

The following product(s) are eligible for auto-renewal.

1.1 G / ML ORAL LIQUID			
00002453304	RAVICTI	RAP	\$ 48.0000

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

GOLIMUMAB

Ankylosing Spondylitis:

"Special authorization coverage may be provided for the reduction in the signs and symptoms of severely active Ankylosing Spondylitis, as defined by the Modified New York criteria for Ankylosing Spondylitis, in adult patients (18 years of age or older) who have active disease as demonstrated by:

- a BASDAI greater than or equal to 4 units, demonstrated on 2 occasions at least 8 weeks apart AND
- a Spinal Pain VAS of greater than or equal to 4 cm (on a 0-10 cm scale), demonstrated on 2 occasions at least 8 weeks apart AND
- who are refractory or intolerant to treatment with 2 or more NSAIDs each taken for a minimum of 4 weeks at maximum tolerated or recommended doses.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.

'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for 50 mg once per month for four doses.
- Patients will be limited to receiving one dose (50 mg) of golimumab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond four doses the patient must meet the following criteria:

- 1) The patient must be assessed by an RA Specialist after the initial four doses to determine response.
- 2) The RA Specialist must confirm, in writing, that the patient is a 'responder' that meets the following criteria:
 - Reduction of the BASDAI score by at least 50% of the pre-treatment value or by 2 or more units, AND
 - Reduction of the Spinal Pain VAS by 2 cm or more.

Following this assessment, continued coverage may be approved for 50 mg once per month for a further 12 month period. Should continued coverage criteria be met, coverage will only be granted for 12 doses per 12 month period. Ongoing coverage may be considered if the patient is re-assessed by an RA Specialist every 12 months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above."

All requests (including renewal requests) for golimumab for Ankylosing Spondylitis must be completed using the Adalimumab/Certolizumab/Etanercept/Golimumab/Infliximab/Secukinumab for Ankylosing Spondylitis Special Authorization Request Form (ABC 60028).

Psoriatic Arthritis:

"Special authorization coverage may be provided for use in combination with methotrexate for reducing signs and symptoms of active arthritis in adult patients (18 years of age or older) with moderate to severe polyarticular psoriatic arthritis (PsA) or pauciarticular PsA with involvement of knee or hip joint who are refractory or intolerant

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

GOLIMUMAB

to:

- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- An adequate trial of another disease modifying anti-rheumatic agent(s) (minimum 4 month trial).

Special authorization coverage of this agent may be provided for use as monotherapy in adult patients for whom methotrexate is contraindicated and/or for those patients who have experienced serious adverse effects.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.

'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for 50 mg per month for four doses.
- Patients will be limited to receiving one dose (50 mg) of golimumab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond four doses, the patient must meet the following criteria:

1) The patient must be assessed by an RA Specialist after four doses to determine response.

2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:

- ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND

- An improvement of 0.22 in HAQ score [reported to two (2) decimal places].

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be approved for 50 mg per month, for a further 12 month period. Should coverage criteria be met, coverage will only be granted for 12 doses per 12-month period. Ongoing coverage may be considered if the following criteria are met at the end of each 12-month period:

1) The patient has been assessed by an RA Specialist to determine response;

2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:

- Confirmation of maintenance of ACR20, or

- Maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.

3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above."

All requests (including renewal requests) for golimumab for Psoriatic Arthritis must be

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

GOLIMUMAB

completed using the Adalimumab/Certolizumab/Etanercept/Golimumab/Infliximab/Ixekizumab/Secukinumab for Psoriatic Arthritis Special Authorization Request Form (ABC 60029).

Rheumatoid Arthritis:

"Special authorization coverage may be provided for use in combination with methotrexate for the reduction in signs and symptoms of severely active Rheumatoid Arthritis (RA) in adult patients (18 years of age or older) who are refractory or intolerant to:

- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- Methotrexate with other disease modifying anti-rheumatic agent(s) (minimum 4-month trial). [e.g., methotrexate with hydroxychloroquine or methotrexate with sulfasalazine]; AND
- Leflunomide (minimum 10 week trial at 20 mg daily).

Special authorization coverage of this agent may be provided for use as monotherapy in adult patients for whom methotrexate is contraindicated and/or for those patients who have experienced serious adverse effects.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.

'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for 50 mg per month for a total of four doses.
- Patients will be limited to receiving one dose (50 mg) of golimumab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another (with the exception of anakinra) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients will not be permitted to switch from anakinra to other biologic agents except under exceptional circumstances.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond four doses, the patient must meet the following criteria:

- 1) The patient must be assessed by an RA Specialist after four doses to determine response.
 - 2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
 - ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND
 - An improvement of 0.22 in HAQ score [reported to two (2) decimal places].
- It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be approved for 50 mg per month, for a further 12 month period. Should continued coverage criteria be met, coverage will

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

GOLIMUMAB

only be granted for 12 doses per 12 month period. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:

- 1) The patient has been assessed by an RA Specialist to determine response;
- 2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
 - Confirmation of maintenance of ACR20, or
 - Maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.
- 3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above."

All requests (including renewal requests) for golimumab for Rheumatoid Arthritis must be completed using the Abatacept/Adalimumab/Anakinra/Certolizumab/Etanercept/Golimumab/Infliximab/Sarilumab/Tocilizumab/Tofacitinib for Rheumatoid Arthritis Special Authorization Request Form (ABC 60027).

Ulcerative Colitis

Special authorization coverage may be provided for the reduction in signs and symptoms and induction and maintenance of clinical remission of Ulcerative Colitis in adult patients (18 years of age or older) with active disease (characterized by a partial Mayo score >4 prior to initiation of biologic therapy) and who are refractory or intolerant to:

- mesalamine: minimum of 4 grams/day for a minimum of 4 weeks; AND
- corticosteroids (failure to respond to prednisone 40 mg daily for 2 weeks, or; steroid dependent i.e. failure to taper off steroids without recurrence of disease or disease requiring a second dose of steroids within 12 months of previous dose).

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.

'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

Immunosuppressive therapy as follows may also be initiated if in the clinician's judgment a trial is warranted:

- i) Azathioprine: minimum of 2 mg/kg/day for a minimum of 2 months; OR
- ii) 6-mercaptopurine: minimum of 1 mg/kg/day for a minimum of 2 months

For coverage, this drug must be prescribed by a Specialist in Gastroenterology as recognized by the College of Physicians and Surgeons and/or the Alberta Medical Association or a physician appropriately trained by the University of Alberta or the University of Calgary and recognized as a prescriber by Alberta Blue Cross ('Specialist').

Initial coverage may be approved for 200 mg of golimumab administered by subcutaneous injection at Week 0, followed by 100 mg at Week 2. As an interim measure, an additional dose of 50 mg of golimumab will be provided at weeks 6 and 10 to allow time to determine whether the patient meets coverage criteria for maintenance dosing, see below.

- Patients will be limited to receiving a one-month supply of golimumab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

GOLIMUMAB

for which it is being prescribed.

For continued coverage beyond three doses, the patient must meet the following criteria:

- 1) The patient must be assessed by a Specialist between week 12 and week 14 to determine response.
- 2) The Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
 - a decrease in the partial Mayo score of greater than or equal to 2 points

Following this assessment, continued coverage may be approved for a dose of 50 mg every 4 weeks for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:

- 1) The patient has been assessed by a Specialist to determine response;
- 2) The Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
 - a decrease in the partial Mayo score of greater than or equal to 2 points from the score prior to initiation of golimumab therapy

Note: For patients who showed a response to induction therapy then experienced secondary loss of response while on maintenance dosing with 50 mg, the maintenance dose may be adjusted from 50 mg to 100 mg by making an additional special authorization request to Alberta Blue Cross for the increased dose.

All requests (including renewal requests) for golimumab for Ulcerative Colitis must be completed using the Adalimumab/Golimumab/Infliximab/Vedolizumab for Ulcerative Colitis Special Authorization Request Form (ABC 60008).

50 MG / SYR INJECTION SYRINGE

<input checked="" type="checkbox"/> 00002324776	SIMPONI	JAI	\$ 1516.0000
<input checked="" type="checkbox"/> 00002324784	SIMPONI	JAI	\$ 1516.0000

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

**GOLIMUMAB
Ulcerative Colitis**

Special authorization coverage may be provided for the reduction in signs and symptoms and induction and maintenance of clinical remission of Ulcerative Colitis in adult patients (18 years of age or older) with active disease (characterized by a partial Mayo score >4 prior to initiation of biologic therapy) and who are refractory or intolerant to:

- mesalamine: minimum of 4 grams/day for a minimum of 4 weeks; AND
- corticosteroids (failure to respond to prednisone 40 mg daily for 2 weeks, or; steroid dependent i.e. failure to taper off steroids without recurrence of disease or disease requiring a second dose of steroids within 12 months of previous dose).

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.

'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

Immunosuppressive therapy as follows may also be initiated if in the clinician's judgment a trial is warranted:

- i) Azathioprine: minimum of 2 mg/kg/day for a minimum of 2 months; OR
- ii) 6-mercaptopurine: minimum of 1 mg/kg/day for a minimum of 2 months

For coverage, this drug must be prescribed by a Specialist in Gastroenterology as recognized by the College of Physicians and Surgeons and/or the Alberta Medical Association or a physician appropriately trained by the University of Alberta or the University of Calgary and recognized as a prescriber by Alberta Blue Cross ('Specialist').

Initial coverage may be approved for 200 mg of golimumab administered by subcutaneous injection at Week 0, followed by 100 mg at Week 2. As an interim measure, an additional dose of 50 mg of golimumab will be provided at weeks 6 and 10 to allow time to determine whether the patient meets coverage criteria for maintenance dosing, see below.

- Patients will be limited to receiving a one-month supply of golimumab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond three doses, the patient must meet the following criteria:

- 1) The patient must be assessed by a Specialist between week 12 and week 14 to determine response.
- 2) The Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
 - a decrease in the partial Mayo score of greater than or equal to 2 points

Following this assessment, continued coverage may be approved for a dose of 50 mg every 4 weeks for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:

- 1) The patient has been assessed by a Specialist to determine response;
- 2) The Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
 - a decrease in the partial Mayo score of greater than or equal to 2 points from the score prior to initiation of golimumab therapy

Note: For patients who showed a response to induction therapy then experienced

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CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

GOLIMUMAB

secondary loss of response while on maintenance dosing with 50 mg, the maintenance dose may be adjusted from 50 mg to 100 mg by making an additional special authorization request to Alberta Blue Cross for the increased dose.

All requests (including renewal requests) for golimumab for Ulcerative Colitis must be completed using the Adalimumab/Golimumab/Infliximab/Vedolizumab for Ulcerative Colitis Special Authorization Request Form (ABC 60008).

100 MG / SYR INJECTION SYRINGE

<input checked="" type="checkbox"/> 00002413175	SIMPONI	JAI	\$ 1516.0000
<input checked="" type="checkbox"/> 00002413183	SIMPONI	JAI	\$ 1516.0000

GOSERELIN ACETATE

"When prescribed for non-cancer, non-cosmetic or non-fertility indications.

Special authorization may be granted for 6 months."

Information is required regarding the patient's diagnosis/indication for use of this medication.

The following product(s) are eligible for auto-renewal.

3.6 MG / SYR (BASE) INJECTION SYRINGE

00002049325 ZOLADEX TSA \$ 422.6778

10.8 MG / SYR (BASE) INJECTION SYRINGE

00002225905 ZOLADEX LA TSA \$ 1204.7322

ICATIBANT ACETATE

"For the treatment of acute attacks of confirmed Type 1 or Type 2 hereditary angioedema (HAE) in patients with C1-esterase inhibitor deficiency. Icatibant is to be used for:

- acute non-laryngeal attack(s) of at least moderate severity, or
- acute laryngeal attack(s) of any severity

This medication must be prescribed by, or in consultation with, a physician experienced in the treatment of HAE.

Special authorization may be granted for 12 months.

Patients will be limited to a maximum of two doses of icatibant per prescription at their pharmacy."

This product is eligible for auto-renewal.

30 MG / SYR (BASE) INJECTION

00002425696 FIRAZYR SOT \$ 2700.0000

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CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

IMIPENEM/ CILASTATIN SODIUM

(Refer to Section 1 - Restricted Benefits of the Alberta Drug Benefit List for coverage of the product when prescribed by a Specialist in Infectious Diseases or Hematology, or a designated prescriber.)

"For the treatment of:

- 1) Second-line therapy of intra-abdominal sepsis where there is failure of first-line therapy (e.g. ampicillin + gentamicin + metronidazole), as defined by clinical deterioration after 72 h of antibiotic therapy or lack of improvement after completion of antibiotic therapy or
- 2) Second-line therapy of severe polymicrobial skin and skin structure infections (e.g. limb threatening diabetic foot) or
- 3) Empiric therapy of mixed synergistic necrotizing gangrene (Fournier's gangrene) or
- 4) Therapy of severe ventilator-associated pneumonia where Pseudomonas and Staphylococcus aureus coverage is needed or
- 5) Second-line therapy of infections due to gram-negative organisms producing inducible beta-lactamases or extended spectrum beta-lactamases where there is resistance to first-line agents or
- 6) For use in other Health Canada approved indications in consultation with a specialist in Infectious Diseases."*

*Special Authorization is only required when the prescriber prescribing the medication is not a Specialist in Infectious Diseases or Hematology, or a designated prescriber.

In order to comply with all of the above criteria, information is required regarding the type of infection and organisms involved. Also, where the criteria restrict coverage of the requested drug to non-first line therapy, information is required regarding previous first-line antibiotic therapy that has been utilized, the patient's response to therapy, and the first line agents the organism is resistant to or why other first-line therapies cannot be used in this patient. Also, where applicable, the specialist in Infectious Diseases that recommended this drug is required.

500 MG / VIAL * 500 MG / VIAL (BASE)	INJECTION		
00000717282	PRIMAXIN	MFC	\$ 26.9767

IMIQUIMOD

"For the treatment of Actinic Keratosis located on the head and neck in patients who have failed treatment with cryotherapy (where appropriate) and 5-fluorouracil (5-FU).

Special authorization may be granted for 6 months."

All requests for imiquimod must be completed using the Imiquimod Special Authorization Request Form (ABC 60038).

The following product(s) are eligible for auto-renewal.

50 MG/G / G	TOPICAL CREAM		
00002482983	TARO-IMIQUIMOD PUMP	TAR	\$ 43.4350
00002239505	ALDARA P	VCL	\$ 52.9314

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

INDACATEROL MALEATE/ GLYCOPYRRONIUM BROMIDE

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD)

FIRST-LINE DRUG PRODUCT(S): LONG-ACTING BRONCHODILATOR (I.E., LONG-ACTING BETA-2 AGONIST [LABA] OR LONG-ACTING MUSCARINIC ANTAGONIST [LAMA])

"For the long-term maintenance treatment of airflow obstruction in patients with moderate to severe (i.e., FEV1 < 80% predicted) chronic obstructive pulmonary disease (COPD), who have an inadequate response to a long-acting bronchodilator (long-acting beta-2 agonist [LABA] or long-acting muscarinic antagonist [LAMA])."

"For the long-term maintenance treatment of airflow obstruction in patients with severe (i.e., FEV1 < 50% predicted) chronic obstructive pulmonary disease (COPD)."

"Special authorization may be granted for 24 months."

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

UP - First-line therapy ineffective

All requests for indacaterol maleate + glycopyrronium bromide must be completed using the Long-Acting Fixed-Dose Combination Products for Asthma/COPD Special Authorization Request Form (ABC 60025).

110 MCG (BASE) * 50 MCG (BASE)	INHALATION CAPSULE			
00002418282	ULTIBRO BREEZHALER	NOV	\$	2.6150

ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

INFANT FORMULA

ORAL POWDER

00000999543 PURAMINO A+ MJO \$ 0.1320

"For the dietary management of infants with:
-cow milk protein allergy OR
-soy protein allergy OR
-multiple food protein intolerance OR
-conditions where an amino acid-based diet is indicated:
-short bowel syndrome
-gastroesophageal reflux disease (GERD)
-eosinophilic esophagitis (EoE)
-malabsorption.

AND

Who have failed or are intolerant to an appropriate trial (1 to 2 week trial is recommended) of an extensively hydrolyzed infant formula.

This product must be prescribed by or in consultation with a general pediatrician, neonatologist, pediatric gastroenterologist or pediatric allergist.

Special authorization may be granted for a maximum of 24 months."

(Refer to Criteria for Special Authorization of Select Drug Products in the Alberta Human Services Drug Benefit Supplement for eligibility in Alberta Human Services clients.)

00000999568 NEOCATE WITH DHA & ARA NUN \$ 0.1581

"For the dietary management of infants with:
-cow milk protein allergy OR
-soy protein allergy OR
-multiple food protein intolerance OR
-conditions where an amino acid-based diet is indicated:
-short bowel syndrome
-gastroesophageal reflux disease (GERD)
-eosinophilic esophagitis (EoE)
-malabsorption.

AND

Who have failed or are intolerant to an appropriate trial (1 to 2 week trial is recommended) of an extensively hydrolyzed infant formula.

This product must be prescribed by or in consultation with a general pediatrician, neonatologist, pediatric gastroenterologist or pediatric allergist.

Special authorization may be granted for a maximum of 24 months."

(Refer to Criteria for Special Authorization of Select Drug Products in the Alberta Human Services Drug Benefit Supplement for eligibility in Alberta Human Services clients.)

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CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

INFLIXIMAB

100 MG / VIAL INJECTION

00002470373 RENFLEXIS SSB \$ 493.0000

Rheumatoid Arthritis:

***Effective January 1, 2019, all new Special Authorization requests for the treatment of Ankylosing Spondylitis, Plaque Psoriasis, Psoriatic Arthritis, Rheumatoid Arthritis, Moderately to Severely Active Crohn's Disease and Fistulizing Crohn's Disease or Ulcerative Colitis for infliximab naive patients will be assessed for coverage with Inflectra or Renflexis. Remicade will not be approved for new infliximab starts for patients with the indications stated above; however, coverage for Remicade will continue for patients who are currently well maintained on Remicade and are considered a 'responder' as defined in criteria.

Additionally, patients will not be permitted to switch between infliximab products, if the patient has been previously trialed on any infliximab product and deemed unresponsive to therapy.***

"Special authorization coverage may be provided for use in combination with methotrexate for the reduction in signs and symptoms of severely active Rheumatoid Arthritis (RA) in adult patients (18 years of age or older) who are refractory or intolerant to:

- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- Methotrexate with other disease modifying anti-rheumatic agent(s) (minimum 4 month trial) [e.g., methotrexate with hydroxychloroquine or methotrexate with sulfasalazine]; AND
- Leflunomide (minimum 10 week trial at 20 mg daily)

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.

'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for three doses as follows: An initial dose of 3 mg/kg, followed by additional 3 mg/kg doses at 2 and 6 weeks after the first infusion.
- Patients will be limited to receiving one dose of infliximab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another (with the exception of anakinra) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients will not be permitted to switch from anakinra to other biologic agents except under exceptional circumstances.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond three doses, the patient must meet the following criteria:

- 1) The patient must be assessed by an RA Specialist after the initial three doses to determine response.
- 2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
 - ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND
 - An improvement of 0.22 in HAQ score [reported to two (2) decimal places].

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be approved for one 3 mg/kg dose every 8 weeks for a period of 12 months [Note: For patients who have an incomplete response, consideration may be given to adjusting the dose up to 10 mg/kg and/or treating as often as every 4 weeks]. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:

- 1) The patient has been assessed by an RA Specialist to determine response;
- 2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
 - confirmation of maintenance of ACR20, OR

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CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

INFLIXIMAB

- maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.

3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above."

All requests (including renewal requests) for infliximab for Rheumatoid Arthritis must be completed using the

Abatacept/Adalimumab/Anakinra/Certolizumab/Etanercept/Golimumab/Infliximab/Sarilumab/Tocilizumab/Tofacitinib for Rheumatoid Arthritis Special Authorization Request Form (ABC 60027).

Moderately to Severely Active Crohn's Disease and Fistulizing Crohn's Disease:

***Effective January 1, 2019, all new Special Authorization requests for the treatment of Ankylosing Spondylitis, Plaque Psoriasis, Psoriatic Arthritis, Rheumatoid Arthritis, Moderately to Severely Active Crohn's Disease and Fistulizing Crohn's Disease or Ulcerative Colitis for infliximab naive patients will be assessed for coverage with Inflectra or Renflexis. Remicade will not be approved for new infliximab starts for patients with the indications stated above; however, coverage for Remicade will continue for patients who are currently well maintained on Remicade and are considered a 'responder' as defined in criteria.

Additionally, patients will not be permitted to switch between infliximab products, if the patient has been previously trialed on any infliximab product and deemed unresponsive to therapy.***

"Special authorization coverage may be approved for coverage of infliximab for the reduction in signs and symptoms and induction and maintenance of clinical remission of Moderately to Severely Active Crohn's Disease and/or treatment of Fistulizing Crohn's Disease in patients who meet the following criteria:

- Infliximab must be prescribed by a Specialist in Gastroenterology or a physician appropriately trained by the University of Alberta or the University of Calgary and recognized as a prescriber by Alberta Blue Cross for infliximab for coverage for the treatment of Moderately to Severely Active Crohn's Disease and/or Fistulizing Crohn's Disease patients ('Specialist').

- Patients must be 18 years of age or older to be considered for coverage of infliximab.

- Patients will be limited to receiving one dose of infliximab per prescription at their pharmacy.

- Patients may be allowed to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy (both primary loss of response and secondary loss of response) or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).

- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.

- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

Prior to initiation of infliximab therapy for New Patients:

'New Patients' are patients who have never been treated with infliximab by any health care provider.

Moderately to Severely Active Crohn's Disease:

Prior to initiation of infliximab therapy, New Patients must have a current Modified (without the physical exam) Harvey Bradshaw Index score of greater than or equal to 7 (New Patient's Baseline Score), AND be Refractory.

Refractory is defined as one or more of the following:

1) Serious adverse effects or reactions to the treatments specified below; OR

2) Contraindications (as defined in product monographs) to the treatments specified below; OR

3) Previous documented lack of effect at doses and for duration of all treatments specified below:

a) mesalamine: minimum of 3 grams/day for a minimum of 6 weeks; AND refractory to, or dependent on, glucocorticoids:

following at least one tapering dosing schedule of 40 mg/day, tapering by 5 mg each week to 20 mg, then tapering by 2.5 mg each week to zero, or similar;

[Note: Patients who have used the above treatments in combination will not be required to be challenged with individual treatments as monotherapy]

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CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

INFLIXIMAB

AND

b) Immunosuppressive therapy as follows:

- Azathioprine: minimum of 2 mg/kg/day for a minimum of 3 months; OR
- 6-mercaptopurine: minimum of 1 mg/kg/day for a minimum of 3 months; OR
- Methotrexate: minimum of 15 mg/week for a minimum of 3 months.

OR

- Immunosuppressive therapy discontinued at less than 3 months due to serious adverse effects or reactions.

Applications for coverage must include information regarding the dosages and duration of trial of each treatment the patient received, a description of any adverse effects, reactions, contraindications and/or lack of effect, as well as any other information requested by Alberta Blue Cross.

Fistulizing Crohn's Disease:

Prior to initiation of infliximab therapy, New Patients must have actively draining perianal or enterocutaneous fistula(s) that have recurred or persisted despite:

a) A course of an appropriate dose of antibiotic therapy (e.g. ciprofloxacin or metronidazole) for a minimum of 3 weeks; AND

b) Immunosuppressive therapy:

- Azathioprine: minimum of 2 mg/kg/day for a minimum of 6 weeks; OR
- 6-mercaptopurine: minimum of 1 mg/kg/day for a minimum of 6 weeks; OR
- Immunosuppressive therapy discontinued at less than 6 weeks due to serious adverse effects or reactions.

[Note: Patients who have used the above treatments in combination for the treatment of Fistulizing Crohn's will not be required to be challenged with individual treatments as monotherapy]

Applications for coverage must include information regarding the dosages and duration of trial of each treatment the patient received, a description of any adverse effects, reactions, contraindications and/or lack of effect, as well as any other information requested by Alberta Blue Cross.

Coverage Criteria for Moderately to Severely Active Crohn's Disease AND/OR Fistulizing Crohn's Disease

- New Patients must meet the criteria above prior to being considered for approval.
- All approvals are also subject to the following applicable criteria.

Induction Dosing for New Patients:

- Coverage for Induction Dosing may only be approved for New Patients (those who have never been treated with infliximab by any health care provider).
- 'Induction Dosing' means a maximum of one 5 mg/kg dose of infliximab per New Patient at each 0, 2 and 6 weeks (for a maximum total of three doses).
- New Patients are eligible to receive Induction Dosing only once, after which time the Maintenance Dosing for New Patients and Continued Coverage for Maintenance Dosing criteria will apply.

Maintenance Dosing:

'Maintenance Dosing' means one 5 mg/kg dose of infliximab per patient provided no more often than every 8 weeks for a period of 12 months to:

- New Patients following the completion of Induction Dosing; OR
- Existing Patients, who are patients that are being treated, or have previously been treated, with infliximab.

Maintenance Dosing for New Patients after Completion of Induction Dosing:

- The New Patient must be assessed by a Specialist between weeks 10 and 14 after the initiation of Induction Dosing to determine response by obtaining a Modified Harvey Bradshaw Index score for patients with Moderately to Severely Active Crohn's Disease and/or closure of individual fistulas as evidenced by no or minimal fistula drainage despite gentle finger compression of fistulas that were draining at baseline for Fistulizing Crohn's; AND
- The Specialist must confirm the Modified Harvey Bradshaw Index score shows a decrease from the New Patient's Baseline Score of greater than or equal to 3 points for patients with Moderately

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INFLIXIMAB

to Severely Active Crohn's and/or confirm closure of individual fistulas as evidenced by no or minimal fistula drainage despite gentle finger compression of fistulas that were draining at baseline for Fistulizing Crohn's.

Maintenance Dosing for Existing Patients:

- The patient must be assessed by a Specialist at least 4 to 8 weeks after the day the last dose of infliximab was administered to the patient and prior to administration of the next dose to obtain: a Modified Harvey Bradshaw Index Score (Existing Patient's Baseline Score) for Moderately to Severely Active Crohn's and/or closure of individual fistulas as evidenced by no or minimal fistula drainage despite gentle finger compression of fistulas that were draining at baseline for Fistulizing Crohn's; AND

- these measures must be provided to Alberta Blue Cross for assessment for continued coverage for maintenance dosing.

(For existing patients with Moderately to Severely Active Crohn's Disease with an incomplete response or for existing patients with Fistulizing Crohn's who respond then lose their response, the dose may be adjusted to 10 mg/kg by making an additional special authorization request to Alberta Blue Cross for the increased dose.)

Continued Coverage for Maintenance Dosing:

Continued coverage may be considered for one 5 mg/kg dose of infliximab per patient provided no more often than every 8 weeks for a period of 12 months, if the following criteria are met at the end of each 12 month period:

- The New Patient or the Existing Patient must be assessed by a Specialist at least 4 to 6 weeks after the day the last dose of infliximab was administered to the patient and prior to the administration of the next dose to obtain a Modified Harvey Bradshaw Index Score for Moderately to Severely Active Crohn's and/or closure of individual fistulas as evidenced by no or minimal fistula drainage despite gentle finger compression of fistulas that were draining at baseline for Fistulizing Crohn's; AND

- For New Patients: The Specialist must confirm that the patient has maintained a greater than or equal to 3 point decrease from the New Patient's Baseline Score for Moderately to Severely Active Crohn's and/or closure of individual fistulas as evidenced by no or minimal fistula drainage despite gentle finger compression of fistulas that were draining at baseline for Fistulizing Crohn's; OR

- For Existing Patients: The Specialist must confirm that the patient has maintained the Existing Patient's Baseline Score and/or closure of individual fistulas as evidenced by no or minimal fistula drainage despite gentle finger compression of fistulas that were draining at baseline for Fistulizing Crohn's.

(For new and existing patients with Moderately to Severely Active Crohn's Disease with an incomplete response or for new and existing patients with Fistulizing Crohn's who respond then lose their response, the maintenance dose may be adjusted to 10 mg/kg by making an additional special authorization request to Alberta Blue Cross for the increased dose.)"

All requests (including renewal requests) for infliximab for Moderately to Severely Active Crohn's Disease and Fistulizing Crohn's Disease must be completed using the Adalimumab/Vedolizumab for Crohn's/Infliximab for Crohn's/Fistulizing Crohn's Disease Special Authorization Request Form (ABC 60031).

Ankylosing Spondylitis:

***Effective January 1, 2019, all new Special Authorization requests for the treatment of Ankylosing Spondylitis, Plaque Psoriasis, Psoriatic Arthritis, Rheumatoid Arthritis, Moderately to Severely Active Crohn's Disease and Fistulizing Crohn's Disease or Ulcerative Colitis for infliximab naive patients will be assessed for coverage with Inflectra or Renflexis. Remicade will not be approved for new infliximab starts for patients with the indications stated above; however, coverage for Remicade will continue for patients who are currently well maintained on Remicade and are considered a 'responder' as defined in criteria.

Additionally, patients will not be permitted to switch between infliximab products, if the patient has been previously trialed on any infliximab product and deemed unresponsive to therapy.***

"Special authorization coverage may be provided for the reduction in the signs and symptoms and improvement in physical function of severely active Ankylosing Spondylitis, as defined by the Modified New York criteria for Ankylosing Spondylitis, in adult patients (18 years of age or older)

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INFLIXIMAB

who have active disease as demonstrated by:

- a BASDAI greater than or equal to 4 units, demonstrated on 2 occasions at least 8 weeks apart AND
- a Spinal Pain VAS of greater than or equal to 4 cm (on a 0-10 cm scale), demonstrated on 2 occasions at least 8 weeks apart AND
- who are refractory or intolerant to treatment with 2 or more NSAIDs each taken for a minimum of 4 weeks at maximum tolerated or recommended doses.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.

'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for three doses as follows: An initial dose of 5 mg/kg, followed by additional 5 mg/kg doses at 2 and 6 weeks after the first infusion.
- Patients will be limited to receiving one dose of infliximab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond three doses, the patient must meet the following criteria:

- 1) The patient must be assessed by an RA Specialist after the initial three doses to determine response.
- 2) The RA Specialist must confirm, in writing, that the patient is a 'responder' that meets the following criteria:
 - Reduction of the BASDAI score by at least 50% of the pre-treatment value or by 2 or more units, AND
 - Reduction of the Spinal Pain VAS by 2 cm or more.

Following this assessment, continued coverage may be approved for one 5 mg/kg dose of infliximab every 6 to 8 weeks for a period of 12 months. Ongoing coverage may be considered if the patient is re-assessed by an RA Specialist every 12 months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above."

All requests (including renewal requests) for infliximab for Ankylosing Spondylitis must be completed using the Adalimumab/Certolizumab/Etanercept/Golimumab/Infliximab/Secukinumab for Ankylosing Spondylitis Special Authorization Request Form (ABC 60028).

Psoriatic Arthritis:

***Effective January 1, 2019, all new Special Authorization requests for the treatment of Ankylosing Spondylitis, Plaque Psoriasis, Psoriatic Arthritis, Rheumatoid Arthritis, Moderately to Severely Active Crohn's Disease and Fistulizing Crohn's Disease or Ulcerative Colitis for infliximab naive patients will be assessed for coverage with Inflectra or Renflexis. Remicade will not be approved for new infliximab starts for patients with the indications stated above; however, coverage for Remicade will continue for patients who are currently well maintained on Remicade and are considered a 'responder' as defined in criteria.

Additionally, patients will not be permitted to switch between infliximab products, if the patient has been previously trialed on any infliximab product and deemed unresponsive to therapy.***

"Special authorization coverage may be provided for use in combination with methotrexate for reducing signs and symptoms and inhibiting the progression of structural damage of active arthritis in adult patients (18 years of age or older) with moderate to severe polyarticular psoriatic arthritis (PsA) or pauciarticular PsA with involvement of knee or hip joint who are refractory or intolerant to:

- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- An adequate trial of another disease modifying anti-rheumatic agent(s) (minimum 4 month trial).

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Special authorization coverage of this agent may be provided for use as monotherapy in adult patients for whom methotrexate is contraindicated and/or for those patients who have experienced serious adverse effects.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.

'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for three doses as follows: An initial dose of 5 mg/kg, followed by additional 5 mg/kg doses at 2 and 6 weeks after the first infusion.
- Patients will be limited to receiving one dose of infliximab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond three doses, the patient must meet the following criteria:

- 1) The patient must be assessed by an RA Specialist after the initial three doses to determine response.
 - 2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
 - ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place];
- AND
- An improvement of 0.22 in HAQ score [reported to two (2) decimal places].
- It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be approved for one 5 mg/kg dose every 8 weeks, for a period of 12 months. Ongoing coverage may be considered if the following criteria are met at the end of each 12-month period:

- 1) The patient has been assessed by an RA Specialist to determine response;
 - 2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
 - Confirmation of maintenance of ACR20, or
 - Maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.
 - 3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.
- It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above."

All requests (including renewal requests) for infliximab for Psoriatic Arthritis must be completed using the Adalimumab/Certolizumab/Etanercept/Golimumab/Infliximab/Ixekizumab/Secukinumab for Psoriatic Arthritis Special Authorization Request Form (ABC 60029).

Plaque Psoriasis:

Effective January 1, 2019, all new Special Authorization requests for the treatment of Ankylosing Spondylitis, Plaque Psoriasis, Psoriatic Arthritis, Rheumatoid Arthritis, Moderately to Severely Active Crohn's Disease and Fistulizing Crohn's Disease or Ulcerative Colitis for infliximab naive patients will be assessed for coverage with Inflectra or Renflexis. Remicade will not be approved for new infliximab starts for patients with the indications stated above; however, coverage for Remicade will continue for patients who are currently well maintained on Remicade and are considered a 'responder' as defined in criteria. Additionally, patients will not be permitted to switch between infliximab products, if the patient has been previously trialed on any infliximab product and deemed unresponsive to therapy.

"Special authorization coverage may be provided for the reduction in signs and symptoms of severe, debilitating plaque psoriasis in patients who:

- Have a total PASI of 10 or more and a DLQI of more than 10, OR

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- Who have significant involvement of the face, palms of the hands, soles of the feet or genital region; AND
- Who are refractory or intolerant to:
 - Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory, OR
 - Cyclosporine (6 weeks treatment); AND
 - Phototherapy (unless restricted by geographic location)

Patients who have a contraindication to either cyclosporine or methotrexate will be required to complete an adequate trial of the other pre-requisite medication prior to potential coverage being considered.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.

'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be prescribed by a Specialist in Dermatology ("Dermatology Specialist").

- Initial coverage may be approved as follows: An initial dose of 5 mg/kg, followed by additional 5 mg/kg doses at 2 and 6 weeks after the first infusion.
- Patients will be limited to receiving one dose of infliximab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond three doses, the patient must meet all of the following criteria:

- 1) The patient must be assessed by a Dermatology Specialist after the initial three doses to determine response.
- 2) The Dermatology Specialist must confirm, in writing, that the patient is a 'responder' that meets the following criteria:
 - Greater than or equal to 75% reduction in PASI score, or
 - Greater than or equal to 50% reduction in PASI score AND improvement of greater than or equal to 5 points in the DLQI.

Following this assessment, continued coverage may be considered for one 5 mg/kg dose of infliximab every 8 weeks for a period of 12 months. Ongoing coverage may be considered if the patient is re-assessed by a Dermatology Specialist every 12 months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above."

PASI and DLQI scores are required for all requests for Plaque Psoriasis including those requests for patients that have significant involvement of the face, palms, soles of feet or genital region.

All requests (including renewal requests) for infliximab for Plaque Psoriasis must be completed using the Adalimumab/Etanercept/Infliximab/Ixekizumab/Risankizumab/Secukinumab/Ustekinumab for Plaque Psoriasis Special Authorization Request Form (ABC 60030).

Ulcerative Colitis:

***Effective January 1, 2019, all new Special Authorization requests for the treatment of Ankylosing Spondylitis, Plaque Psoriasis, Psoriatic Arthritis, Rheumatoid Arthritis, Moderately to Severely Active Crohn's Disease and Fistulizing Crohn's Disease or Ulcerative Colitis for infliximab naive patients will be assessed for coverage with Inflectra or Renflexis. Remicade will not be approved for new infliximab starts for patients with the indications stated above; however, coverage for Remicade will continue for patients who are currently well maintained on Remicade and are considered a 'responder' as defined in criteria.

Additionally, patients will not be permitted to switch between infliximab products, if the patient has been previously trialed on any infliximab product and deemed unresponsive to therapy.***

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"Special authorization coverage may be provided for the reduction in signs and symptoms and induction and maintenance of clinical remission of Ulcerative Colitis in adult patients (18 years of age or older) with active disease (characterized by a partial Mayo score >4 prior to initiation of biologic therapy) and who are refractory or intolerant to:

- mesalamine: minimum of 4 grams/day for a minimum of 4 weeks

AND

- corticosteroids (failure to respond to prednisone 40 mg daily for 2 weeks, or; steroid dependent i.e. failure to taper off steroids without recurrence of disease or disease requiring a second dose of steroids within 12 months of previous dose).

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.

'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

Immunosuppressive therapy as follows may also be initiated if in the clinician's judgment a trial is warranted:

i) Azathioprine: minimum of 2 mg/kg/day for a minimum of 2 months; OR

ii) 6-mercaptopurine: minimum of 1 mg/kg/day for a minimum of 2 months

For coverage, this drug must be prescribed by a Specialist in Gastroenterology or a physician appropriately trained by the University of Alberta or the University of Calgary and recognized as a prescriber by Alberta Blue Cross ('Specialist').

Initial coverage may be approved for three doses of 5 mg/kg of infliximab at 0, 2 and 6 weeks.

- Patients will be limited to receiving a one dose of infliximab per prescription at their pharmacy.

- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).

- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.

- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond three doses, the patient must meet the following criteria:

1) The patient must be assessed by a Specialist between weeks 10 and 14 after the initiation of therapy to determine response.

2) The Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:

- a decrease in the partial Mayo score of greater than or equal to 2 points

Following this assessment, continued coverage may be approved for dose of 5 mg/kg every 8 weeks for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:

1) The patient has been assessed by a Specialist in Gastroenterology to determine response;

2) The Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:

- a decrease in the partial Mayo score of greater than or equal to 2 points from the score prior to initiation of infliximab therapy

Note: For patients who showed a response to induction therapy then experienced secondary loss of response while on maintenance dosing with 5 mg/kg, the maintenance dose may be adjusted from 5 mg/kg to 10 mg/kg by making an additional special authorization request to Alberta Blue Cross for the increased dose."

All requests (including renewal requests) for infliximab for Ulcerative Colitis must be completed using the Adalimumab/Golimumab/Infliximab/Vedolizumab for Ulcerative Colitis Special Authorization Request Form (ABC 60008).

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Rheumatoid Arthritis:

***Effective January 1, 2019, all new Special Authorization requests for the treatment of Ankylosing Spondylitis, Plaque Psoriasis, Psoriatic Arthritis, Rheumatoid Arthritis, Moderately to Severely

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Active Crohn's Disease and Fistulizing Crohn's Disease or Ulcerative Colitis for infliximab naive patients will be assessed for coverage with Inflectra or Renflexis. Remicade will not be approved for new infliximab starts for patients with the indications stated above; however, coverage for Remicade will continue for patients who are currently well maintained on Remicade and are considered a 'responder' as defined in criteria.

Additionally, patients will not be permitted to switch between infliximab products, if the patient has been previously trialed on any infliximab product and deemed unresponsive to therapy.***

"Special authorization coverage may be provided for use in combination with methotrexate for the reduction in signs and symptoms of severely active Rheumatoid Arthritis (RA) in adult patients (18 years of age or older) who are refractory or intolerant to:

- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- Methotrexate with other disease modifying anti-rheumatic agent(s) (minimum 4 month trial) [e.g., methotrexate with hydroxychloroquine or methotrexate with sulfasalazine]; AND
- Leflunomide (minimum 10 week trial at 20 mg daily)

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.

'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for three doses as follows: An initial dose of 3 mg/kg, followed by additional 3 mg/kg doses at 2 and 6 weeks after the first infusion.
- Patients will be limited to receiving one dose of infliximab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another (with the exception of anakinra) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients will not be permitted to switch from anakinra to other biologic agents except under exceptional circumstances.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond three doses, the patient must meet the following criteria:

- 1) The patient must be assessed by an RA Specialist after the initial three doses to determine response.
- 2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
 - ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND
 - An improvement of 0.22 in HAQ score [reported to two (2) decimal places].

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be approved for one 3 mg/kg dose every 8 weeks for a period of 12 months [Note: For patients who have an incomplete response, consideration may be given to adjusting the dose up to 10 mg/kg and/or treating as often as every 4 weeks]. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:

- 1) The patient has been assessed by an RA Specialist to determine response;
- 2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
 - confirmation of maintenance of ACR20, OR
 - maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.
- 3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above."

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All requests (including renewal requests) for infliximab for Rheumatoid Arthritis must be completed using the Abatacept/Adalimumab/Anakinra/Certolizumab/Etanercept/Golimumab/Infliximab/Sarilumab/Tocilizumab/Tofacitinib for Rheumatoid Arthritis Special Authorization Request Form (ABC 60027).

Moderately to Severely Active Crohn's Disease and Fistulizing Crohn's Disease:

Effective January 1, 2019, all new Special Authorization requests for the treatment of Ankylosing Spondylitis, Plaque Psoriasis, Psoriatic Arthritis, Rheumatoid Arthritis, Moderately to Severely Active Crohn's Disease and Fistulizing Crohn's Disease or Ulcerative Colitis for infliximab naive patients will be assessed for coverage with Inflectra or Renflexis. Remicade will not be approved for new infliximab starts for patients with the indications stated above; however, coverage for Remicade will continue for patients who are currently well maintained on Remicade and are considered a 'responder' as defined in criteria. Additionally, patients will not be permitted to switch between infliximab products, if the patient has been previously trialed on any infliximab product and deemed unresponsive to therapy.

"Special authorization coverage may be approved for coverage of infliximab for the reduction in signs and symptoms and induction and maintenance of clinical remission of Moderately to Severely Active Crohn's Disease and/or treatment of Fistulizing Crohn's Disease in patients who meet the following criteria:

- Infliximab must be prescribed by a Specialist in Gastroenterology or a physician appropriately trained by the University of Alberta or the University of Calgary and recognized as a prescriber by Alberta Blue Cross for infliximab for coverage for the treatment of Moderately to Severely Active Crohn's Disease and/or Fistulizing Crohn's Disease patients ('Specialist').
- Patients must be 18 years of age or older to be considered for coverage of infliximab.
- Patients will be limited to receiving one dose of infliximab per prescription at their pharmacy.
- Patients may be allowed to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy (both primary loss of response and secondary loss of response) or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

Prior to initiation of infliximab therapy for New Patients:

'New Patients' are patients who have never been treated with infliximab by any health care provider.

Moderately to Severely Active Crohn's Disease:

Prior to initiation of infliximab therapy, New Patients must have a current Modified (without the physical exam) Harvey Bradshaw Index score of greater than or equal to 7 (New Patient's Baseline Score), AND be Refractory.

Refractory is defined as one or more of the following:

- 1) Serious adverse effects or reactions to the treatments specified below; OR
- 2) Contraindications (as defined in product monographs) to the treatments specified below; OR
- 3) Previous documented lack of effect at doses and for duration of all treatments specified below:
 - a) mesalamine: minimum of 3 grams/day for a minimum of 6 weeks; AND refractory to, or dependent on, glucocorticoids:
following at least one tapering dosing schedule of 40 mg/day, tapering by 5 mg each week to 20 mg, then tapering by 2.5 mg each week to zero, or similar;

[Note: Patients who have used the above treatments in combination will not be required to be challenged with individual treatments as monotherapy]

AND

b) Immunosuppressive therapy as follows:

- Azathioprine: minimum of 2 mg/kg/day for a minimum of 3 months; OR
- 6-mercaptopurine: minimum of 1 mg/kg/day for a minimum of 3 months; OR
- Methotrexate: minimum of 15 mg/week for a minimum of 3 months.

OR

- Immunosuppressive therapy discontinued at less than 3 months due to serious adverse effects or

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reactions.

Applications for coverage must include information regarding the dosages and duration of trial of each treatment the patient received, a description of any adverse effects, reactions, contraindications and/or lack of effect, as well as any other information requested by Alberta Blue Cross.

Fistulizing Crohn's Disease:

Prior to initiation of infliximab therapy, New Patients must have actively draining perianal or enterocutaneous fistula(s) that have recurred or persisted despite:

a) A course of an appropriate dose of antibiotic therapy (e.g. ciprofloxacin or metronidazole) for a minimum of 3 weeks; AND

b) Immunosuppressive therapy:

- Azathioprine: minimum of 2 mg/kg/day for a minimum of 6 weeks; OR

- 6-mercaptopurine: minimum of 1 mg/kg/day for a minimum of 6 weeks; OR

- Immunosuppressive therapy discontinued at less than 6 weeks due to serious adverse effects or reactions.

[Note: Patients who have used the above treatments in combination for the treatment of Fistulizing Crohn's will not be required to be challenged with individual treatments as monotherapy]

Applications for coverage must include information regarding the dosages and duration of trial of each treatment the patient received, a description of any adverse effects, reactions, contraindications and/or lack of effect, as well as any other information requested by Alberta Blue Cross.

Coverage Criteria for Moderately to Severely Active Crohn's Disease AND/OR Fistulizing Crohn's Disease

- New Patients must meet the criteria above prior to being considered for approval.

- All approvals are also subject to the following applicable criteria.

Induction Dosing for New Patients:

- Coverage for Induction Dosing may only be approved for New Patients (those who have never been treated with infliximab by any health care provider).

- 'Induction Dosing' means a maximum of one 5 mg/kg dose of infliximab per New Patient at each 0, 2 and 6 weeks (for a maximum total of three doses).

- New Patients are eligible to receive Induction Dosing only once, after which time the Maintenance Dosing for New Patients and Continued Coverage for Maintenance Dosing criteria will apply.

Maintenance Dosing:

'Maintenance Dosing' means one 5 mg/kg dose of infliximab per patient provided no more often than every 8 weeks for a period of 12 months to:

- New Patients following the completion of Induction Dosing; OR

- Existing Patients, who are patients that are being treated, or have previously been treated, with infliximab.

Maintenance Dosing for New Patients after Completion of Induction Dosing:

- The New Patient must be assessed by a Specialist between weeks 10 and 14 after the initiation of Induction Dosing to determine response by obtaining a Modified Harvey Bradshaw Index score for patients with Moderately to Severely Active Crohn's Disease and/or closure of individual fistulas as evidenced by no or minimal fistula drainage despite gentle finger compression of fistulas that were draining at baseline for Fistulizing Crohn's; AND

- The Specialist must confirm the Modified Harvey Bradshaw Index score shows a decrease from the New Patient's Baseline Score of greater than or equal to 3 points for patients with Moderately to Severely Active Crohn's and/or confirm closure of individual fistulas as evidenced by no or minimal fistula drainage despite gentle finger compression of fistulas that were draining at baseline for Fistulizing Crohn's.

Maintenance Dosing for Existing Patients:

- The patient must be assessed by a Specialist at least 4 to 8 weeks after the day the last dose of

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infliximab was administered to the patient and prior to administration of the next dose to obtain: a Modified Harvey Bradshaw Index Score (Existing Patient's Baseline Score) for Moderately to Severely Active Crohn's and/or closure of individual fistulas as evidenced by no or minimal fistula drainage despite gentle finger compression of fistulas that were draining at baseline for Fistulizing Crohn's; AND

- these measures must be provided to Alberta Blue Cross for assessment for continued coverage for maintenance dosing.

(For existing patients with Moderately to Severely Active Crohn's Disease with an incomplete response or for existing patients with Fistulizing Crohn's who respond then lose their response, the dose may be adjusted to 10 mg/kg by making an additional special authorization request to Alberta Blue Cross for the increased dose.)

Continued Coverage for Maintenance Dosing:

Continued coverage may be considered for one 5 mg/kg dose of infliximab per patient provided no more often than every 8 weeks for a period of 12 months, if the following criteria are met at the end of each 12 month period:

- The New Patient or the Existing Patient must be assessed by a Specialist at least 4 to 6 weeks after the day the last dose of infliximab was administered to the patient and prior to the administration of the next dose to obtain a Modified Harvey Bradshaw Index Score for Moderately to Severely Active Crohn's and/or closure of individual fistulas as evidenced by no or minimal fistula drainage despite gentle finger compression of fistulas that were draining at baseline for Fistulizing Crohn's; AND
- For New Patients: The Specialist must confirm that the patient has maintained a greater than or equal to 3 point decrease from the New Patient's Baseline Score for Moderately to Severely Active Crohn's and/or closure of individual fistulas as evidenced by no or minimal fistula drainage despite gentle finger compression of fistulas that were draining at baseline for Fistulizing Crohn's; OR
- For Existing Patients: The Specialist must confirm that the patient has maintained the Existing Patient's Baseline Score and/or closure of individual fistulas as evidenced by no or minimal fistula drainage despite gentle finger compression of fistulas that were draining at baseline for Fistulizing Crohn's.

(For new and existing patients with Moderately to Severely Active Crohn's Disease with an incomplete response or for new and existing patients with Fistulizing Crohn's who respond then lose their response, the maintenance dose may be adjusted to 10 mg/kg by making an additional special authorization request to Alberta Blue Cross for the increased dose.)"

All requests (including renewal requests) for infliximab for Moderately to Severely Active Crohn's Disease and Fistulizing Crohn's Disease must be completed using the Adalimumab/Vedolizumab for Crohn's/Infliximab for Crohn's/Fistulizing Crohn's Disease Special Authorization Request Form (ABC 60031).

Ankylosing Spondylitis:

***Effective January 1, 2019, all new Special Authorization requests for the treatment of Ankylosing Spondylitis, Plaque Psoriasis, Psoriatic Arthritis, Rheumatoid Arthritis, Moderately to Severely Active Crohn's Disease and Fistulizing Crohn's Disease or Ulcerative Colitis for infliximab naive patients will be assessed for coverage with Inflectra or Renflexis. Remicade will not be approved for new infliximab starts for patients with the indications stated above; however, coverage for Remicade will continue for patients who are currently well maintained on Remicade and are considered a 'responder' as defined in criteria.

Additionally, patients will not be permitted to switch between infliximab products, if the patient has been previously trialed on any infliximab product and deemed unresponsive to therapy.***

"Special authorization coverage may be provided for the reduction in the signs and symptoms and improvement in physical function of severely active Ankylosing Spondylitis, as defined by the Modified New York criteria for Ankylosing Spondylitis, in adult patients (18 years of age or older) who have active disease as demonstrated by:

- a BASDAI greater than or equal to 4 units, demonstrated on 2 occasions at least 8 weeks apart AND
- a Spinal Pain VAS of greater than or equal to 4 cm (on a 0-10 cm scale), demonstrated on 2 occasions at least 8 weeks apart AND
- who are refractory or intolerant to treatment with 2 or more NSAIDS each taken for a minimum of

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4 weeks at maximum tolerated or recommended doses.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.

'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for three doses as follows: An initial dose of 5 mg/kg, followed by additional 5 mg/kg doses at 2 and 6 weeks after the first infusion.
- Patients will be limited to receiving one dose of infliximab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond three doses, the patient must meet the following criteria:

- 1) The patient must be assessed by an RA Specialist after the initial three doses to determine response.
- 2) The RA Specialist must confirm, in writing, that the patient is a 'responder' that meets the following criteria:
 - Reduction of the BASDAI score by at least 50% of the pre-treatment value or by 2 or more units, AND
 - Reduction of the Spinal Pain VAS by 2 cm or more.

Following this assessment, continued coverage may be approved for one 5 mg/kg dose of infliximab every 6 to 8 weeks for a period of 12 months. Ongoing coverage may be considered if the patient is re-assessed by an RA Specialist every 12 months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above."

All requests (including renewal requests) for infliximab for Ankylosing Spondylitis must be completed using the Adalimumab/Certolizumab/Etanercept/Golimumab/Infliximab/Secukinumab for Ankylosing Spondylitis Special Authorization Request Form (ABC 60028).

Psoriatic Arthritis:

***Effective January 1, 2019, all new Special Authorization requests for the treatment of Ankylosing Spondylitis, Plaque Psoriasis, Psoriatic Arthritis, Rheumatoid Arthritis, Moderately to Severely Active Crohn's Disease and Fistulizing Crohn's Disease or Ulcerative Colitis for infliximab naive patients will be assessed for coverage with Inflectra or Renflexis. Remicade will not be approved for new infliximab starts for patients with the indications stated above; however, coverage for Remicade will continue for patients who are currently well maintained on Remicade and are considered a 'responder' as defined in criteria.

Additionally, patients will not be permitted to switch between infliximab products, if the patient has been previously trialed on any infliximab product and deemed unresponsive to therapy.***

"Special authorization coverage may be provided for use in combination with methotrexate for reducing signs and symptoms and inhibiting the progression of structural damage of active arthritis in adult patients (18 years of age or older) with moderate to severe polyarticular psoriatic arthritis (PsA) or pauciarticular PsA with involvement of knee or hip joint who are refractory or intolerant to:

- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- An adequate trial of another disease modifying anti-rheumatic agent(s) (minimum 4 month trial).

Special authorization coverage of this agent may be provided for use as monotherapy in adult patients for whom methotrexate is contraindicated and/or for those patients who have experienced serious adverse effects.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.

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'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for three doses as follows: An initial dose of 5 mg/kg, followed by additional 5 mg/kg doses at 2 and 6 weeks after the first infusion.
- Patients will be limited to receiving one dose of infliximab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond three doses, the patient must meet the following criteria:

- 1) The patient must be assessed by an RA Specialist after the initial three doses to determine response.
 - 2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
 - ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place];
- AND
- An improvement of 0.22 in HAQ score [reported to two (2) decimal places].
- It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be approved for one 5 mg/kg dose every 8 weeks, for a period of 12 months. Ongoing coverage may be considered if the following criteria are met at the end of each 12-month period:

- 1) The patient has been assessed by an RA Specialist to determine response;
 - 2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
 - Confirmation of maintenance of ACR20, or
 - Maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.
 - 3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.
- It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above."

All requests (including renewal requests) for infliximab for Psoriatic Arthritis must be completed using the Adalimumab/Certolizumab/Etanercept/Golimumab/Infliximab/Ixekizumab/Secukinumab for Psoriatic Arthritis Special Authorization Request Form (ABC 60029).

Plaque Psoriasis:

Effective January 1, 2019, all new Special Authorization requests for the treatment of Ankylosing Spondylitis, Plaque Psoriasis, Psoriatic Arthritis, Rheumatoid Arthritis, Moderately to Severely Active Crohn's Disease and Fistulizing Crohn's Disease or Ulcerative Colitis for infliximab naive patients will be assessed for coverage with Inflectra or Renflexis. Remicade will not be approved for new infliximab starts for patients with the indications stated above; however, coverage for Remicade will continue for patients who are currently well maintained on Remicade and are considered a 'responder' as defined in criteria. Additionally, patients will not be permitted to switch between infliximab products, if the patient has been previously trialed on any infliximab product and deemed unresponsive to therapy.

"Special authorization coverage may be provided for the reduction in signs and symptoms of severe, debilitating plaque psoriasis in patients who:

- Have a total PASI of 10 or more and a DLQI of more than 10, OR
- Who have significant involvement of the face, palms of the hands, soles of the feet or genital region; AND
- Who are refractory or intolerant to:
 - Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted

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- as refractory, OR
- Cyclosporine (6 weeks treatment); AND
 - Phototherapy (unless restricted by geographic location)

Patients who have a contraindication to either cyclosporine or methotrexate will be required to complete an adequate trial of the other pre-requisite medication prior to potential coverage being considered.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.

'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be prescribed by a Specialist in Dermatology ("Dermatology Specialist").

- Initial coverage may be approved as follows: An initial dose of 5 mg/kg, followed by additional 5 mg/kg doses at 2 and 6 weeks after the first infusion.
- Patients will be limited to receiving one dose of infliximab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond three doses, the patient must meet all of the following criteria:

- 1) The patient must be assessed by a Dermatology Specialist after the initial three doses to determine response.
- 2) The Dermatology Specialist must confirm, in writing, that the patient is a 'responder' that meets the following criteria:
 - Greater than or equal to 75% reduction in PASI score, or
 - Greater than or equal to 50% reduction in PASI score AND improvement of greater than or equal to 5 points in the DLQI.

Following this assessment, continued coverage may be considered for one 5 mg/kg dose of infliximab every 8 weeks for a period of 12 months. Ongoing coverage may be considered if the patient is re-assessed by a Dermatology Specialist every 12 months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above."

PASI and DLQI scores are required for all requests for Plaque Psoriasis including those requests for patients that have significant involvement of the face, palms, soles of feet or genital region.

All requests (including renewal requests) for infliximab for Plaque Psoriasis must be completed using the Adalimumab/Etanercept/Infliximab/Ixekizumab/Risankizumab/Secukinumab/Ustekinumab for Plaque Psoriasis Special Authorization Request Form (ABC 60030).

Ulcerative Colitis:

***Effective January 1, 2019, all new Special Authorization requests for the treatment of Ankylosing Spondylitis, Plaque Psoriasis, Psoriatic Arthritis, Rheumatoid Arthritis, Moderately to Severely Active Crohn's Disease and Fistulizing Crohn's Disease or Ulcerative Colitis for infliximab naive patients will be assessed for coverage with Inflectra or Renflexis. Remicade will not be approved for new infliximab starts for patients with the indications stated above; however, coverage for Remicade will continue for patients who are currently well maintained on Remicade and are considered a 'responder' as defined in criteria.

Additionally, patients will not be permitted to switch between infliximab products, if the patient has been previously trialed on any infliximab product and deemed unresponsive to therapy.***

"Special authorization coverage may be provided for the reduction in signs and symptoms and induction and maintenance of clinical remission of Ulcerative Colitis in adult patients (18 years of age or older) with active disease (characterized by a partial Mayo score >4 prior to initiation of biologic therapy) and who are refractory or intolerant to:

- mesalamine: minimum of 4 grams/day for a minimum of 4 weeks
- AND

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- corticosteroids (failure to respond to prednisone 40 mg daily for 2 weeks, or; steroid dependent i.e. failure to taper off steroids without recurrence of disease or disease requiring a second dose of steroids within 12 months of previous dose).

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.

'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

Immunosuppressive therapy as follows may also be initiated if in the clinician's judgment a trial is warranted:

- i) Azathioprine: minimum of 2 mg/kg/day for a minimum of 2 months; OR
- ii) 6-mercaptopurine: minimum of 1 mg/kg/day for a minimum of 2 months

For coverage, this drug must be prescribed by a Specialist in Gastroenterology or a physician appropriately trained by the University of Alberta or the University of Calgary and recognized as a prescriber by Alberta Blue Cross ('Specialist').

Initial coverage may be approved for three doses of 5 mg/kg of infliximab at 0, 2 and 6 weeks.

- Patients will be limited to receiving a one dose of infliximab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond three doses, the patient must meet the following criteria:

- 1) The patient must be assessed by a Specialist between weeks 10 and 14 after the initiation of therapy to determine response.
- 2) The Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
 - a decrease in the partial Mayo score of greater than or equal to 2 points

Following this assessment, continued coverage may be approved for dose of 5 mg/kg every 8 weeks for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:

- 1) The patient has been assessed by a Specialist in Gastroenterology to determine response;
- 2) The Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
 - a decrease in the partial Mayo score of greater than or equal to 2 points from the score prior to initiation of infliximab therapy

Note: For patients who showed a response to induction therapy then experienced secondary loss of response while on maintenance dosing with 5 mg/kg, the maintenance dose may be adjusted from 5 mg/kg to 10 mg/kg by making an additional special authorization request to Alberta Blue Cross for the increased dose."

All requests (including renewal requests) for infliximab for Ulcerative Colitis must be completed using the Adalimumab/Golimumab/Infliximab/Vedolizumab for Ulcerative Colitis Special Authorization Request Form (ABC 60008).

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100 MG / VIAL INJECTION

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Plaque Psoriasis:

Effective January 1, 2019, all new Special Authorization requests for the treatment of Ankylosing Spondylitis, Plaque Psoriasis, Psoriatic Arthritis, Rheumatoid Arthritis, Moderately to Severely Active Crohn's Disease and Fistulizing Crohn's Disease or Ulcerative Colitis for infliximab naive patients will be assessed for coverage with Inflectra or Renflexis. Remicade will not be approved for new infliximab starts for patients with the indications stated above; however, coverage for Remicade will continue for patients who are currently well maintained on Remicade and are considered a 'responder' as defined in criteria. Additionally, patients will not be permitted to switch between infliximab products, if the patient has been previously trialed on any infliximab product and deemed unresponsive to therapy.

"Special authorization coverage may be provided for the reduction in signs and symptoms of severe, debilitating plaque psoriasis in patients who:

- Have a total PASI of 10 or more and a DLQI of more than 10, OR
- Who have significant involvement of the face, palms of the hands, soles of the feet or genital region; AND
- Who are refractory or intolerant to:
 - Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory, OR
 - Cyclosporine (6 weeks treatment); AND
 - Phototherapy (unless restricted by geographic location)

Patients who have a contraindication to either cyclosporine or methotrexate will be required to complete an adequate trial of the other pre-requisite medication prior to potential coverage being considered.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.

'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be prescribed by a Specialist in Dermatology ("Dermatology Specialist").

- Initial coverage may be approved as follows: An initial dose of 5 mg/kg, followed by additional 5 mg/kg doses at 2 and 6 weeks after the first infusion.
- Patients will be limited to receiving one dose of infliximab per prescription at their pharmacy.
- Patients will be permitted to switch from another biologic agent to infliximab following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to infliximab if previously trialed and deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond three doses, the patient must meet all of the following criteria:

- 1) The patient must be assessed by a Dermatology Specialist after the initial three doses to determine response.
- 2) The Dermatology Specialist must confirm, in writing, that the patient is a 'responder' that meets the following criteria:
 - Greater than or equal to 75% reduction in PASI score, or
 - Greater than or equal to 50% reduction in PASI score AND improvement of greater than or equal to 5 points in the DLQI.

Following this assessment, continued coverage may be considered for one 5 mg/kg dose of infliximab every 8 weeks for a period of 12 months. Ongoing coverage may be considered if the patient is re-assessed by a Dermatology Specialist every 12 months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above."

PASI and DLQI scores are required for all requests for Plaque Psoriasis including those requests for patients that have significant involvement of the face, palms, soles of feet or genital region.

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All requests (including renewal requests) for infliximab for Plaque Psoriasis must be completed using the Adalimumab/Etanercept/Infliximab/Ixekizumab/Rizankinumab/Secukinumab/Ustekinumab for Plaque Psoriasis Special Authorization Request Form (ABC 60030).

Psoriatic Arthritis:

***Effective January 1, 2019, all new Special Authorization requests for the treatment of Ankylosing Spondylitis, Plaque Psoriasis, Psoriatic Arthritis, Rheumatoid Arthritis, Moderately to Severely Active Crohn's Disease and Fistulizing Crohn's Disease or Ulcerative Colitis for infliximab naive patients will be assessed for coverage with Inflectra or Renflexis. Remicade will not be approved for new infliximab starts for patients with the indications stated above; however, coverage for Remicade will continue for patients who are currently well maintained on Remicade and are considered a 'responder' as defined in criteria.

Additionally, patients will not be permitted to switch between infliximab products, if the patient has been previously trialed on any infliximab product and deemed unresponsive to therapy.***

"Special authorization coverage may be provided for use in combination with methotrexate for reducing signs and symptoms and inhibiting the progression of structural damage of active arthritis in adult patients (18 years of age or older) with moderate to severe polyarticular psoriatic arthritis (PsA) or pauciarticular PsA with involvement of knee or hip joint who are refractory or intolerant to:

- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- An adequate trial of another disease modifying anti-rheumatic agent(s) (minimum 4 month trial).

Special authorization coverage of this agent may be provided for use as monotherapy in adult patients for whom methotrexate is contraindicated and/or for those patients who have experienced serious adverse effects.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.

'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for three doses as follows: An initial dose of 5 mg/kg, followed by additional 5 mg/kg doses at 2 and 6 weeks after the first infusion.
- Patients will be limited to receiving one dose of infliximab per prescription at their pharmacy.
- Patients will be permitted to switch from another biologic agent to infliximab following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to infliximab if previously trialed and deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond three doses, the patient must meet the following criteria:

- 1) The patient must be assessed by an RA Specialist after the initial three doses to determine response.
- 2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
 - ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND
 - An improvement of 0.22 in HAQ score [reported to two (2) decimal places].

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be approved for one 5 mg/kg dose every 8 weeks, for a period of 12 months. Ongoing coverage may be considered if the following criteria are met at the end of each 12-month period:

- 1) The patient has been assessed by an RA Specialist to determine response;
- 2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
 - Confirmation of maintenance of ACR20, or
 - Maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal

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place] from baseline.

3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above."

All requests (including renewal requests) for infliximab for Psoriatic Arthritis must be completed using the Adalimumab/Certolizumab/Etanercept/Golimumab/Infliximab/Ixekizumab/Secukinumab for Psoriatic Arthritis Special Authorization Request Form (ABC 60029).

Rheumatoid Arthritis:

***Effective January 1, 2019, all new Special Authorization requests for the treatment of Ankylosing Spondylitis, Plaque Psoriasis, Psoriatic Arthritis, Rheumatoid Arthritis, Moderately to Severely Active Crohn's Disease and Fistulizing Crohn's Disease or Ulcerative Colitis for infliximab naive patients will be assessed for coverage with Inflectra or Renflexis. Remicade will not be approved for new infliximab starts for patients with the indications stated above; however, coverage for Remicade will continue for patients who are currently well maintained on Remicade and are considered a 'responder' as defined in criteria.

Additionally, patients will not be permitted to switch between infliximab products, if the patient has been previously trialed on any infliximab product and deemed unresponsive to therapy.***

"Special authorization coverage may be provided for use in combination with methotrexate for the reduction in signs and symptoms of severely active Rheumatoid Arthritis (RA) in adult patients (18 years of age or older) who are refractory or intolerant to:

- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- Methotrexate with other disease modifying anti-rheumatic agent(s) (minimum 4 month trial) [e.g., methotrexate with hydroxychloroquine or methotrexate with sulfasalazine]; AND
- Leflunomide (minimum 10 week trial at 20 mg daily)

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.

'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for three doses as follows: An initial dose of 3 mg/kg, followed by additional 3 mg/kg doses at 2 and 6 weeks after the first infusion.
- Patients will be limited to receiving one dose of infliximab per prescription at their pharmacy.
- Patients will be permitted to switch from another biologic agent (with the exception of anakinra) to infliximab following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to infliximab if previously trialed and deemed unresponsive to therapy.
- Patients will not be permitted to switch from anakinra to other biologic agents except under exceptional circumstances.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond the initial three doses, the patient must meet the following criteria:
1) The patient must be assessed by an RA Specialist after the initial three doses to determine response.

2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:

- ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND
- An improvement of 0.22 in HAQ score [reported to two (2) decimal places].

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Continued coverage may be approved for one 3 mg/kg dose every 8 weeks for a period of 12

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months [Note: For patients who have an incomplete response, consideration may be given to adjusting the dose up to 10 mg/kg and/or treating as often as every 4 weeks]. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:

- 1) The patient has been assessed by an RA Specialist to determine response;
 - 2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
 - confirmation of maintenance of ACR20, OR
 - maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.
 - 3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.
- It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above."

All requests (including renewal requests) for infliximab for Rheumatoid Arthritis must be completed using the Abatacept/Adalimumab/Anakinra/Certolizumab/Etanercept/Golimumab/Infliximab/Sarilumab/Tocilizumab/Tofacitinib for Rheumatoid Arthritis Special Authorization Request Form (ABC 60027).

Ankylosing Spondylitis:

Effective January 1, 2019, all new Special Authorization requests for the treatment of Ankylosing Spondylitis, Plaque Psoriasis, Psoriatic Arthritis, Rheumatoid Arthritis, Moderately to Severely Active Crohn's Disease and Fistulizing Crohn's Disease or Ulcerative Colitis for infliximab naive patients will be assessed for coverage with Inflectra or Renflexis. Remicade will not be approved for new infliximab starts for patients with the indications stated above; however, coverage for Remicade will continue for patients who are currently well maintained on Remicade and are considered a 'responder' as defined in criteria. Additionally, patients will not be permitted to switch between infliximab products, if the patient has been previously trialed on any infliximab product and deemed unresponsive to therapy.

"Special authorization coverage may be provided for the reduction in the signs and symptoms and improvement in physical function of severely active Ankylosing Spondylitis, as defined by the Modified New York criteria for Ankylosing Spondylitis, in adult patients (18 years of age or older) who have active disease as demonstrated by:

- a BASDAI greater than or equal to 4 units, demonstrated on 2 occasions at least 8 weeks apart AND
- a Spinal Pain VAS of greater than or equal to 4 cm (on a 0-10 cm scale), demonstrated on 2 occasions at least 8 weeks apart AND
- who are refractory or intolerant to treatment with 2 or more NSAIDS each taken for a minimum of 4 weeks at maximum tolerated or recommended doses.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.

'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for three doses as follows: An initial dose of 5 mg/kg, followed by additional 5 mg/kg doses at 2 and 6 weeks after the first infusion.
- Patients will be limited to receiving one dose of infliximab per prescription at their pharmacy.
- Patients will be permitted to switch from another biologic agent to infliximab following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to infliximab if previously trialed and deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond three doses, the patient must meet the following criteria:

- 1) The patient must be assessed by an RA Specialist after the initial three doses to determine response.
- 2) The RA Specialist must confirm, in writing, that the patient is a 'responder' that meets the following criteria:

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- Reduction of the BASDAI score by at least 50% of the pre-treatment value or by 2 or more units, AND
- Reduction of the Spinal Pain VAS by 2 cm or more.

Following this assessment, continued coverage may be approved for one 5 mg/kg dose of infliximab every 6 to 8 weeks for a period of 12 months. Ongoing coverage may be considered if the patient is re-assessed by an RA Specialist every 12 months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above."

All requests (including renewal requests) for infliximab for Ankylosing Spondylitis must be completed using the Adalimumab/Certolizumab/Etanercept/Golimumab/Infliximab/Secukinumab for Ankylosing Spondylitis Special Authorization Request Form (ABC 60028).

Moderately to Severely Active Crohn's Disease and Fistulizing Crohn's Disease:

***Effective January 1, 2019, all new Special Authorization requests for the treatment of Ankylosing Spondylitis, Plaque Psoriasis, Psoriatic Arthritis, Rheumatoid Arthritis, Moderately to Severely Active Crohn's Disease and Fistulizing Crohn's Disease or Ulcerative Colitis for infliximab naive patients will be assessed for coverage with Inflectra or Renflexis. Remicade will not be approved for new infliximab starts for patients with the indications stated above; however, coverage for Remicade will continue for patients who are currently well maintained on Remicade and are considered a 'responder' as defined in criteria.

Additionally, patients will not be permitted to switch between infliximab products, if the patient has been previously trialed on any infliximab product and deemed unresponsive to therapy.***

"Special authorization coverage may be approved for coverage of infliximab for the reduction in signs and symptoms and induction and maintenance of clinical remission of Moderately to Severely Active Crohn's Disease and/or treatment of Fistulizing Crohn's Disease in patients who meet the following criteria:

- Infliximab must be prescribed by a Specialist in Gastroenterology or a physician appropriately trained by the University of Alberta or the University of Calgary and recognized as a prescriber by Alberta Blue Cross for infliximab for coverage for the treatment of Moderately to Severely Active Crohn's Disease and/or Fistulizing Crohn's Disease patients ('Specialist').
- Patients must be 18 years of age or older to be considered for coverage of infliximab.
- Patients will be limited to receiving one dose of infliximab per prescription at their pharmacy.
- Patients will be permitted to switch from another biologic to infliximab following an adequate trial of the first biologic agent if unresponsive to therapy (both primary loss of response and secondary loss of response) or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to infliximab if previously trialed and deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

Prior to initiation of infliximab therapy for New Patients:

'New Patients' are patients who have never been treated with infliximab by any health care provider.

Moderately to Severely Active Crohn's Disease:

Prior to initiation of infliximab therapy, New Patients must have a current Modified (without the physical exam) Harvey Bradshaw Index score of greater than or equal to 7 (New Patient's Baseline Score), AND be Refractory.

Refractory is defined as one or more of the following:

- 1) Serious adverse effects or reactions to the treatments specified below; OR
- 2) Contraindications (as defined in product monographs) to the treatments specified below; OR
- 3) Previous documented lack of effect at doses and for duration of all treatments specified below:
 - a) mesalamine: minimum of 3 grams/day for a minimum of 6 weeks; AND refractory to, or dependent on, glucocorticoids:
following at least one tapering dosing schedule of 40 mg/day, tapering by 5 mg each week to 20 mg, then tapering by 2.5 mg each week to zero, or similar;

[Note: Patients who have used the above treatments in combination will not be required to be challenged with individual treatments as monotherapy]

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AND

b) Immunosuppressive therapy as follows:

- Azathioprine: minimum of 2 mg/kg/day for a minimum of 3 months; OR
- 6-mercaptopurine: minimum of 1 mg/kg/day for a minimum of 3 months; OR
- Methotrexate: minimum of 15 mg/week for a minimum of 3 months.

OR

- Immunosuppressive therapy discontinued at less than 3 months due to serious adverse effects or reactions.

Applications for coverage must include information regarding the dosages and duration of trial of each treatment the patient received, a description of any adverse effects, reactions, contraindications and/or lack of effect, as well as any other information requested by Alberta Blue Cross.

Fistulizing Crohn's Disease:

Prior to initiation of infliximab therapy, New Patients must have actively draining perianal or enterocutaneous fistula(s) that have recurred or persisted despite:

a) A course of an appropriate dose of antibiotic therapy (e.g. ciprofloxacin or metronidazole) for a minimum of 3 weeks; AND

b) Immunosuppressive therapy:

- Azathioprine: minimum of 2 mg/kg/day for a minimum of 6 weeks; OR
- 6-mercaptopurine: minimum of 1 mg/kg/day for a minimum of 6 weeks; OR
- Immunosuppressive therapy discontinued at less than 6 weeks due to serious adverse effects or reactions.

[Note: Patients who have used the above treatments in combination for the treatment of Fistulizing Crohn's will not be required to be challenged with individual treatments as monotherapy]

Applications for coverage must include information regarding the dosages and duration of trial of each treatment the patient received, a description of any adverse effects, reactions, contraindications and/or lack of effect, as well as any other information requested by Alberta Blue Cross.

Coverage Criteria for Moderately to Severely Active Crohn's Disease AND/OR Fistulizing Crohn's Disease

- New Patients must meet the criteria above prior to being considered for approval.
- All approvals are also subject to the following applicable criteria.

Induction Dosing for New Patients:

- Coverage for Induction Dosing may only be approved for New Patients (those who have never been treated with infliximab by any health care provider).
- 'Induction Dosing' means a maximum of one 5 mg/kg dose of infliximab per New Patient at each 0, 2 and 6 weeks (for a maximum total of three doses).
- New Patients are eligible to receive Induction Dosing only once, after which time the Maintenance Dosing for New Patients and Continued Coverage for Maintenance Dosing criteria will apply.

Maintenance Dosing:

'Maintenance Dosing' means one 5 mg/kg dose of infliximab per patient provided no more often than every 8 weeks for a period of 12 months to:

- New Patients following the completion of Induction Dosing; OR
- Existing Patients, who are patients that are being treated, or have previously been treated, with infliximab.

Maintenance Dosing for New Patients after Completion of Induction Dosing:

- The New Patient must be assessed by a Specialist between weeks 10 and 14 after the initiation of Induction Dosing to determine response by obtaining a Modified Harvey Bradshaw Index score for patients with Moderately to Severely Active Crohn's Disease and/or closure of individual fistulas as evidenced by no or minimal fistula drainage despite gentle finger compression of fistulas that were draining at baseline for Fistulizing Crohn's; AND
- The Specialist must confirm the Modified Harvey Bradshaw Index score shows a decrease from the New Patient's Baseline Score of greater than or equal to 3 points for patients with Moderately

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INFLIXIMAB

to Severely Active Crohn's and/or confirm closure of individual fistulas as evidenced by no or minimal fistula drainage despite gentle finger compression of fistulas that were draining at baseline for Fistulizing Crohn's.

Maintenance Dosing for Existing Patients:

- The patient must be assessed by a Specialist at least 4 to 8 weeks after the day the last dose of infliximab was administered to the patient and prior to administration of the next dose to obtain: a Modified Harvey Bradshaw Index Score (Existing Patient's Baseline Score) for Moderately to Severely Active Crohn's and/or closure of individual fistulas as evidenced by no or minimal fistula drainage despite gentle finger compression of fistulas that were draining at baseline for Fistulizing Crohn's; AND

- these measures must be provided to Alberta Blue Cross for assessment for continued coverage for maintenance dosing.

(For existing patients with Moderately to Severely Active Crohn's Disease with an incomplete response or for existing patients with Fistulizing Crohn's who respond then lose their response, the dose may be adjusted to 10 mg/kg by making an additional special authorization request to Alberta Blue Cross for the increased dose.)

Continued Coverage for Maintenance Dosing:

Continued coverage may be considered for one 5 mg/kg dose of infliximab per patient provided no more often than every 8 weeks for a period of 12 months, if the following criteria are met at the end of each 12 month period:

- The New Patient or the Existing Patient must be assessed by a Specialist at least 4 to 6 weeks after the day the last dose of infliximab was administered to the patient and prior to the administration of the next dose to obtain a Modified Harvey Bradshaw Index Score for Moderately to Severely Active Crohn's and/or closure of individual fistulas as evidenced by no or minimal fistula drainage despite gentle finger compression of fistulas that were draining at baseline for Fistulizing Crohn's; AND

- For New Patients: The Specialist must confirm that the patient has maintained a greater than or equal to 3 point decrease from the New Patient's Baseline Score for Moderately to Severely Active Crohn's and/or closure of individual fistulas as evidenced by no or minimal fistula drainage despite gentle finger compression of fistulas that were draining at baseline for Fistulizing Crohn's; OR

- For Existing Patients: The Specialist must confirm that the patient has maintained the Existing Patient's Baseline Score and/or closure of individual fistulas as evidenced by no or minimal fistula drainage despite gentle finger compression of fistulas that were draining at baseline for Fistulizing Crohn's.

(For new and existing patients with Moderately to Severely Active Crohn's Disease with an incomplete response or for new and existing patients with Fistulizing Crohn's who respond then lose their response, the maintenance dose may be adjusted to 10 mg/kg by making an additional special authorization request to Alberta Blue Cross for the increased dose.)"

All requests (including renewal requests) for infliximab for Moderately to Severely Active Crohn's Disease and Fistulizing Crohn's Disease must be completed using the Adalimumab/Vedolizumab for Crohn's/Infliximab for Crohn's/Fistulizing Crohn's Disease Special Authorization Request Form (ABC 60031).

Ulcerative Colitis:

***Effective January 1, 2019, all new Special Authorization requests for the treatment of Ankylosing Spondylitis, Plaque Psoriasis, Psoriatic Arthritis, Rheumatoid Arthritis, Moderately to Severely Active Crohn's Disease and Fistulizing Crohn's Disease or Ulcerative Colitis for infliximab naive patients will be assessed for coverage with Inflectra or Renflexis. Remicade will not be approved for new infliximab starts for patients with the indications stated above; however, coverage for Remicade will continue for patients who are currently well maintained on Remicade and are considered a 'responder' as defined in criteria.

Additionally, patients will not be permitted to switch between infliximab products, if the patient has been previously trialed on any infliximab product and deemed unresponsive to therapy.***

Special authorization coverage may be provided for the reduction in signs and symptoms and induction and maintenance of clinical remission of Ulcerative Colitis in adult patients (18 years of age or older) with active disease (characterized by a partial Mayo score >4 prior to initiation of

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CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

INFLIXIMAB

biologic therapy) and who are refractory or intolerant to:

- mesalamine: minimum of 4 grams/day for a minimum of 4 weeks

AND

- corticosteroids (failure to respond to prednisone 40 mg daily for 2 weeks, or; steroid dependent i.e. failure to taper off steroids without recurrence of disease or disease requiring a second dose of steroids within 12 months of previous dose).

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.

'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

Immunosuppressive therapy as follows may also be initiated if in the clinician's judgment a trial is warranted:

i) Azathioprine: minimum of 2 mg/kg/day for a minimum of 2 months; OR

ii) 6-mercaptopurine: minimum of 1 mg/kg/day for a minimum of 2 months

For coverage, this drug must be prescribed by a Specialist in Gastroenterology or a physician appropriately trained by the University of Alberta or the University of Calgary and recognized as a prescriber by Alberta Blue Cross ('Specialist').

Initial coverage may be approved for three doses of 5 mg/kg of infliximab at 0, 2 and 6 weeks.

- Patients will be limited to receiving a one dose of infliximab per prescription at their pharmacy.

- Patients will be permitted to switch from another biologic agent to infliximab following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).

- Patients will not be permitted to switch back to infliximab if previously trialed and deemed unresponsive to therapy.

- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond three doses, the patient must meet the following criteria:

1) The patient must be assessed by a Specialist between weeks 10 and 14 after the initiation of therapy to determine response.

2) The Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:

- a decrease in the partial Mayo score of greater than or equal to 2 points

Following this assessment, continued coverage may be approved for dose of 5 mg/kg every 8 weeks for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:

1) The patient has been assessed by a Specialist in Gastroenterology to determine response;

2) The Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:

- a decrease in the partial Mayo score of greater than or equal to 2 points from the score prior to initiation of infliximab therapy

Note: For patients who showed a response to induction therapy then experienced secondary loss of response while on maintenance dosing with 5 mg/kg, the maintenance dose may be adjusted from 5 mg/kg to 10 mg/kg by making an additional special authorization request to Alberta Blue Cross for the increased dose.

All requests (including renewal requests) for infliximab for Ulcerative Colitis must be completed using the Adalimumab/Golimumab/Infliximab/Vedolizumab for Ulcerative Colitis Special Authorization Request Form (ABC 60008).

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INTERFERON BETA-1A

Relapsing Remitting Multiple Sclerosis (RRMS):

"Special authorization coverage may be provided for the reduction of the frequency and severity of clinical relapses and reduction of the number and volume of active brain lesions, identified on MRI scans, in ambulatory patients with relapsing remitting multiple sclerosis.

Coverage

For coverage, this drug must be prescribed by a registered MS Neurologist. A current assessment must be completed by a registered MS Neurologist at every request.

To register to become an MS Neurologist please complete the Registration for MS Neurologist Status Form (ABC 60002).

Initial Coverage

- 1) The registered MS Neurologist must confirm a diagnosis of RRMS;
- 2) The patient must have active disease which is defined as at least two relapses* of MS during the previous two years or in the two years prior to starting an MS disease modifying therapy (DMT).

*A relapse is defined as the appearance of new symptoms or worsening of old symptoms, lasting at least 48 hours in the absence of fever, not associated with withdrawal from steroids. Onset of clinical relapses must be separated by a period of at least one month. At least one definite gadolinium-enhancing T1 MRI lesion (not questionable faint enhancement) obtained at least 90 days after initiation of the DMT and at least 90 days before or after a relapse may substitute for one clinical relapse.

- 3) The patient must be ambulatory with or without aid (The registered MS Neurologist must provide a current updated Expanded Disability Status Scale (EDSS) score less than or equal to 6.5).

Coverage may be approved for up to 12 months. Patients will be limited to receiving a one-month supply of interferon beta-1a per prescription at their pharmacy for the first 12 months of coverage.

Continued Coverage

For continued coverage beyond the initial coverage period, the patient must meet the following criteria:

- 1) The patient must be assessed by a registered MS Neurologist;
- 2) The registered MS Neurologist must confirm a diagnosis of RRMS;
- 3) The registered MS Neurologist must provide a current updated EDSS score. The patient must not have an EDSS score of 7.0 or above sustained for one year or more.

Coverage of this drug may be considered in a patient with a sustained EDSS score of 7.0 or above in exceptional circumstances. For MS DMT coverage to be considered, details of the exceptional circumstance must be provided in a letter from the registered MS Neurologist and accompany the Special Authorization Request Form.

Continued coverage may be approved for up to 12 months. Patients may receive up to 100 days' supply of interferon beta-1a per prescription at their pharmacy.

Restarting After an Interruption in Therapy Greater Than 12 Months

In order to be eligible for coverage, after an interruption in therapy greater than 12 months, the

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CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

INTERFERON BETA-1A

patient must meet the following criteria:

- 1) At least one relapse* per 12 month period; or
- 2) At least two relapses* during the previous 24 month period."

All requests (including renewal requests) for interferon beta-1a must be completed using the Dimethyl Fumarate/Glatiramer Acetate/Interferon Beta-1a/Ocrelizumab/Peginterferon Beta-1a/Teriflunomide for RRMS/Interferon Beta-1b for SPMS or RRMS Special Authorization Request Form (ABC 60001).

44 MCG / ML INJECTION CARTRIDGE			
00002318253	REBIF (1.5 ML CARTRIDGE)	SRO	\$ 267.0400
88 MCG / ML INJECTION CARTRIDGE			
00002318261	REBIF (1.5 ML CARTRIDGE)	SRO	\$ 325.0900
6 MIU / SYR INJECTION SYRINGE			
00002269201	AVONEX PS/PEN (30 MCG/0.5 ML)	BIO	\$ 419.8047
22 MCG / SYR INJECTION SYRINGE			
00002237319	REBIF (0.5 ML SYRINGE)	SRO	\$ 133.5200
44 MCG / SYR INJECTION SYRINGE			
00002237320	REBIF (0.5 ML SYRINGE)	SRO	\$ 162.5470

**ALBERTA DRUG BENEFIT LIST
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INTERFERON BETA-1B

Relapsing Remitting Multiple Sclerosis (RRMS):

"Special authorization coverage may be provided for the reduction of the frequency and severity of clinical relapses and reduction of the number and volume of active brain lesions, identified on MRI scans, in ambulatory patients with relapsing remitting multiple sclerosis.

Coverage

For coverage, this drug must be prescribed by a registered MS Neurologist. A current assessment must be completed by a registered MS Neurologist at every request.

To register to become an MS Neurologist please complete the Registration for MS Neurologist Status Form (ABC 60002).

Initial Coverage

- 1) The registered MS Neurologist must confirm a diagnosis of RRMS;
- 2) The patient must have active disease which is defined as at least two relapses* of MS during the previous two years or in the two years prior to starting an MS disease modifying therapy (DMT).

*A relapse is defined as the appearance of new symptoms or worsening of old symptoms, lasting at least 48 hours in the absence of fever, not associated with withdrawal from steroids. Onset of clinical relapses must be separated by a period of at least one month. At least one definite gadolinium-enhancing T1 MRI lesion (not questionable faint enhancement) obtained at least 90 days after initiation of the DMT and at least 90 days before or after a relapse may substitute for one clinical relapse.

- 3) The patient must be ambulatory with or without aid (The registered MS Neurologist must provide a current updated Expanded Disability Status Scale (EDSS) score less than or equal to 6.5).

Coverage may be approved for up to 12 months. Patients will be limited to receiving a one-month supply of interferon beta-1b per prescription at their pharmacy for the first 12 months of coverage.

Continued Coverage

For continued coverage beyond the initial coverage period, the patient must meet the following criteria:

- 1) The patient must be assessed by a registered MS Neurologist;
- 2) The registered MS Neurologist must confirm a diagnosis of RRMS;
- 3) The registered MS Neurologist must provide a current updated EDSS score. The patient must not have an EDSS score of 7.0 or above sustained for one year or more.

Coverage of this drug may be considered in a patient with a sustained EDSS score of 7.0 or above in exceptional circumstances. For MS DMT coverage to be considered, details of the exceptional circumstance must be provided in a letter from the registered MS Neurologist and accompany the Special Authorization Request Form.

Continued coverage may be approved for up to 12 months. Patients may receive up to 100 days' supply of interferon beta-1b per prescription at their pharmacy.

Restarting After an Interruption in Therapy Greater Than 12 Months

In order to be eligible for coverage, after an interruption in therapy greater than 12 months, the

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INTERFERON BETA-1B

patient must meet the following criteria:

- 1) At least one relapse* per 12 month period; or
- 2) At least two relapses* during the previous 24 month period."

All requests (including renewal requests) for interferon beta-1b must be completed using the Dimethyl Fumarate/Glatiramer Acetate/ Interferon Beta-1a/ Interferon Beta-1b/ Teriflunomide Special Authorization Request Form (ABC 60001).

Secondary Progressive Multiple Sclerosis with Relapses (SPMS with relapses):

"Special authorization coverage may be provided for the slowing of progression in disability and the reduction of the frequency of clinical relapses in patients with secondary progressive multiple sclerosis with relapses.

Coverage

For coverage, this drug must be prescribed by a registered MS Neurologist. A current assessment must be completed by a registered MS Neurologist at every request.

To register to become an MS Neurologist please complete the Registration for MS Neurologist Status Form (ABC 60002).

Initial Coverage

- 1) The registered MS Neurologist must confirm a diagnosis of SPMS with relapses;
- 2) The patient must have active disease which is defined as two relapses* of MS during the previous two years or in the two years prior to starting an MS disease modifying therapy (DMT).

*A relapse is defined as the appearance of new symptoms or worsening of old symptoms (documented by a physician), lasting at least 72 hours in the absence of fever, not associated with withdrawal from steroids, and preceded by stability for at least one month. Onset of clinical relapses must be separated by a period of at least one month. At least one definite gadolinium-enhancing T1 MRI lesion (not questionable faint enhancement) obtained at least 90 days after initiation of the DMT and at least 90 days before or after a relapse may substitute for one clinical relapse.

- 3) The patient must be ambulatory to 100m without an aid (The registered MS Neurologist must provide an updated Expanded Disability Status Scale (EDSS) score of less than or equal to 5.5).

Coverage may be approved for up to 12 months. Patients will be limited to receiving a one-month supply of interferon beta-1b per prescription at their pharmacy for the first 12 months of coverage.

Continued Coverage

For continued coverage beyond the initial coverage period, the patient must meet the following criteria:

- 1) The patient must be assessed by a registered MS Neurologist;
- 2) The registered MS Neurologist must confirm a diagnosis of SPMS with relapses;
- 3) The registered MS Neurologist must provide a current updated EDSS score. The patient must not have an EDSS score of 7.0 or above sustained for one year or more.

Coverage of this drug may be considered in a patient with a sustained EDSS score of 7.0 or above in exceptional circumstances. For MS DMT coverage to be considered, details of the exceptional circumstance must be provided in a letter from the registered MS Neurologist and

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INTERFERON BETA-1B

accompany the Special Authorization Request Form.

Continued coverage may be approved for up to 12 months. Patients may receive up to 100 days' supply of interferon beta-1b per prescription at their pharmacy.

Restarting After an Interruption in Therapy Greater Than 12 Months

In order to be eligible for coverage, after an interruption in therapy greater than 12 months, the patient must meet the following criteria:

- 1) At least one relapse* per 12 month period; or
- 2) At least two relapses* during the previous 24 month period."

All requests (including renewal requests) for interferon beta-1b must be completed using the Dimethyl Fumarate/Glatiramer Acetate/Interferon Beta-1a/Ocrelizumab/Peginterferon Beta-1a/Teriflunomide for RRMS/Interferon Beta-1b for SPMS or RRMS Special Authorization Request Form (ABC 60001).

9.6 MIU / VIAL INJECTION

00002169649	BETASERON (0.3 MG)	BAI	\$	99.3593
00002337819	EXTAVIA (0.3 MG)	NOV	\$	99.3593

IPRATROPIUM BROMIDE

"For use in patients with manual dexterity problems or visual limitations who are unable to prepare a dose of the drug using the multi-dose solution."

"For use in patients who are hypersensitive to preservatives contained in multi-dose solutions."

"Special authorization for both criteria may be granted for 24 months."

Information is required regarding the nature of the difficulties experienced by the patient in preparing a dose using the multi-dose preparation; or the nature of the patient's hypersensitivity to the preservatives contained in the multi-dose solution.

The following product(s) are eligible for auto-renewal.

125 MCG / ML INHALATION UNIT DOSE SOLUTION

00002231135	PMS-IPRATROPIUM	PMS	\$	1.1505
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250 MCG / ML INHALATION UNIT DOSE SOLUTION

00002231244	PMS-IPRATROPIUM (1ML)	PMS	\$	0.6590
00002231245	PMS-IPRATROPIUM (2ML)	PMS	\$	0.6590
00002216221	TEVA-IPRATROPIUM STERINEBS	TEV	\$	0.6590

ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

ISAVUCONAZONIUM SULFATE

(Refer to Section 1 - Restricted Benefits of the Alberta Drug Benefit List for coverage of the product when prescribed by a Specialist in Infectious Diseases or a designated prescriber.)

"For the treatment of invasive aspergillosis in adult patients who are refractory to or intolerant of voriconazole and caspofungin."*

"For the treatment of invasive mucormycosis."*

"This medication must be prescribed in consultation with a specialist in Infectious Diseases."

*Special Authorization is only required when the prescriber prescribing the medication is not a Specialist in Infectious Diseases or a designated prescriber.

100 MG ORAL CAPSULE				
00002483971	CRESEMBA	AVP	\$	78.8300
200 MG / VIAL INJECTION				
00002483998	CRESEMBA	AVP	\$	400.0000

ITRACONAZOLE

(Refer to Section 1 - Restricted Benefits of the Alberta Drug Benefit List for coverage of the product when prescribed by a Specialist in Infectious Diseases or a designated prescriber.)

"For the treatment of oral and/or esophageal candidiasis in immunocompromised patients who are intolerant to fluconazole, or who have failed fluconazole as evidenced by significant clinical deterioration due to the fungal infection during a course of therapy or no resolution after a full course of therapy."*

*Special Authorization is only required when the prescriber prescribing the medication is not a Specialist in Infectious Diseases or a designated prescriber.

10 MG / ML ORAL SOLUTION				
00002484315	JAMP ITRACONAZOLE	JPC	\$	0.6167
00002231347	SPORANOX	JAI	\$	0.8632

**ALBERTA DRUG BENEFIT LIST
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IVABRADINE HYDROCHLORIDE

"For the treatment of heart failure (HF) in patients with the following criteria:

- 1) Reduced left ventricular ejection fraction (LVEF) (less than or equal to 35%)
And
- 2) New York Heart Association (NYHA) class II or III HF symptoms despite at least FOUR weeks of optimal treatment with:
 - a stable dose of an angiotensin converting enzyme inhibitor (ACEI) or an angiotensin II receptor antagonist (ARB)
 - in combination with a beta-blocker and, if tolerated, a mineralocorticoid receptor antagonist (MRA)And
- 3) Who are in sinus rhythm with a resting heart rate greater than or equal to 77 beats per minute (bpm) on average using either an ECG on at least three separate visits or by continuous monitoring
And
- 4) Who had at least one hospitalization due to HF in the last year

For coverage, this drug must be initiated by a Specialist in Cardiology or Internal Medicine, and the initial request must be completed by the Specialist.

Special authorization may be granted for six months."

This product is eligible for auto-renewal.

All requests (including renewal requests) for ivabradine hydrochloride must be completed using the Eplerenone/Ivabradine/Sacubitril+Valsartan Special Authorization Request Form (ABC 60050).

5 MG (BASE) ORAL TABLET				
00002459973	LANCORA	SEV	\$	0.8802
7.5 MG (BASE) ORAL TABLET				
00002459981	LANCORA	SEV	\$	1.6112

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

IVACAFTOR

"For the treatment of cystic fibrosis (CF) in patients age six (6) years and older who have one of the following mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene: G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N, or S549R; and

For the treatment of cystic fibrosis (CF) in patients aged 18 and older with an R117H mutation in the CFTR gene.

For coverage, this drug must be prescribed by a prescriber affiliated with one of the following Alberta Cystic Fibrosis Clinics:

- Cystic Fibrosis Clinic, Adult: Kaye Edmonton Clinic
- Cystic Fibrosis Services - Adult Outpatient: Foothills Medical Centre
- Cystic Fibrosis Clinic, Pediatric: Stollery Children's Hospital
- Pediatric Cystic Fibrosis Clinic: Alberta Children's Hospital

Initial coverage may be approved for up to 150 mg every 12 hours for 6 months. Patients will be limited to receiving a one-month supply per prescription at their pharmacy.

Renewal Criteria

The sweat chloride test will be repeated at the next routine review appointment after starting ivacaftor to determine whether sweat chloride levels are reducing and to check compliance with the drug regimen. The sweat chloride level will then be re-checked 6 months after starting treatment to determine whether the full reduction (as detailed below) has been achieved. Thereafter sweat chloride levels will be checked annually.

For continued coverage of up to 150mg every 12 hours beyond the initial 6-month authorization, the patient will be considered to have responded to treatment if either:

- a) The patient's sweat chloride test falls below 60mmoL/L; OR
- b) The patient's sweat chloride test falls by at least 30%

In cases where the baseline sweat chloride test is already below 60mmoL/L, the patient will be considered to have responded to treatment if either:

- c) The patient's sweat chloride test falls by at least 30%; OR
- d) The patient demonstrates a sustained absolute improvement in FEV1 of at least 5%. In this instance FEV1 will be compared with the baseline pre-treatment level one month and three months after starting treatment.

Following this assessment, continued coverage of up to 150 mg every 12 hours may be approved for a period of 12 months. Patients will be limited to receiving a one-month supply per prescription at their pharmacy.

If the expected reduction in sweat chloride does not occur, the patient's CF clinician will first explore any challenges in following the recommended dosing schedule for ivacaftor. The patient's sweat chloride will then be retested around one week later and funding discontinued if the patient does not meet the above criteria."

All requests (including renewal requests) for ivacaftor must be completed using the Ivacaftor Special Authorization Request Form (ABC 60004).

150 MG ORAL TABLET

00002397412 KALYDECO

VER

\$ 420.0000

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

IXEKIZUMAB

Plaque Psoriasis

"Special authorization coverage may be provided for the reduction in signs and symptoms of severe, debilitating plaque psoriasis in patients who:

- Have a total PASI of 10 or more and a DLQI of more than 10, OR
- Who have significant involvement of the face, palms of the hands, soles of the feet or genital region; AND
- Who are refractory to or intolerant to:
 - Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory, OR
 - Cyclosporine (6 weeks treatment); AND
 - Phototherapy (unless restricted by geographic location)

Patients who have a contraindication to either cyclosporine or methotrexate will be required to complete an adequate trial of the other pre-requisite medication prior to potential coverage being considered.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.

'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be prescribed by a Specialist in Dermatology ("Dermatology Specialist").

- Initial coverage may be approved for one 160 mg dose (two 80 mg injections) at weeks 0, followed by 80 mg (one injection) at Weeks 2, 4, 6, 8, 10, and 12.
- Patients will be limited to receiving a one-month supply of ixekizumab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage, the patient must meet all of the following criteria:

- 1) The patient must be assessed by a Dermatology Specialist after the initial 12 weeks of therapy to determine response.
- 2) The Dermatology Specialist must confirm, in writing, that the patient is a 'responder' that meets the following criteria:
 - Greater than or equal to 75% reduction in PASI score, OR
 - Greater than or equal to 50% reduction in PASI score AND improvement of greater than or equal to 5 points in the DLQI.

Following this assessment, continued coverage may be considered for 80 mg every 4 weeks for a period of 12 months. Ongoing coverage may be considered if the patient is re-assessed by a Dermatology Specialist every 12 months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above."

PASI and DLQI scores are required for all requests for Plaque Psoriasis including those requests for patients that have significant involvement of the face, palms, soles of feet or genital region.

All requests (including renewal requests) for ixekizumab for Plaque Psoriasis must be completed

**ALBERTA DRUG BENEFIT LIST
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IXEKIZUMAB

using the
Adalimumab/Etanercept/Infliximab/Ixekizumab/Risankizumab/Secukinumab/Ustekinumab for
Plaque Psoriasis Special Authorization Request Form (ABC 60030).

Psoriatic Arthritis

"Special authorization coverage may be provided for use in combination with methotrexate for reducing signs and symptoms and inhibiting the progression of structural damage of active arthritis in adult patients (18 years of age or older) with moderate to severe polyarticular psoriatic arthritis (PsA) or pauciarticular PsA with involvement of knee or hip joint who are refractory or intolerant to:

- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- An adequate trial of another disease modifying anti-rheumatic agent(s) (minimum 4 month trial).

Special authorization coverage of this agent may be provided for use as monotherapy in adult patients for whom methotrexate is contraindicated and/or for those patients who have experienced serious adverse effects.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.

'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

Initial coverage may be approved for one 160 mg dose (two 80 mg injections) at week 0, followed by 80 mg (one injection) at weeks 4, 8, 12, 16, 20 & 24.

- Patients will be limited to receiving a one-month supply of ixekizumab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond 24 weeks, the patient must meet the following criteria:

- 1) The patient must be assessed by an RA Specialist after the initial 24 weeks to determine response.
- 2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
 - ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND
 - An improvement of 0.22 in HAQ score [reported to two (2) decimal places].

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be considered for 80 mg every 4 weeks for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:

- 1) The patient has been assessed by an RA Specialist to determine response;

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

IXEKIZUMAB

2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:

- Confirmation of maintenance of ACR20, or
- Maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.

3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above."

All requests (including renewal requests) for ixekizumab for Psoriatic Arthritis must be completed using the

Adalimumab/Certolizumab/Etanercept/Golimumab/Infliximab/Ixekizumab/Secukinumab for Psoriatic Arthritis Special Authorization Request Form (ABC 60029).

80 MG / SYR INJECTION SYRINGE

<input checked="" type="checkbox"/>	00002455110	TALTZ	LIL	\$	1621.7900
<input checked="" type="checkbox"/>	00002455102	TALTZ AUTOINJECTOR	LIL	\$	1621.7900

LACOSAMIDE

"For adjunctive therapy in patients with refractory partial-onset seizures who meet all of the following criteria:

- Are currently receiving two or more antiepileptic medications, AND
- Have failed or demonstrated intolerance to three other antiepileptic medications, AND
- Therapy must be initiated by a Neurologist.

For the purpose of administering these criteria failure is defined as inability to achieve satisfactory seizure control.

Special authorization may be granted for six months.

Coverage cannot be provided for brivaracetam, eslicarbazepine, lacosamide or perampanel when these medications are intended for use in combination."

Each of these products is eligible for auto-renewal.

50 MG ORAL TABLET

00002475332	AURO-LACOSAMIDE	AUR	\$	0.6313
00002487802	MAR-LACOSAMIDE	MAR	\$	0.6313
00002490544	MINT-LACOSAMIDE	MPI	\$	0.6313
00002478196	PHARMA-LACOSAMIDE	PMS	\$	0.6313
00002474670	SANDOZ LACOSAMIDE	SDZ	\$	0.6313
00002472902	TEVA-LACOSAMIDE	TEV	\$	0.6313
00002357615	VIMPAT	UCB	\$	2.4093

100 MG ORAL TABLET

00002475340	AURO-LACOSAMIDE	AUR	\$	0.8750
00002487810	MAR-LACOSAMIDE	MAR	\$	0.8750
00002490552	MINT-LACOSAMIDE	MPI	\$	0.8750
00002478218	PHARMA-LACOSAMIDE	PMS	\$	0.8750
00002474689	SANDOZ LACOSAMIDE	SDZ	\$	0.8750
00002472910	TEVA-LACOSAMIDE	TEV	\$	0.8750
00002357623	VIMPAT	UCB	\$	3.4477

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

LACOSAMIDE

150 MG ORAL TABLET

00002475359	AURO-LACOSAMIDE	AUR	\$	1.1763
00002487829	MAR-LACOSAMIDE	MAR	\$	1.1763
00002490560	MINT-LACOSAMIDE	MPI	\$	1.1763
00002478226	PHARMA-LACOSAMIDE	PMS	\$	1.1763
00002474697	SANDOZ LACOSAMIDE	SDZ	\$	1.1763
00002472929	TEVA-LACOSAMIDE	TEV	\$	1.1763
00002357631	VIMPAT	UCB	\$	4.4862

200 MG ORAL TABLET

00002475367	AURO-LACOSAMIDE	AUR	\$	1.4500
00002487837	MAR-LACOSAMIDE	MAR	\$	1.4500
00002490579	MINT-LACOSAMIDE	MPI	\$	1.4500
00002478234	PHARMA-LACOSAMIDE	PMS	\$	1.4500
00002474700	SANDOZ LACOSAMIDE	SDZ	\$	1.4500
00002472937	TEVA-LACOSAMIDE	TEV	\$	1.4500
00002357658	VIMPAT	UCB	\$	5.5247

LANREOTIDE ACETATE

"For the treatment of acromegaly when prescribed by or in consultation with a Specialist in Internal Medicine.

Special authorization may be granted for 12 months."

The following product(s) are eligible for auto-renewal.

60 MG / SYR INJECTION SYRINGE

00002283395	SOMATULINE AUTOGEL (0.3 ML SYRINGE)	ISP	\$	1195.8951
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90 MG / SYR INJECTION SYRINGE

00002283409	SOMATULINE AUTOGEL (0.3 ML SYRINGE)	ISP	\$	1595.2501
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120 MG / SYR INJECTION SYRINGE

00002283417	SOMATULINE AUTOGEL (0.5 ML SYRINGE)	ISP	\$	1996.7757
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**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

LETERMOVIR

"For the prophylaxis therapy of cytomegalovirus (CMV) infection in adult CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT), in patients with undetectable CMV viremia at baseline, and who meet the following criteria:

- is a recipient of umbilical cord blood as stem cell source, or
- a haploidentical recipient, or
- a recipient of T-cell depleted grafts, or
- a recipient treated with antithymocyte globulin (ATG) for conditioning, or
- a recipient requiring high-dose steroids (defined as the use of greater than or equal to 1 mg/kg/day of prednisone or equivalent dose of another corticosteroid) or other immunosuppression for acute graft versus host disease (GVHD), or
- a recipient treated with ATG for steroid-refractory acute GVHD treatment, or
- a recipient with documented history of CMV disease prior to transplantation.

For coverage, this drug must be prescribed by the Director of the Alberta Blood & Marrow Transplant Program, or their designates.

Coverage may be approved at a dosage of up to 480 mg per day administered orally or intravenously.

Duration of therapy will be limited to 100 days, per patient, per HSCT procedure.

Patients will be limited to 14 days supply of letermovir per prescription at their pharmacy."

240 MG ORAL TABLET			
00002469375	PREVMIS	MFC	\$ 238.7160
480 MG ORAL TABLET			
00002469383	PREVMIS	MFC	\$ 238.7160
20 MG / ML INJECTION			
<input checked="" type="checkbox"/> 00002469405	PREVMIS	MFC	\$ 19.5454
<input checked="" type="checkbox"/> 00002469367	PREVMIS	MFC	\$ 19.8933

LEUPROLIDE ACETATE

"When prescribed for non-cancer, non-cosmetic or non-fertility indications.

Special authorization may be granted for 6 months."

Information is required regarding the patient's diagnosis/indication for use of this medication.

The following product(s) are eligible for auto-renewal.

3.75 MG / VIAL INJECTION			
00000884502	LUPRON DEPOT	ABV	\$ 364.7500
5 MG / ML INJECTION			
00000727695	LUPRON	ABV	\$ 67.6464
7.5 MG / VIAL INJECTION			
00000836273	LUPRON DEPOT	ABV	\$ 387.9700
11.25 MG / VIAL INJECTION			
00002239834	LUPRON DEPOT	ABV	\$ 1086.7500
22.5 MG / VIAL INJECTION			
00002230248	LUPRON DEPOT	ABV	\$ 1071.0000

ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

LEVOCARNITINE

"For the treatment of primary carnitine deficiency. Information is required regarding the total plasma carnitine levels."

"For the treatment of patients with an inborn error of metabolism that results in secondary carnitine deficiency. Information is required regarding the patient's diagnosis."

"Special authorization may be granted for 6 months."

In order to comply with the first criteria: Information is required regarding pre-treatment total plasma carnitine levels.

The following product(s) are eligible for auto-renewal.

330 MG ORAL TABLET				
00002144328	CARNITOR	SGM	\$	1.8858
100 MG / ML ORAL SOLUTION				
00002492105	ODAN LEVOCARNITINE	ODN	\$	0.4854
00002144336	CARNITOR	SGM	\$	0.5711
200 MG / ML INJECTION				
00002144344	CARNITOR	SGM	\$	13.2000

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

LEVODOPA/ CARBIDOPA

Special authorization coverage may be provided for the treatment of patients with advanced levodopa-responsive Parkinson's disease, who meet the following criteria:

- 1) The patient experiences severe disability associated with at least 25% of the waking day in the off state and/or ongoing, bothersome levodopa-induced dyskinesias, despite having tried frequent dosing of levodopa (at least five doses per day). Time in the off state, frequency of motor fluctuations, and severity of associated disability should be assessed by a movement disorder subspecialist and be based on an adequate and reliable account from longitudinal specialist care, clinical interview of a patient and/or care partner, or motor symptom diary.
- 2) The patient has received an adequate trial of maximally tolerated doses of levodopa, with demonstrated clinical response.
- 3) The patient has failed or is intolerant to adequate trials of each of the following adjunctive medications, if not contraindicated: a catechol-O-methyl transferase (COMT) inhibitor, a dopamine agonist, a monoamine oxidase (MAO-B) inhibitor, and amantadine.
- 4) The patient is able to administer the medication and care for the administration port and infusion pump. Alternatively, trained personnel or a care partner must be available to perform these tasks reliably.
- 5) The patient does not have a contraindication to the insertion of a percutaneous endoscopic gastrostomy-jejunostomy (PEG-J) tube.
- 6) The patient does not have severe psychosis or dementia.
- 7) Levodopa/carbidopa intestinal gel is initiated by a movement disorder subspecialist who has appropriate training in its use and is practising in a movement disorder clinic that provides ongoing management and support for patients receiving treatment.

Initial coverage may be approved for a period of 12 months.

Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:

- The patient demonstrates a significant reduction in the time spent in the off state and/or in ongoing, bothersome levodopa-induced dyskinesias, along with an improvement in the related disability.

All requests for levodopa/carbidopa intestinal gel must be completed using the Levodopa/Carbidopa Intestinal Gel Special Authorization Request Form (ABC 60068).

2,000 MG * 500 MG	INTRAINTESTINAL GEL		
00002292165	DUODOPA	ABV	\$ 169.8100

ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

LEVOFLOXACIN

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

FIRST-LINE DRUG PRODUCT(S): TOBRAMYCIN INHALATION SOLUTION

"For the treatment of chronic pulmonary Pseudomonas aeruginosa infections when used as cyclic treatment (28-day cycles) in patients 18 years of age and older with moderate to severe cystic fibrosis (CF) and deteriorating clinical condition despite treatment with inhaled tobramycin."

"Coverage will not be considered when inhaled levofloxacin and other inhaled antibiotic(s) (e.g. tobramycin, aztreonam) are intended for use in combination, either concurrently or for antibiotic cycling during off-treatment periods."

"Special authorization may be granted for 6 months."

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

UP - First-line therapy ineffective
UQ - First-line therapy not tolerated

100 MG / ML INHALATION SOLUTION				
00002442302	QUINSAIR	RAP	\$	26.8703

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

LINAGLIPTIN

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

FIRST-LINE DRUG PRODUCT(S): METFORMIN
SECOND-LINE DRUG PRODUCT(S): SULFONYLUREAS
AND WHERE INSULIN IS NOT AN OPTION

As add-on therapy for the treatment of Type 2 diabetes in patients with intolerance to and/or inadequate glycemic control on:

- a sufficient trial (i.e. a minimum of 6 months) of metformin, AND
- a sulfonylurea, AND
- for whom insulin is not an option.

Or, for whom these products are contraindicated.

Special authorization may be granted for 24 months.

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

- UP - First-line therapy ineffective
- UQ - First-line therapy not tolerated
- CA - Prior adverse reaction
- CB - Previous treatment failure
- CJ - Product is not effective

All requests for linagliptin must be completed using the DPP-4/SGLT2 Inhibitors/GLP-1 Receptor Agonist Special Authorization Request Form (ABC 60012).

5 MG ORAL TABLET

00002370921	TRAJENTA	BOE	\$	2.6571
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ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

LINAGLIPTIN/ METFORMIN HCL

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

FIRST-LINE DRUG PRODUCT(S): METFORMIN
SECOND-LINE DRUG PRODUCT(S): SULFONYLUREAS
AND WHERE INSULIN IS NOT AN OPTION

As add-on therapy for the treatment of Type 2 diabetes in patients with intolerance to and/or inadequate glycemic control on:

- a sufficient trial (i.e. a minimum of 6 months) of metformin, AND
- a sulfonylurea, AND
- for whom insulin is not an option.

Or, for whom these products are contraindicated.

Special authorization may be granted for 24 months.

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

- UP - First-line therapy ineffective
- UQ - First-line therapy not tolerated
- CA - Prior adverse reaction
- CB - Previous treatment failure
- CJ - Product is not effective

All requests for linagliptin+metformin must be completed using the DPP-4/SGLT2 Inhibitors/GLP-1 Receptor Agonist Special Authorization Request Form (ABC 60012).

2.5 MG * 500 MG ORAL TABLET				
00002403250	JENTADUETO	BOE	\$	1.3897
2.5 MG * 850 MG ORAL TABLET				
00002403269	JENTADUETO	BOE	\$	1.3897
2.5 MG * 1,000 MG ORAL TABLET				
00002403277	JENTADUETO	BOE	\$	1.3897

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

LINEZOLID

(Refer to Section 1 - Restricted Benefits of the Alberta Drug Benefit List for coverage of the product when prescribed by a Specialist in Infectious Diseases or a designated prescriber.)

"For the treatment of:

- 1) Vancomycin-resistant enterococcus infections or
- 2) Methicillin-resistant Staphylococcus aureus (MRSA)/methicillin-resistant coagulase-negative Staphylococcus infections in patients who are unresponsive to or intolerant of vancomycin or
- 3) Susceptible organisms in patients severely intolerant or allergic to all other appropriate alternatives (e.g. beta-lactam antibiotics, clindamycin, trimethoprim/sulfamethoxazole and vancomycin) or to facilitate patient discharge from hospital where it otherwise would not be possible.

This product must be prescribed in consultation with a specialist in Infectious Diseases in all instances."*

*Special Authorization is only required when the prescriber prescribing the medication is not a Specialist in Infectious Diseases or a designated prescriber.

In order to comply with the above criteria, information is required regarding the type of infection and organisms involved. Information is also required regarding previous antibiotic therapy that has been utilized and the patient's response to therapy and the first line agents the organism is resistant to or why other first-line therapies cannot be used in this patient. The specialist in Infectious Diseases that recommended this drug is also required.

600 MG ORAL TABLET

00002426552	APO-LINEZOLID	APX	\$	37.0500
00002422689	SANDOZ LINEZOLID	SDZ	\$	37.0500
00002243684	ZYVOXAM	PFI	\$	75.7024

MEGESTROL ACETATE

"For the treatment of non-cancer indications (e.g. cachexia in HIV/AIDS patients and cancer patients).

Special authorization may be granted for 6 months."

(Please note: The above megestrol acetate products are benefits not requiring special authorization for individuals approved by Alberta Health for Palliative Coverage. Refer to the Palliative Coverage Drug Benefit Supplement for additional information on this coverage.)

The following product(s) are eligible for auto-renewal.

40 MG ORAL TABLET

00002195917	MEGESTROL	AAP	\$	1.3807
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160 MG ORAL TABLET

00002195925	MEGESTROL	AAP	\$	6.0186
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**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

MEPOLIZUMAB

"Special authorization coverage may be provided for add-on maintenance treatment of adult patients with severe eosinophilic asthma if the following clinical criteria and conditions are met:

Patient is inadequately controlled with high-dose inhaled corticosteroids (ICS) and one or more additional asthma controller(s) (e.g., a long-acting beta-agonist [LABA]).

AND

Patient has a blood eosinophil count of greater than or equal to 300 cells/mcL AND has experienced two or more clinically significant asthma exacerbations* in the 12 months prior to treatment initiation with mepolizumab;

OR

Patient has a blood eosinophil count of greater than or equal to 150 cells/mcL AND is receiving daily maintenance treatment with oral corticosteroids (OCS).

For coverage, the drug must be initiated and monitored by a respirologist or clinical immunologist or allergist.

Initial coverage may be approved for 12 months of 100 mg administered every 4 weeks.

-Patients will be limited to receiving a one-month supply of mepolizumab per prescription at their pharmacy.

-Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).

-Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.

-Coverage cannot be provided for mepolizumab when this medication is intended for use in combination with other biologics for the treatment of asthma.

If ALL the following criteria are met, special authorization may be approved for 100 mg administered every 4 weeks for a further 12-month period.

- 1) An improvement in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 when compared to pre-treatment baseline or an ACQ-5 score of less than or equal to 1; AND
- 2) Maintenance or reduction in the number of clinically significant exacerbations* compared to the 12 months prior to initiation of treatment with mepolizumab; AND
- 3) For patients on daily maintenance therapy with OCS prior to initiating mepolizumab, a decrease in the OCS dose.

Continued coverage may be considered for 100 mg administered every 4 weeks if ALL of the following criteria are met at the end of each additional 12-month period:

- 1) The ACQ-5 score achieved during the first 12 months of therapy is at least maintained throughout treatment or the ACQ-5 score is less than or equal to 1; AND
- 2) Maintenance or reduction in the number of clinically significant exacerbations* compared to the previous 12-month period; AND

3) For patients on daily maintenance therapy with OCS prior to initiating mepolizumab, the reduction in the OCS dose achieved after the first 12 months of therapy is at least maintained throughout treatment.

* Clinically significant asthma exacerbation is defined as worsening of asthma such that the treating physician elected to administer systemic glucocorticoids for at least 3 days or the patient visited an emergency department or was hospitalized."

All requests (including renewal requests) for mepolizumab must be completed using the Benralizumab/Mepolizumab Special Authorization Request Form (ABC 60061).

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

MEPOLIZUMAB

100 MG / VIAL INJECTION

00002449781	NUCALA	GSK	\$	1938.4600
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MEROPENEM

(Refer to Section 1 - Restricted Benefits of the Alberta Drug Benefit List for coverage of the product when prescribed by a Specialist in Infectious Diseases or Hematology, or a designated prescriber.)

- "1) For second-line therapy of infections due to gram-negative organisms producing inducible beta-lactamases or extended spectrum beta-lactamases where there is resistance to first-line agents or
- 2) For therapy for infections involving multi-resistant Pseudomonas aeruginosa, where there is documented susceptibility to meropenem or
- 3) For use in other Health Canada approved indications, in consultation with a specialist in Infectious Diseases."*

*Special Authorization is only required when the prescriber prescribing the medication is not a Specialist in Infectious Diseases or Hematology, or a designated prescriber.

In order to comply with all of the above criteria, information is required regarding the type of infection and organisms involved. Also, where the criteria restrict coverage of the requested drug to non-first line therapy, information is required regarding previous first-line antibiotic therapy that has been utilized, the patient's response to therapy, and the first line agents the organism is resistant to or why other first-line therapies cannot be used in this patient. Also, where applicable, the specialist in Infectious Diseases that recommended this drug is required.

500 MG / VIAL INJECTION

00002378787	MEROPENEM	SDZ	\$	9.2225
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1 G / VIAL INJECTION

00002378795	MEROPENEM	SDZ	\$	18.4450
00002436507	MEROPENEM FOR INJECTION USP	STM	\$	18.4450

**METHYLPREDNISOLONE ACETATE/ NEOMYCIN SULFATE/
ALUMINUM CHLORHYDROXIDE COMPLEX/ SULFUR**

"For the treatment of severe acne as defined by scarring acne."

"For the treatment of acne rosacea and seborrheic dermatitis."

"Special authorization may be granted for 6 months."

The following product(s) are eligible for auto-renewal.

2.5 MG / ML * 2.5 MG / ML * 100 MG / ML * 50 MG / ML TOPICAL LOTION

00000195057	NEO-MEDROL ACNE	PFI	\$	0.3028
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ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

MIGALASTAT HYDROCHLORIDE

"For treatment of adults (18 years of age or older) with laboratory-confirmed diagnosis of Fabry Disease (a deficiency of alpha-galactosidase [alpha-Gal A]) who have an alpha-Gal A mutation that is determined to be amenable by an in vitro assay.

The patient must also be otherwise eligible for enzyme replacement therapy (ERT) for the treatment of Fabry Disease as determined and assessed through the Canadian Fabry Disease Initiative (CFDI).

For coverage, this drug must be prescribed by a physician affiliated with the Canadian Fabry Disease Initiative (CFDI).

Coverage cannot be provided for use in combination with any ERT.

Initial coverage may be approved up to 12 months.

For continued coverage beyond 12 months, confirmation of continued response is required. Continued coverage may be approved for a period of 12 months."

All requests (including renewal requests) for migalastat must be completed using the Migalastat Special Authorization Request Form (ABC 60071).

123 MG (BASE) ORAL CAPSULE			
00002468042 GALAFOLD	AMI	\$	1700.0000

MIRABEGRON

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

FIRST-LINE DRUG PRODUCT(S): SOLIFENACIN OR TOLTERODINE LA

"For patients who have failed on or are intolerant to solifenacin or tolterodine LA.

Special authorization may be granted for 24 months.

Coverage cannot be provided for mirabegron when this medication is intended for use in combination with other overactive bladder agents."

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

UP - First-line therapy ineffective
UQ - First-line therapy not tolerated

25 MG ORAL EXTENDED-RELEASE TABLET			
00002402874 MYRBETRIQ	ASP	\$	1.4600
50 MG ORAL EXTENDED-RELEASE TABLET			
00002402882 MYRBETRIQ	ASP	\$	1.4600

ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

MODAFINIL

"For the treatment of documented narcolepsy. This drug product must be prescribed by a specialist in Neurology or Psychiatry, or a sleep specialist affiliated with a recognized level 1 lab.

Special authorization may be granted for 6 months."

The following product(s) are eligible for auto-renewal.

100 MG ORAL TABLET

00002285398	APO-MODAFINIL	APX	\$	0.3427
00002430487	AURO-MODAFINIL	AUR	\$	0.3427
00002432560	MAR-MODAFINIL	MAR	\$	0.3427
00002420260	TEVA-MODAFINIL	TEV	\$	0.3427
00002239665	ALERTEC	TMP	\$	1.4403

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

MONTELUKAST SODIUM

(Refer to 48:10.24 of the Alberta Drug Benefit List for coverage of patients 6 to 18 years of age inclusive).

"For the prophylaxis and chronic treatment of asthma in patients over the age of 18 who meet one of the following criteria:

- a) when used as adjunctive therapy in patients who do not respond adequately to high doses of inhaled glucocorticosteroids and long-acting beta 2 agonists. Patients must be unable to use long-acting beta 2 agonists or have demonstrated persistent symptoms while on long-acting beta 2 agonists, or
- b) cannot operate inhaler devices."

"For the prophylaxis of exercise-induced bronchoconstriction in patients over the age of 18 where tachyphylaxis exists for long-acting beta 2 agonists."

"Special authorization for both criteria may be granted for 6 months."

In order to comply with the first criteria, information should indicate either

- a) current use of inhaled steroids and contraindications or poor response to long-acting beta 2 agonists (e.g. salmeterol or formoterol) or,
- b) the nature of the patient's difficulties with using inhaler devices.

In order to comply with the second criteria, information should include the nature of the patient's response to long-acting beta 2 agonists (e.g. salmeterol or formoterol).

All requests (including renewal requests) for montelukast must be completed using the Montelukast/Zafirlukast Special Authorization Request Form (ABC 60039).

The following product(s) are eligible for auto-renewal.

10 MG (BASE)	ORAL TABLET			
00002374609	APO-MONTELUKAST	APX	\$	0.4231
00002401274	AURO-MONTELUKAST	AUR	\$	0.4231
00002391422	JAMP-MONTELUKAST	JPC	\$	0.4231
00002399997	MAR-MONTELUKAST	MAR	\$	0.4231
00002408643	MINT-MONTELUKAST	MPI	\$	0.4231
00002379333	MONTELUKAST	SNS	\$	0.4231
00002382474	MONTELUKAST	SIV	\$	0.4231
00002379236	MONTELUKAST SODIUM	AHI	\$	0.4231
00002373947	PMS-MONTELUKAST FC	PMS	\$	0.4231
00002389517	RAN-MONTELUKAST	RAN	\$	0.4231
00002328593	SANDOZ MONTELUKAST	SDZ	\$	0.4231
00002355523	TEVA-MONTELUKAST	TEV	\$	0.4231
00002238217	SINGULAIR	MFC	\$	2.4823
5 MG (BASE)	ORAL CHEWABLE TABLET			
00002377616	APO-MONTELUKAST	APX	\$	0.3082
00002442361	JAMP-MONTELUKAST	JPC	\$	0.3082
00002399873	MAR-MONTELUKAST	MAR	\$	0.3082
00002408635	MINT-MONTELUKAST	MPI	\$	0.3082
00002382466	MONTELUKAST	SIV	\$	0.3082
00002354985	PMS-MONTELUKAST	PMS	\$	0.3082
00002330393	SANDOZ MONTELUKAST	SDZ	\$	0.3082
00002355515	TEVA-MONTELUKAST	TEV	\$	0.3082
00002238216	SINGULAIR	MFC	\$	1.6902

ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

NARATRIPTAN HCL

(Refer to 28:32.28 of the Alberta Drug Benefit List for coverage of patients 18 to 64 years of age inclusive.)

"For the treatment of acute migraine attacks in patients 65 years of age and older where other standard therapy has failed."

"For the treatment of acute migraine attacks in patients 65 years of age and older who have been using naratriptan hydrochloride prior to turning 65."

"Special authorization for both criteria may be granted for 24 months."

In order to comply with the first criteria, information is required regarding previous medications utilized and the patient's response to therapy.

The following product(s) are eligible for auto-renewal.

1 MG (BASE) ORAL TABLET				
00002314290	TEVA-NARATRIPTAN	TEV	\$	11.9041
00002237820	AMERGE	GSK	\$	15.1256
2.5 MG (BASE) ORAL TABLET				
00002322323	SANDOZ NARATRIPTAN	SDZ	\$	6.1436
00002314304	TEVA-NARATRIPTAN	TEV	\$	6.1436
00002237821	AMERGE	GSK	\$	15.9429

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

NATALIZUMAB

Relapsing Remitting Multiple Sclerosis (RRMS):

Special authorization coverage may be provided for the treatment of relapsing remitting multiple sclerosis (RRMS) to reduce the frequency of clinical relapses, to decrease the number and volume of active brain lesions identified on magnetic resonance imaging (MRI) scans and to delay the progression of physical disability, in adult patients (18 years of age or older) who are refractory or intolerant to at least ONE of the following:

- interferon beta
- glatiramer acetate
- dimethyl fumarate
- teriflunomide
- peginterferon beta.

Definition of 'intolerant'

Demonstrating serious adverse effects or contraindications to treatments as defined in the product monograph, or a persisting adverse event that is unresponsive to recommended management techniques and which is incompatible with further use of that class of MS disease modifying therapy (DMT).

Definition of 'refractory'

-Development of neutralizing antibodies to interferon beta.

-When the above MS DMTs are taken at the recommended doses for a full and adequate course of treatment, within a consecutive 12-month period while the patient was on the MS DMT, the patient has:

- 1) Been adherent to the MS DMT (greater than 80% of approved doses have been administered);
- 2) Experienced at least two relapses* of MS confirmed by the presence of neurologic deficits on examination.
 - i. The first qualifying clinical relapse must have begun at least one month after treatment initiation.
 - ii. Both qualifying relapses must be classified with a relapse severity of moderate, severe or very severe**.

*A relapse is defined as the appearance of new symptoms or worsening of old symptoms, lasting at least 48 hours in the absence of fever, not associated with withdrawal from steroids. Onset of clinical relapses must be separated by a period of at least one month. At least one definite gadolinium-enhancing T1 MRI lesion (not questionable faint enhancement) obtained at least 90 days after initiation of the DMT and at least 90 days before or after a relapse may substitute for one clinical relapse.

**Relapse severity: with moderate relapses modification or more time is required to carry out activities of daily living; with severe relapses there is inability to carry out some activities of daily living; with very severe relapses activities of daily living must be completed by others.

Coverage

For coverage, this drug must be prescribed by a registered MS Neurologist. A current assessment must be completed by a registered MS Neurologist at every request.

To register to become an MS Neurologist please complete the Registration for MS Neurologist Status Form (ABC 60002).

Initial Coverage

- 1) The registered MS Neurologist must confirm a diagnosis of RRMS;

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

NATALIZUMAB

2) The patient must have active disease which is defined as at least two relapses* of MS during the previous two years or in the two years prior to starting an MS DMT. In most cases this will be satisfied by the 'refractory' to treatment criterion but if a patient failed an MS DMT more than one year earlier, ongoing active disease must be confirmed.

3) The patient must be ambulatory with or without aid (The registered MS Neurologist must provide a current updated Expanded Disability Status Scale (EDSS) score less than or equal to 6.5).

Coverage will not be approved when any MS DMT or other immunosuppressive therapy is to be used in combination with natalizumab.

Coverage of natalizumab will not be approved if the patient was deemed to be refractory to natalizumab in the past, i.e., has not met the 'responder' criteria below in 'Continued Coverage'.

Following assessment of the request, coverage may be approved for up to 13 doses of 300 mg (i.e., one dose administered every 4 weeks for a period up to 12 months). Patients will be limited to receiving one dose (4 weeks supply) of natalizumab per prescription at their pharmacy.

Continued Coverage

For continued coverage beyond the initial coverage period, the patient must meet the following criteria:

- 1) The patient must be assessed by a registered MS Neurologist;
- 2) The registered MS Neurologist must confirm a diagnosis of RRMS;
- 3) The registered MS Neurologist must provide a current updated EDSS score. The patient must not have an EDSS score of 7.0 or above sustained for one year or more;

Coverage of this drug may be considered in a patient with a sustained EDSS score of 7.0 or above in exceptional circumstances. For MS DMT coverage to be considered, details of the exceptional circumstance must be provided in a letter from the registered MS Neurologist and accompany the Special Authorization Request Form.

4) At the first renewal there must be evidence that neutralizing antibodies to natalizumab are absent.

5) The registered MS Neurologist must confirm in writing that the patient is a 'responder' who has experienced no more than one inflammatory event in the last year (defined as either a clinical relapse or gadolinium-enhancing lesion). In instances where a patient has had four or more clinical relapses in the year prior to starting treatment, there must be at least a 50% reduction in relapse rate over the entire treatment period.

Following assessment of the request, continued coverage may be approved for maintenance therapy of 300 mg every 4 weeks for a period up to 12 months. Patients will be limited to receiving one dose of natalizumab per prescription at their pharmacy.

Restarting After an Interruption in Therapy Greater Than 12 Months

In order to be eligible for coverage, after an interruption in therapy greater than 12 months, the patient must meet the following criteria:

- 1) At least one relapse* per 12 month period; or
- 2) At least two relapses* during the previous 24 month period.

All requests (including renewal requests) for natalizumab must be completed using the Alemtuzumab/Fingolimod/Natalizumab For Multiple Sclerosis Special Authorization Request Form (ABC 60000).

ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

NATALIZUMAB

20 MG / ML INJECTION

00002286386 TYSABRI BIO \$ 181.4455

NINTEDANIB ESILATE

"Initial approval criteria:

Adult patients with a diagnosis of mild to moderate idiopathic pulmonary fibrosis (IPF):

- Diagnosis confirmed by a respirologist and a high-resolution CT scan within the previous 24 months.
- All other causes of restrictive lung disease (e.g. collagen vascular disorder or hypersensitivity pneumonitis) should be excluded.
- Mild to moderate IPF is defined as forced vital capacity (FVC) greater than or equal to 50% of predicted.
- Patient is under the care of a physician with experience in IPF.

Initial approval period: 7 months (allow 4 weeks for repeat pulmonary function tests)

Initial renewal criteria (at 6 months):

Patients must NOT demonstrate progression of disease defined as an absolute decline in percent predicted FVC of greater than or equal to 10% from initiation of therapy until renewal (initial 6 month treatment period). If a patient has experienced progression as defined above, then the results should be validated with a confirmatory pulmonary function test conducted 4 weeks later.

Approval period: 6 months

Second and subsequent renewals (at 12 months and thereafter):

Patients must NOT demonstrate progression of disease defined as an absolute decline in percent predicted FVC of greater than or equal to 10% within any 12 month period. If a patient has experienced progression as defined above, then the results should be validated with a confirmatory pulmonary function test conducted 4 weeks later.

Approval period: 12 months

Exclusion Criteria:

Combination use of pirfenidone and nintedanib will not be funded.

Notes:

Patients who have experienced intolerance or failure to pirfenidone or nintedanib will be considered for the alternate agent provided that the patient continues to meet the above coverage criteria."

All requests for nintedanib must be completed using the Nintedanib/Pirfenidone Special Authorization Request Form (ABC 60051).

100 MG (BASE) ORAL CAPSULE

00002443066 OFEV BOE \$ 28.3216

150 MG (BASE) ORAL CAPSULE

00002443074 OFEV BOE \$ 56.6431

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

NITISINONE

"For the treatment of adult and pediatric patients with hereditary tyrosinemia type 1 (HT-1) in combination with dietary restriction of tyrosine and phenylalanine, when prescribed by a physician with experience in the diagnosis and management of HT-1."

Special authorization may be granted for 12 months.

The following product(s) are eligible for auto-renewal.

2 MG ORAL TABLET			
00002458616	NITISINONE	CYC	\$ 12.9500
5 MG ORAL TABLET			
00002458624	NITISINONE	CYC	\$ 25.0600
10 MG ORAL TABLET			
00002458632	NITISINONE	CYC	\$ 47.4000
2 MG ORAL CAPSULE			
<input checked="" type="checkbox"/>	00002457717	MDK-NITISINONE	MEN \$ 12.9500
<input checked="" type="checkbox"/>	00002459698	ORFADIN	BVM \$ 12.9500
5 MG ORAL CAPSULE			
<input checked="" type="checkbox"/>	00002457725	MDK-NITISINONE	MEN \$ 25.0600
<input checked="" type="checkbox"/>	00002459701	ORFADIN	BVM \$ 25.0600
10 MG ORAL CAPSULE			
<input checked="" type="checkbox"/>	00002457733	MDK-NITISINONE	MEN \$ 47.4000
<input checked="" type="checkbox"/>	00002459728	ORFADIN	BVM \$ 47.4000
20 MG ORAL CAPSULE			
<input checked="" type="checkbox"/>	00002470055	MDK-NITISINONE	MEN \$ 128.1000
<input checked="" type="checkbox"/>	00002459736	ORFADIN	BVM \$ 128.1000

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

NUSINERSEN SODIUM

"For patients diagnosed with 5q Spinal Muscular Atrophy (SMA) under the care of a specialist with experience in the diagnosis and management of SMA, if the following clinical criteria are met:

- 1) Genetic documentation of 5q SMA homozygous gene deletion, homozygous mutation, or compound heterozygote, AND
 - 2) Patients who:
 - are pre-symptomatic with two or three copies of SMN2, OR
 - have had disease duration of less than six months, two copies of SMN2, and symptom onset after the first week after birth and on or before seven months of age, OR
 - are under the age of 18 with symptom onset after six months of age, regardless of the ability to walk independently.
- AND
- 3) Patient is not currently requiring permanent invasive ventilation*, AND
 - 4) A baseline assessment using an age-appropriate scale (the Hammersmith Infant Neurological Examination [HINE] Section 2, Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders [CHOP INTEND], or Hammersmith Functional Motor Scale-Expanded [HFMSE]) must be completed prior to initiation of nusinersen treatment.

Other patients who do not meet the expanded funding criteria may be considered in exceptional cases.

Initial coverage may be approved for three 12 mg doses at Day 0, Day 14 and Day 28, followed by one 12 mg dose at Day 63.

Patients will be limited to receiving one dose of nusinersen per prescription at their pharmacy.

For continued coverage, the patient must meet the following criteria:

- 1) There is demonstrated achievement or maintenance of motor milestone function (as assessed using age-appropriate scales: the [HINE] Section 2), CHOP INTEND, or HFMSE) since treatment initiation in patients who were pre-symptomatic at the time of treatment initiation;
OR
There is demonstrated maintenance of motor milestone function (as assessed using age-appropriate scales: the HINE Section 2, CHOP INTEND, or HFMSE) since treatment initiation in patients who were symptomatic at the time of treatment initiation;
AND
- 2) Patient does not require permanent invasive ventilation*.

Continued coverage may be considered for one 12 mg maintenance dose at a time, to be administered at 4-month intervals.

Each maintenance dose cannot be considered prior to 4 months elapsing from the date of the previous dose.

Treatment should be discontinued if, prior to the fifth dose or every subsequent dose of nusinersen, the above renewal criteria are not met.

*Permanent invasive ventilation is defined as the use of tracheostomy and a ventilator due to progression of SMA that is not due to an identifiable and reversible cause."

All requests (including renewal requests) for nusinersen must be completed using the Nusinersen Special Authorization Request Form (ABC 60064).

2.4 MG / ML (BASE)	INJECTION		
00002465663	SPINRAZA	BIO	\$ 23600.0000

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

OBETICHOLIC ACID

"For the treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA, or as monotherapy in adults unable to tolerate UDCA, where the following criteria are met:

- I. A confirmed diagnosis of PBC, defined as:
- Positive antimitochondrial antibodies (AMA); or
 - Liver biopsy results consistent with PBC.

AND

- II.a. The patient has received ursodeoxycholic acid (UDCA) for a minimum of 12 months and has experienced an inadequate response to UDCA and can benefit from the addition of obeticholic acid. An inadequate response is defined as:
- alkaline phosphatase (ALP) greater than or equal to 1.67 x upper limit of normal (ULN) and/or
 - bilirubin > ULN and < 2 x ULN.

OR

- II.b. The patient has experienced documented and unmanageable intolerance to UDCA and can benefit from switching therapy to obeticholic acid.

AND

- III. Initiated by a gastroenterologist or hepatologist (or an internal medicine specialist with an interest in gastroenterology / hepatology on a case-by-case basis, in geographic areas where access to these specialities is not available).

Initial coverage may be approved for a period of 12 months.

Ongoing coverage may be considered only if the patient continues to benefit from treatment with obeticholic acid as evidenced by:

- A reduction in the ALP level to less than 1.67 x ULN; or
- A 15% reduction in the ALP level compared with values before beginning treatment with obeticholic acid.

Continued coverage may be approved for up to 12 months."

All requests (including renewal requests) for obeticholic acid must be completed using the Obeticholic Acid Special Authorization Request Form (ABC 60065).

5 MG ORAL TABLET

00002463121	OCALIVA	ICP	\$	100.8986
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10 MG ORAL TABLET

00002463148	OCALIVA	ICP	\$	100.8986
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**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

OCRELIZUMAB

Relapsing Remitting Multiple Sclerosis (RRMS)

"Special authorization coverage may be provided for the reduction of the frequency and severity of clinical relapses and reduction of the number and volume of active brain lesions, identified on MRI scans, in ambulatory adult patients (18 years of age or older) with relapsing remitting multiple sclerosis.

Coverage

For coverage, this drug must be prescribed by a registered MS Neurologist. A current assessment must be completed by a registered MS Neurologist at every request.

To register to become an MS Neurologist, please complete the Registration for MS Neurologist Status Form (ABC 60002).

Initial Coverage

- 1) The registered MS Neurologist must confirm a diagnosis of RRMS;
- 2) The patient must have active disease which is defined as at least two relapses* of MS during the previous two years or in the two years prior to starting an MS disease modifying therapy (DMT).

*A relapse is defined as the appearance of new symptoms or worsening of old symptoms, lasting at least 48 hours in the absence of fever, not associated with withdrawal from steroids. Onset of clinical relapses must be separated by a period of at least one month. At least one definite gadolinium-enhancing T1 MRI lesion (not questionable faint enhancement) obtained at least 90 days after initiation of the DMT and at least 90 days before or after a relapse may substitute for one clinical relapse.

- 3) The patient must be ambulatory with or without aid (The registered MS Neurologist must provide a current updated Expanded Disability Status Scale (EDSS) score less than or equal to 6.5).

Initial coverage may be approved for an initial dose of ocrelizumab 300 mg given by intravenous (IV) infusion, followed 2 weeks later by a second 300 mg dose. A maintenance dose of ocrelizumab 600 mg at 6 months will also be provided in the initial coverage period. Patients will be limited to receiving one dose of ocrelizumab per prescription at their pharmacy.

Continued Coverage

For continued coverage beyond the initial coverage period, the patient must meet the following criteria:

- 1) The patient must be assessed by a registered MS Neurologist;
- 2) The registered MS Neurologist must confirm a diagnosis of RRMS;
- 3) The registered MS Neurologist must provide a current updated EDSS score. The patient must not have an EDSS score of 7.0 or above sustained for one year or more. Coverage of this drug may be considered in a patient with a sustained EDSS score of 7.0 or above in exceptional circumstances. For MS DMT coverage to be considered, details of the exceptional circumstance must be provided in a letter from the registered MS Neurologist and accompany the Special Authorization Request Form.

Continued coverage may be approved for one dose of ocrelizumab 600 mg every 6 months for up to 12 months. Patients may receive one dose of ocrelizumab 600 mg per prescription at their pharmacy.

Restarting After an Interruption in Therapy Greater Than 12 Months

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

OCRELIZUMAB

In order to be eligible for coverage, after an interruption in therapy greater than 12 months, the patient must meet the following criteria:

- 1) At least one relapse* per 12 month period; or
- 2) At least two relapses* during the previous 24 month period."

All requests (including renewal requests) for ocrelizumab for RRMS must be completed using the Dimethyl Fumarate/Glatiramer Acetate /Interferon Beta-1b/Ocrelizumab/Peginterferon Beta-1a/Teriflunomide for RRMS/Interferon Beta-1a for SPMS or RRMS Special Authorization Request Form (ABC 60001).

Primary Progressive Multiple Sclerosis (PPMS)

"Special authorization coverage may be provided for the management of adult patients with early primary progressive multiple sclerosis (PPMS), as defined by disease duration and level of disability in conjunction with imaging features characteristic of inflammatory activity.

For coverage, this drug must be prescribed by a registered MS Neurologist. A current assessment must be completed by a registered MS Neurologist at every request.

To register to become an MS Neurologist, please complete the Registration for MS Neurologist Status Form (ABC 60002).

Initial Coverage

- 1) The registered MS Neurologist must confirm a diagnosis of PPMS (based on McDonald criteria 2017);
- 2) The patient must have an Expanded Disability Status Scale (EDSS) score between 3.0 and 6.5;
- 3) The patient must have a score of at least 2.0 on the Functional Systems scale for the pyramidal system due to lower extremity findings;
- 4) There are documented imaging features characteristic of inflammatory activity;
- 5) Disease duration must be less than 15 years for those with an EDSS greater than 5.0, or less than 10 years for those with an EDSS of 5.0 or less.

Initial coverage may be approved for an initial dose of ocrelizumab 300 mg given by intravenous (IV) infusion, followed 2 weeks later by a second 300 mg dose. A maintenance dose of ocrelizumab 600 mg at 6 months will also be provided in the initial coverage period. Patients will be limited to receiving one dose of ocrelizumab per prescription at their pharmacy.

Continued Coverage

For continued coverage beyond the initial coverage period, the patient must be assessed between 6 months and 12 months, and every 12 months thereafter, and the request must meet the following criteria:

- 1) The registered MS Neurologist must confirm a diagnosis of PPMS;
- 2) A current updated EDSS score must be provided and the patient must not have an EDSS score of 7.0 or above.

Continued coverage may be approved for one dose of ocrelizumab 600 mg every 6 months for up to 12 months. Patients may receive one dose of ocrelizumab 600 mg per prescription at their pharmacy."

All requests (including renewal requests) for ocrelizumab for PPMS must be completed using

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

OCRELIZUMAB

the Ocrelizumab for PPMS Special Authorization Request Form (ABC 60067).

30 MG / ML INJECTION			
00002467224	OCREVUS	HLR	\$ 815.0000

OCTREOTIDE ACETATE

"For control of symptoms in patients with metastatic carcinoid and vasoactive intestinal peptide-secreting tumors (VIPomas) when prescribed by or in consultation with a Specialist in Internal Medicine, Palliative Care or General Surgery."

"For the treatment of acromegaly when prescribed by or in consultation with a Specialist in Internal Medicine."

"For the treatment of intractable diarrhea which has not responded to less costly therapy [e.g. associated with (secondary to) AIDS, intra-abdominal fistulas, short bowel syndrome]. Treatment for these indications must be prescribed by or in consultation with a Specialist in, Internal Medicine, Palliative Care, or General Surgery."

"Special authorization may be granted for 12 months."

In order to comply with the third criterion, information is required regarding previous medications utilized and the patient's response to therapy.

The following product(s) are eligible for auto-renewal.

50 MCG / ML (BASE)	INJECTION		
00002248639	OCTREOTIDE ACETATE OMEGA	OMG	\$ 1.7465
00000839191	SANDOSTATIN	NOV	\$ 5.1460
100 MCG / ML (BASE)	INJECTION		
00002248640	OCTREOTIDE ACETATE OMEGA	OMG	\$ 3.2970
00000839205	SANDOSTATIN	NOV	\$ 9.7135
200 MCG / ML (BASE)	INJECTION		
00002248642	OCTREOTIDE ACETATE OMEGA	OMG	\$ 6.3420
00002049392	SANDOSTATIN	NOV	\$ 18.6861
500 MCG / ML (BASE)	INJECTION		
00002248641	OCTREOTIDE ACETATE OMEGA	OMG	\$ 15.4945
10 MG / VIAL (BASE)	INJECTION		
00002239323	SANDOSTATIN LAR	NOV	\$ 1315.7400
20 MG / VIAL (BASE)	INJECTION		
00002239324	SANDOSTATIN LAR	NOV	\$ 1699.8900
30 MG / VIAL (BASE)	INJECTION		
00002239325	SANDOSTATIN LAR	NOV	\$ 2180.9400

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

OMALIZUMAB

Asthma

"Special authorization coverage may be provided for adults and adolescents (12 years of age and above) with severe persistent asthma who are identified as having severe disease despite optimized standard therapy. Optimized standard therapy defined by a full trial of, and documented compliance with:

- high dose inhaled corticosteroid (budesonide 1600 micrograms per day or fluticasone propionate 1000 micrograms per day or equivalent) for at least twelve (12) months; AND,
- long-acting beta-2 agonist therapy (at least salmeterol 50 micrograms daily or 24 micrograms of formoterol fumarate daily) for at least twelve (12) months; AND,
- Therapeutic trial with systemic corticosteroids (at least 10mg per day prednisolone (or equivalent)) for at least 4 weeks in the previous twelve (12) months, unless contraindicated or not tolerated.

For coverage, the drug must be initiated and monitored by a respirologist or clinical immunologist or allergist and meet the following clinical criteria (Initial Coverage or Continued Coverage, as appropriate). Patients will be limited to receiving a one (1) month supply of omalizumab per prescription at their pharmacy.

INITIAL COVERAGE:

Special authorization requests must meet all of the following criteria for initial approval:

- 1) Confirmation of severe persistent asthma through recent clinical and physiologic review with exclusion of other obstructive airways processes contributing to symptoms of severe asthma (i.e. psychogenic dyspnea; cardiac dyspnea);
- 2) Must be a non-smoker;
- 3) Confirmation of IgE mediated allergy to a perennial allergen by clinical history and allergy skin testing;
- 4) Baseline IgE level greater than/equal to 30 IU/mL and less than/equal to 700 IU/mL;
- 5) A weight between 20kg and 150kg;
- 6) An Asthma Control Questionnaire (ACQ-5) of at least 1.25, on at least two occasions over the past 6 months in a stable state;
- 7) Must provide documentation:
 - Spirometry measurement of FEV₁;
 - Asthma Quality of Life Questionnaire (AQLQ - Juniper) score;
 - Number of exacerbations of asthma within the previous twelve (12) month period that resulted in:
 - an emergency room visit or hospitalization;
 - physician visits resulting in oral corticosteroids or an increased dose of oral corticosteroids;
 - chronic use (greater than 50% of the year) of oral corticosteroids;
- 8) One (1) or more severe exacerbations of asthma requiring a hospital admission or Emergency Room visit within the previous year while on systemic corticosteroids; OR
 - One (1) or more severe exacerbations of asthma requiring a hospital admission or Emergency Room visit requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least three (3) days, or parenteral corticosteroids); OR
 - Three (3) or more severe exacerbations of asthma within the previous year which required a physician visit and resulted in courses (or chronic use greater than 50% of the year), or increased dose of systemic corticosteroids.

Initial coverage may be approved for twenty-eight (28) weeks of up to 375 mg administered every 2 weeks based on the recommended dose and dosage adjustment outlined in the Health

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

OMALIZUMAB

Canada approved Product Monograph.

CONTINUED MAINTENANCE TREATMENT:

A patient must be assessed for response to initial coverage of omalizumab with a minimum of twenty-four (24) weeks of therapy with omalizumab, and this assessment must be submitted to Alberta Blue Cross no later than four (4) weeks from the date of assessment.

The assessment must be done by a respirologist or clinical immunologist or allergist or such other clinicians as the Minister may designate. If the following criteria are met, special authorization may be granted for a further twelve (12) month period. Continued coverage may be considered if the following criteria are met at the end of each additional twelve (12) month period:

- 1) Demonstrated that the patient has an Improvement in FEV1 greater than 12% (and for adults a minimum greater than 200 mL) from initiation of therapy; OR
Unchanged FEV1 with a clinically meaningful Improvement in Asthma Quality of Life Questionnaire score from baseline (greater than/equal to 0.5 mean from baseline); AND
- a decrease in the ACQ-5 of at least 0.5; OR
- a ACQ-5 score of less than/equal to 1.
- 2) Patients must demonstrate at least a 25% reduction in the number of exacerbations, which required oral corticosteroids from the twelve (12) months prior to initiation of omalizumab that required systemic corticosteroids; OR
For patients that were on chronic (greater than 50% of the year) courses of oral corticosteroids in the twelve (12) months prior to initiation of omalizumab, tapering of oral corticosteroid use by at least 25% from baseline.
- 3) A reduction in the number of exacerbations that have led to a hospital admission or emergency room visits, compared to the twelve (12) months prior to the commencement of omalizumab."

All requests (including renewal requests) for omalizumab for Asthma must be completed using the Omalizumab for Asthma Special Authorization Request Form (ABC 60020).

Chronic Idiopathic Urticaria

"For the treatment of adults and adolescents (12 years of age and above) with moderate to severe chronic idiopathic urticaria (CIU), defined as having a baseline Urticaria Activity Score over 7 days (UAS7) of greater than or equal to 16, who remain symptomatic (presence of hives and/or associated itching) despite optimum management with available oral therapies. Oral therapies should include a therapeutic trial with H1 antihistamines, unless contraindicated or not tolerated.

For coverage, the drug must be initiated and monitored by a Specialist in Dermatology, Clinical Immunology or Allergy.

Coverage may be approved for a period of 24 weeks at a maximum dose of 300 mg every 4 weeks.

Patients will be limited to receiving a one-month supply of omalizumab per prescription at their pharmacy.

Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

Continued coverage of a further 24-week treatment period may be considered if the patient has experienced:

- complete symptom control (i.e., UAS7 of 0) for less than 12 consecutive weeks; OR
- partial symptom control, with a reduction in baseline UAS7 of greater than or equal to 9.5 points.

ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

OMALIZUMAB

Treatment cessation should be considered for patients who experience complete symptom control for at least 12 consecutive weeks at the end of a 24-week treatment period.

In patients where treatment is discontinued due to temporary symptom control, treatment re-initiation should be considered should CIU symptoms reappear."

All requests (including renewal requests) for omalizumab for Chronic Idiopathic Urticaria must be completed using the Omalizumab for Chronic Idiopathic Urticaria Special Authorization Request Form (ABC 60056).

150 MG / VIAL INJECTION

00002260565 XOLAIR

NOV

\$ 643.4100

ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

PALIPERIDONE PALMITATE

"For the management of the manifestations of schizophrenia in patients who demonstrate a pattern of significant non-compliance that compromises therapeutic success and who possess clinical evidence of previous successful treatment with risperidone or paliperidone therapy;

AND who meet at least one of the following criteria:

- Experiences extra-pyramidal symptoms with either an oral or depot first generation antipsychotic agent that precludes the use of a first generation antipsychotic depot product; OR

- Is refractory to trials of at least two other antipsychotic therapies.

Special Authorization may be granted for six months."

All requests (including renewal requests) for paliperidone prolonged release injection must be completed using the Aripiprazole/Paliperidone/Risperidone Prolonged Release Injection Special Authorization Request Form (ABC 60024).

The following product(s) are eligible for auto-renewal.

50 MG / SYR (BASE)	INJECTION SYRINGE			
00002354217	INVEGA SUSTENNA (0.5 ML SYR)	JAI	\$	311.4300

"For the management of the manifestations of schizophrenia in patients who demonstrate a pattern of significant non-compliance that compromises therapeutic success and who possess clinical evidence of previous successful treatment with risperidone or paliperidone therapy;

AND who meet at least one of the following criteria:

- Experiences extra-pyramidal symptoms with either an oral or depot first generation antipsychotic agent that precludes the use of a first generation antipsychotic depot product; OR

- Is refractory to trials of at least two other antipsychotic therapies.

Special Authorization may be granted for six months."

All requests (including renewal requests) for paliperidone prolonged release injection must be completed using the Aripiprazole/Paliperidone/Risperidone Prolonged Release Injection Special Authorization Request Form (ABC 60024).

The following product(s) are eligible for auto-renewal.

75 MG / SYR (BASE)	INJECTION SYRINGE			
00002354225	INVEGA SUSTENNA (0.75 ML SYR)	JAI	\$	467.1800

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

PALIPERIDONE PALMITATE

"For the management of the manifestations of schizophrenia in patients who demonstrate a pattern of significant non-compliance that compromises therapeutic success and who possess clinical evidence of previous successful treatment with risperidone or paliperidone therapy;

AND who meet at least one of the following criteria:

- Experiences extra-pyramidal symptoms with either an oral or depot first generation antipsychotic agent that precludes the use of a first generation antipsychotic depot product; OR

- Is refractory to trials of at least two other antipsychotic therapies.

Special Authorization may be granted for six months."

All requests (including renewal requests) for paliperidone prolonged release injection must be completed using the Aripiprazole/Paliperidone/Risperidone Prolonged Release Injection Special Authorization Request Form (ABC 60024).

The following product(s) are eligible for auto-renewal.

100 MG / SYR (BASE)	INJECTION SYRINGE			
00002354233	INVEGA SUSTENNA (1 ML SYR)	JAI	\$	467.1800

"For the management of the manifestations of schizophrenia in patients who demonstrate a pattern of significant non-compliance that compromises therapeutic success and who possess clinical evidence of previous successful treatment with risperidone or paliperidone therapy;

AND who meet at least one of the following criteria:

- Experiences extra-pyramidal symptoms with either an oral or depot first generation antipsychotic agent that precludes the use of a first generation antipsychotic depot product; OR

- Is refractory to trials of at least two other antipsychotic therapies.

Special Authorization may be granted for six months."

All requests (including renewal requests) for paliperidone prolonged release injection must be completed using the Aripiprazole/Paliperidone/Risperidone Prolonged Release Injection Special Authorization Request Form (ABC 60024).

The following product(s) are eligible for auto-renewal.

150 MG / SYR (BASE)	INJECTION SYRINGE			
00002354241	INVEGA SUSTENNA (1.5 ML SYR)	JAI	\$	622.8900

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

PALIPERIDONE PALMITATE

"For the management of the manifestations of schizophrenia in patients who demonstrate a pattern of significant non-compliance that compromises therapeutic success and who possess clinical evidence of previous successful treatment with risperidone or paliperidone therapy;

AND who meet at least one of the following criteria:

- Experiences extra-pyramidal symptoms with either an oral or depot first generation antipsychotic agent that precludes the use of a first generation antipsychotic depot product; OR

- Is refractory to trials of at least two other antipsychotic therapies.

To be considered for coverage of Invega Trinza, patients must have been maintained on Invega Sustenna for at least four months. The last two doses of Invega Sustenna should be the same dosage strength and dosing interval, before initiating Invega Trinza.

Special Authorization may be granted for six months."

All requests (including renewal requests) for paliperidone prolonged release injection must be completed using the Aripiprazole/Paliperidone/Risperidone Prolonged Release Injection Special Authorization Request Form (ABC 60024).

The following product(s) are eligible for auto-renewal.

175 MG / SYR (BASE)	INJECTION SYRINGE		
00002455943	INVEGA TRINZA (0.875 ML SYR)	JAI	\$ 934.2900

"For the management of the manifestations of schizophrenia in patients who demonstrate a pattern of significant non-compliance that compromises therapeutic success and who possess clinical evidence of previous successful treatment with risperidone or paliperidone therapy;

AND who meet at least one of the following criteria:

- Experiences extra-pyramidal symptoms with either an oral or depot first generation antipsychotic agent that precludes the use of a first generation antipsychotic depot product; OR

- Is refractory to trials of at least two other antipsychotic therapies.

To be considered for coverage of Invega Trinza, patients must have been maintained on Invega Sustenna for at least four months. The last two doses of Invega Sustenna should be the same dosage strength and dosing interval, before initiating Invega Trinza.

Special Authorization may be granted for six months."

All requests (including renewal requests) for paliperidone prolonged release injection must be completed using the Aripiprazole/Paliperidone/Risperidone Prolonged Release Injection Special Authorization Request Form (ABC 60024).

The following product(s) are eligible for auto-renewal.

263 MG / SYR (BASE)	INJECTION SYRINGE		
00002455986	INVEGA TRINZA (1.315 ML SYR)	JAI	\$ 1401.5400

ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

PALIPERIDONE PALMITATE

"For the management of the manifestations of schizophrenia in patients who demonstrate a pattern of significant non-compliance that compromises therapeutic success and who possess clinical evidence of previous successful treatment with risperidone or paliperidone therapy;

AND who meet at least one of the following criteria:

- Experiences extra-pyramidal symptoms with either an oral or depot first generation antipsychotic agent that precludes the use of a first generation antipsychotic depot product; OR

- Is refractory to trials of at least two other antipsychotic therapies.

To be considered for coverage of Invega Trinza, patients must have been maintained on Invega Sustenna for at least four months. The last two doses of Invega Sustenna should be the same dosage strength and dosing interval, before initiating Invega Trinza.

Special Authorization may be granted for six months."

All requests (including renewal requests) for paliperidone prolonged release injection must be completed using the Aripiprazole/Paliperidone/Risperidone Prolonged Release Injection Special Authorization Request Form (ABC 60024).

The following product(s) are eligible for auto-renewal.

350 MG / SYR (BASE)	INJECTION SYRINGE		
00002455994	INVEGA TRINZA (1.75 ML SYR)	JAI	\$ 1401.5400

"For the management of the manifestations of schizophrenia in patients who demonstrate a pattern of significant non-compliance that compromises therapeutic success and who possess clinical evidence of previous successful treatment with risperidone or paliperidone therapy;

AND who meet at least one of the following criteria:

- Experiences extra-pyramidal symptoms with either an oral or depot first generation antipsychotic agent that precludes the use of a first generation antipsychotic depot product; OR

- Is refractory to trials of at least two other antipsychotic therapies.

To be considered for coverage of Invega Trinza, patients must have been maintained on Invega Sustenna for at least four months. The last two doses of Invega Sustenna should be the same dosage strength and dosing interval, before initiating Invega Trinza.

Special Authorization may be granted for six months."

All requests (including renewal requests) for paliperidone prolonged release injection must be completed using the Aripiprazole/Paliperidone/Risperidone Prolonged Release Injection Special Authorization Request Form (ABC 60024).

The following product(s) are eligible for auto-renewal.

525 MG / SYR (BASE)	INJECTION SYRINGE		
00002456001	INVEGA TRINZA (2.625 ML SYR)	JAI	\$ 1868.6700

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

PEGFILGRASTIM

Effective March 1, 2020, all Special Authorization requests for pegfilgrastim will be assessed for coverage with Fulphila or Lapelga. Neulasta will not be approved for new pegfilgrastim starts or repeat treatments (e.g., new course of chemotherapy).

"In patients with non-myeloid malignancies, receiving myelosuppressive anti-neoplastic drugs with curative intent, to decrease the incidence of infection, as manifested by febrile neutropenia."

All requests for pegfilgrastim must be completed using the Filgrastim/Pegfilgrastim/Plerixafor Special Authorization Request Form (ABC 60013).

Please note: Coverage cannot be considered for palliative patients.

6 MG / SYR INJECTION SYRINGE

<input checked="" type="checkbox"/> 00002484153	FULPHILA (0.6 ML SYRINGE)	BGP	\$ 1600.0000
<input checked="" type="checkbox"/> 00002474565	LAPELGA (0.6 ML SYRINGE)	APX	\$ 1878.7300
<input checked="" type="checkbox"/> 00002249790	NEULASTA (0.6 ML SYRINGE)	AMG	\$ 2555.0600

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

PEGINTERFERON ALFA-2A

****The Special Authorization Criteria outlined below remain part of the Alberta Drug Benefit List to enable patients who initiated therapy with Pegasys for Chronic Hepatitis C prior to December 31, 2017 to complete their course of treatment. No new patients will be approved to initiate Pegasys therapy for the treatment of Chronic Hepatitis C after January 2, 2018.****

(Refer to 08:18.20 of the Alberta Drug Benefit List for coverage of peginterferon alfa-2a for the treatment of Chronic Hepatitis B.)

Chronic Hepatitis C

"For the treatment of chronic hepatitis C in adult patients with evidence of active liver disease, who qualify for treatment with Pegasys RBV (peginterferon alfa-2a/ribavirin) but who are intolerant to ribavirin.

All Chronic Hepatitis C Patients Prior to Initiation of Therapy:

- To determine treatment duration and prognosis, HCV genotype testing is required for all patients.
- At least three weeks before anticipated start date of therapy, please submit to Alberta Blue Cross a Peginterferon Alfa-2a for Chronic Hepatitis C Special Authorization Request Form (ABC 60045), along with appropriate lab results. In order to meet the requirements of provincial privacy legislation, the patient's signature must be affixed to each completed form.

All Chronic Hepatitis C Patients (with the Exception of Advanced Fibrosis or Cirrhosis Patients):

Prior to initiation of therapy:

- Patients must have a baseline serum sample stored for future viral load testing in the event that the week 12 HCV RNA test is positive.

Initial Alberta Blue Cross approval periods (for patients meeting criteria):

- Patients may receive an initial approval for 14 weeks of coverage.

At 12 weeks of treatment:

- HCV RNA testing is required for all patients at the 12th week of treatment.
- If the HCV RNA test is positive, viral load testing is required on the previously stored baseline serum sample, and the 12 week serum sample, for evaluation of continued coverage.

Renewal approval period (for patients meeting criteria):

- Patients who respond to therapy, as measured by a reduction of viral load by at least 2 logs (100 fold) or HCV RNA not detected at 12 weeks, may be approved for an additional 34 weeks of coverage (total 48 weeks).

All Chronic Hepatitis C Patients with Advanced Fibrosis or Cirrhosis:

Initial Alberta Blue Cross approval periods (for patients meeting criteria):

- Patients with advanced fibrosis or cirrhosis may receive approval for 48 weeks of coverage.

Consideration for therapy in chronic hepatitis C patients who have previously received therapy:

- Consideration for therapy in patients who have previously received therapy may be given for patients who meet at least one of the following criteria:

ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

PEGINTERFERON ALFA-2A

- Advanced fibrosis or cirrhosis.
- Patients who have relapsed following non-pegylated interferon/ribavarin combination therapy."

In order to comply with this criterion: Confirmation of the diagnosis of chronic hepatitis C and presence of active liver disease is required. Information must include the patient's pre-treatment serum HCV RNA (by PCR) status. Information is also required regarding whether liver enzymes (ALT/AST) are elevated, or the results of a liver biopsy, or the results of transient elastography. All requests for peginterferon alfa-2a for Chronic Hepatitis C must be completed using the Peginterferon Alfa-2a for Chronic Hepatitis C Special Authorization Request Form (ABC 60045). In order to meet the requirements of provincial privacy legislation, the patient's signature must be affixed to each completed form.

180 MCG / SYR INJECTION SYRINGE

00002248077	PEGASYS (0.5 ML SYRINGE)	HLR	\$	419.7000
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**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

PEGINTERFERON BETA-1A

"Special authorization coverage may be provided for the reduction of the frequency and severity of clinical relapses and reduction of the number and volume of active brain lesions, identified on MRI scans, in ambulatory patients with relapsing remitting multiple sclerosis.

Coverage

For coverage, this drug must be prescribed by a registered MS Neurologist. A current assessment must be completed by a registered MS Neurologist at every request.

To register to become an MS Neurologist please complete the Registration for MS Neurologist Status Form (ABC 60002).

Initial Coverage

- 1) The registered MS Neurologist must confirm a diagnosis of RRMS;
- 2) The patient must have active disease which is defined as at least two relapses* of MS during the previous two years or in the two years prior to starting an MS disease modifying therapy (DMT).

*A relapse is defined as the appearance of new symptoms or worsening of old symptoms, lasting at least 48 hours in the absence of fever, not associated with withdrawal from steroids. Onset of clinical relapses must be separated by a period of at least one month. At least one definite gadolinium-enhancing T1 MRI lesion (not questionable faint enhancement) obtained at least 90 days after initiation of the DMT and at least 90 days before or after a relapse may substitute for one clinical relapse.

- 3) The patient must be ambulatory with or without aid (The registered MS Neurologist must provide a current updated Expanded Disability Status Scale (EDSS) score less than or equal to 6.5).

Coverage may be approved for up to 12 months. Patients will be limited to receiving a one-month supply of peg-interferon beta-1a per prescription at their pharmacy for the first 12 months of coverage.

Continued Coverage

For continued coverage beyond the initial coverage period, the patient must meet the following criteria:

- 1) The patient must be assessed by a registered MS Neurologist;
- 2) The registered MS Neurologist must confirm a diagnosis of RRMS;
- 3) The registered MS Neurologist must provide a current updated EDSS score. The patient must not have an EDSS score of 7.0 or above sustained for one year or more.

Coverage of this drug may be considered in a patient with a sustained EDSS score of 7.0 or above in exceptional circumstances. For MS DMT coverage to be considered, details of the exceptional circumstance must be provided in a letter from the registered MS Neurologist and accompany the Special Authorization Request Form.

Continued coverage may be approved for up to 12 months. Patients may receive up to 100 days' supply of peg-interferon beta-1a per prescription at their pharmacy.

Restarting After an Interruption in Therapy Greater Than 12 Months

In order to be eligible for coverage, after an interruption in therapy greater than 12 months, the patient must meet the following criteria:

- 1) At least one relapse* per 12 month period; or
- 2) At least two relapses* during the previous 24 month period."

All requests (including renewal requests) for interferon beta-1b must be completed using the

ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

PEGINTERFERON BETA-1A

Dimethyl Fumarate/Glatiramer Acetate/Interferon Beta-1a/Ocrelizumab/Peginterferon Beta-1a/Teriflunomide for RRMS/Interferon Beta-1b for SPMS or RRMS Special Authorization Request Form (ABC 60001).

125 MCG / SYR INJECTION SYRINGE

00002444399 PLEGRIDY

BIO

\$ 885.8010

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

PEGINTERFERON BETA-1A/ PEGINTERFERON BETA-1A

"Special authorization coverage may be provided for the reduction of the frequency and severity of clinical relapses and reduction of the number and volume of active brain lesions, identified on MRI scans, in ambulatory patients with relapsing remitting multiple sclerosis.

Coverage

For coverage, this drug must be prescribed by a registered MS Neurologist. A current assessment must be completed by a registered MS Neurologist at every request.

To register to become an MS Neurologist please complete the Registration for MS Neurologist Status Form (ABC 60002).

Initial Coverage

- 1) The registered MS Neurologist must confirm a diagnosis of RRMS;
- 2) The patient must have active disease which is defined as at least two relapses* of MS during the previous two years or in the two years prior to starting an MS disease modifying therapy (DMT).

*A relapse is defined as the appearance of new symptoms or worsening of old symptoms, lasting at least 48 hours in the absence of fever, not associated with withdrawal from steroids. Onset of clinical relapses must be separated by a period of at least one month. At least one definite gadolinium-enhancing T1 MRI lesion (not questionable faint enhancement) obtained at least 90 days after initiation of the DMT and at least 90 days before or after a relapse may substitute for one clinical relapse.

- 3) The patient must be ambulatory with or without aid (The registered MS Neurologist must provide a current updated Expanded Disability Status Scale (EDSS) score less than or equal to 6.5).

Coverage may be approved for up to 12 months. Patients will be limited to receiving a one-month supply of peg-interferon beta-1a per prescription at their pharmacy for the first 12 months of coverage.

Continued Coverage

For continued coverage beyond the initial coverage period, the patient must meet the following criteria:

- 1) The patient must be assessed by a registered MS Neurologist;
- 2) The registered MS Neurologist must confirm a diagnosis of RRMS;
- 3) The registered MS Neurologist must provide a current updated EDSS score. The patient must not have an EDSS score of 7.0 or above sustained for one year or more.

Coverage of this drug may be considered in a patient with a sustained EDSS score of 7.0 or above in exceptional circumstances. For MS DMT coverage to be considered, details of the exceptional circumstance must be provided in a letter from the registered MS Neurologist and accompany the Special Authorization Request Form.

Continued coverage may be approved for up to 12 months. Patients may receive up to 100 days' supply of peg-interferon beta-1a per prescription at their pharmacy.

Restarting After an Interruption in Therapy Greater Than 12 Months

In order to be eligible for coverage, after an interruption in therapy greater than 12 months, the patient must meet the following criteria:

- 1) At least one relapse* per 12 month period; or

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

PEGINTERFERON BETA-1A/ PEGINTERFERON BETA-1A

2) At least two relapses* during the previous 24 month period."

All requests (including renewal requests) for interferon beta-1b must be completed using the Dimethyl Fumarate/Glatiramer Acetate/Interferon Beta-1a/Ocrelizumab/Peginterferon Beta-1a/Teriflunomide for RRMS/Interferon Beta-1b for SPMS or RRMS Special Authorization Request Form (ABC 60001).

63 MCG / SYR * 94 MCG / SYR INJECTION SYRINGE			
00002444402	PLEGRIDY	BIO	\$ 885.8010

PERAMPANEL

"For adjunctive therapy in patients with refractory partial-onset seizures or primary generalized tonic-clonic (PGTC) seizures who meet all of the following criteria:

- Are currently receiving two or more antiepileptic medications, AND
- Have failed or demonstrated intolerance to three other antiepileptic medications, AND
- Therapy must be initiated by a Neurologist.

For the purpose of administering these criteria failure is defined as inability to achieve satisfactory seizure control.

Special authorization may be granted for six months.

Coverage cannot be provided for brivaracetam, eslicarbazepine, lacosamide or perampanel when these medications are intended for use in combination.

Each of these products are eligible for auto-renewal"

2 MG ORAL TABLET			
00002404516	FYCOMPA	EIS	\$ 9.7807
4 MG ORAL TABLET			
00002404524	FYCOMPA	EIS	\$ 9.7807
6 MG ORAL TABLET			
00002404532	FYCOMPA	EIS	\$ 9.7807
8 MG ORAL TABLET			
00002404540	FYCOMPA	EIS	\$ 9.7807
10 MG ORAL TABLET			
00002404559	FYCOMPA	EIS	\$ 9.7807
12 MG ORAL TABLET			
00002404567	FYCOMPA	EIS	\$ 9.7807

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

PIBRENTASVIR/ GLECAPREVIR

"For treatment-naïve or treatment-experienced (1) adult patients with chronic hepatitis C infection who

meet all of the following criteria:

I) Prescribed by or in consultation with a hepatologist, gastroenterologist or infectious disease specialist

(except on a case-by-case basis, in geographic areas where access to these specialties is not available);

AND

II) Laboratory confirmed hepatitis C genotype (2) 1, 2, 3, 4, 5, 6;

AND

III) Laboratory confirmed quantitative HCV RNA value within the last 6 months:

AND

IV) Fibrosis (3) stage of F0 or greater (Metavir scale or equivalent).

Duration of therapy reimbursed:

- Treatment-naïve, without cirrhosis: 8 weeks

- Treatment-naïve, with compensated cirrhosis (4): 12 weeks

- Treatment-experienced (1) genotype 1, 2, 4, 5, or 6, without cirrhosis: 8 weeks

- Treatment-experienced (1) genotype 1, 2, 4, 5, or 6, with compensated cirrhosis (4): 12 weeks

- NS3/4A protease inhibitor treatment-experienced (5) genotype 1, without cirrhosis or with compensated cirrhosis (4): 12 weeks

- NS5A inhibitor treatment-experienced (6) genotype 1, without cirrhosis or with compensated cirrhosis (4): 16 weeks

- Treatment-experienced (1) genotype 3, without cirrhosis or with compensated cirrhosis (4): 16 weeks

Exclusion criteria:

- Patients currently being treated with another HCV antiviral agent

Notes:

1. Treatment experienced is defined as those who have previously been treated with a regimen containing interferon, peginterferon (P), ribavirin (R), and/or sofosbuvir (e.g. PR, SOF + PR, SOF + R),

but have no prior treatment experience with an NS3/4A protease inhibitor or NS5A inhibitor.

2. HCV genotype testing is optional for treatment naïve patients.

3. Fibrosis score test is optional. Acceptable methods include liver biopsy, transient elastography

(FibroScan), fibrotest and serum biomarker panels (such as AST-to-Platelet Ratio Index or Fibrosis-4 score) either alone or in combination.

4. Compensated cirrhosis is defined as cirrhosis with Child-Turcotte-Pugh A (i.e. score 5 to 6).

5. NS3/4A protease inhibitor treatment-experienced is defined as those who have previously been treated with a regimen containing a non-structural protein 3/4A (NS3/4A) protease inhibitor, but without an NS5A inhibitor.

6. NS5A inhibitor treatment-experienced is defined as those who have previously been treated with a regimen containing an NS5A inhibitor, but without an NS3/4A protease inhibitor, such as daclatasavir + sofosbuvir, ledipasvir/sofosbuvir, or sofosbuvir/velpatasvir.

7. Health care professionals are advised to refer to the product monograph and prescribing guidelines for appropriate use of the drug product, including use in special populations."

All requests for glecaprevir/pibrentasvir must be completed using the Antivirals for Chronic Hepatitis C Special Authorization Request Form (ABC 60022).

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

PIBRENTASVIR/ GLECAPREVIR

40 MG * 100 MG ORAL TABLET

00002467550 MAVIRET

ABV

\$ 238.0952

PIPERACILLIN SODIUM/ TAZOBACTAM SODIUM

(Refer to Section 1 - Restricted Benefits of the Alberta Drug Benefit List for coverage of the product when prescribed by a Specialist in Infectious Diseases or Hematology, or a designated prescriber.)

"For the treatment of:

- 1) Second-line therapy of intra-abdominal sepsis where there are serious adverse events due to first-line therapy or documented failure of first-line therapy (e.g. ampicillin + gentamicin + metronidazole), as defined by clinical deterioration after 72 h of antibiotic therapy or lack of improvement after completion of antibiotic therapy or
- 2) Second-line therapy of severe polymicrobial skin and skin structure infections (e.g. limb threatening diabetic foot) or
- 3) Therapy of severe ventilator-associated pneumonia where Pseudomonas and Staphylococcus aureus coverage is needed, or
- 4) Therapy for infections involving multi-resistant Pseudomonas aeruginosa from pulmonary secretions in cystic fibrosis patients, lung transplant patients or patients with bronchiectasis , where there is documented susceptibility to piperacillin/tazobactam sodium, or
- 5) For use in other Health Canada approved indications, in consultation with a specialist in Infectious Diseases."*

*Special Authorization is only required when the prescriber prescribing the medication is not a Specialist in Infectious Diseases or Hematology, or a designated prescriber.

In order to comply with all of the above criteria, information is required regarding the type of infection and organisms involved. Also, where the criteria restrict coverage of the requested drug to non-first line therapy, information is required regarding previous first-line antibiotic therapy that has been utilized, the patient's response to therapy, and the first line agents the organism is resistant to or why other first-line therapies cannot be used in this patient. Also, where applicable, the specialist in Infectious Diseases that recommended this drug is required.

2 G / VIAL (BASE) * 250 MG / VIAL (BASE)	INJECTION			
00002308444	PIPERACILLIN AND TAZOBACTAM	APX	\$	4.1727
00002362619	PIPERACILLIN AND TAZOBACTAM	STM	\$	4.1727
00002401312	PIPERACILLIN AND TAZOBACTAM	TGT	\$	4.1727
00002299623	PIPERACILLIN SODIUM/TAZOBACTAM SODIUM	SDZ	\$	4.1727
3 G / VIAL (BASE) * 375 MG / VIAL (BASE)	INJECTION			
00002308452	PIPERACILLIN AND TAZOBACTAM	APX	\$	6.2591
00002362627	PIPERACILLIN AND TAZOBACTAM	STM	\$	6.2591
00002401320	PIPERACILLIN AND TAZOBACTAM	TGT	\$	6.2591
00002299631	PIPERACILLIN SODIUM/TAZOBACTAM SODIUM	SDZ	\$	6.2591
00002370166	PIPERACILLIN/TAZOBACTAM	TEV	\$	6.2591
4 G / VIAL (BASE) * 500 MG / VIAL (BASE)	INJECTION			
00002308460	PIPERACILLIN AND TAZOBACTAM	APX	\$	8.3458
00002362635	PIPERACILLIN AND TAZOBACTAM	STM	\$	8.3458
00002401339	PIPERACILLIN AND TAZOBACTAM	TGT	\$	8.3458
00002299658	PIPERACILLIN SODIUM/TAZOBACTAM SODIUM	SDZ	\$	8.3458
00002370174	PIPERACILLIN/TAZOBACTAM	TEV	\$	8.3458

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

PIRFENIDONE

"Initial approval criteria:

Adult patients with a diagnosis of mild to moderate idiopathic pulmonary fibrosis (IPF):

- Diagnosis confirmed by a respirologist and a high-resolution CT scan within the previous 24 months.
- All other causes of restrictive lung disease (e.g. collagen vascular disorder or hypersensitivity pneumonitis) should be excluded.
- Mild to moderate IPF is defined as forced vital capacity (FVC) greater than or equal to 50% of predicted.
- Patient is under the care of a physician with experience in IPF.

Initial approval period: 7 months (allow 4 weeks for repeat pulmonary function tests)

Initial renewal criteria (at 6 months):

Patients must NOT demonstrate progression of disease defined as an absolute decline in percent predicted FVC of greater than or equal to 10% from initiation of therapy until renewal (initial 6 month treatment period). If a patient has experienced progression as defined above, then the results should be validated with a confirmatory pulmonary function test conducted 4 weeks later.

Approval period: 6 months

Second and subsequent renewals (at 12 months and thereafter):

Patients must NOT demonstrate progression of disease defined as an absolute decline in percent predicted FVC of greater than or equal to 10% within any 12 month period. If a patient has experienced progression as defined above, then the results should be validated with a confirmatory pulmonary function test conducted 4 weeks later.

Approval period: 12 months

Exclusion Criteria:

Combination use of pirfenidone and nintedanib will not be funded.

Notes:

Patients who have experienced intolerance or failure to pirfenidone or nintedanib will be considered for the alternate agent provided that the patient continues to meet the above coverage criteria."

All requests for pirfenidone must be completed using the Nintedanib/Pirfenidone Special Authorization Request Form (ABC 60051).

267 MG ORAL TABLET			
00002464489	ESBRIET	HLR	\$ 13.4240
801 MG ORAL TABLET			
00002464500	ESBRIET	HLR	\$ 40.2720
267 MG ORAL CAPSULE			
00002393751	ESBRIET	HLR	\$ 13.6251

ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

PLERIXAFOR

"For the treatment of patients with Non-Hodgkin's lymphoma (NHL) or multiple myeloma (MM) undergoing Peripheral Blood Progenitor Cell (PBPC) collection and therapy, in combination with filgrastim, when prescribed by a designated prescriber."

Coverage may be approved for a maximum of 4 doses (0.24mg/kg given daily) for a single mobilization attempt.

All requests for Plerixafor must be completed using the Filgrastim/Pegfilgrastim/Plerixafor Special Authorization Request Form (ABC 60013).

Special authorization may be granted for 12 months.

20 MG / VIAL INJECTION			
00002377225	MOZOBIL	SAV	\$ 7555.0000

PROPRANOLOL HCL

"For the treatment of proliferating infantile hemangioma requiring systemic therapy and at least one of the following:

- Life- or function-threatening hemangioma, OR
- Ulcerated hemangioma with pain and/or lack of response to simple wound care measures, OR
- Hemangioma with a risk of permanent scarring or disfigurement.

Special authorization may be granted for 12 months.

Continued coverage may be approved for a period of 12 months for patients who are responding to therapy or experience relapse of symptoms after treatment discontinuation."

3.75 MG / ML ORAL SOLUTION			
00002457857	HEMANGIOL	PIE	\$ 2.2808

QUINAGOLIDE

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

FIRST-LINE DRUG PRODUCT(S): BROMOCRIPTINE

"For the treatment of hyperprolactinemia in patients who are intolerant to or who have failed bromocriptine. Special authorization may be granted for 24 months."

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

UP - First-line therapy ineffective
UQ - First-line therapy not tolerated

0.075 MG ORAL TABLET			
00002223767	NORPROLAC	FEI	\$ 1.1485
0.15 MG ORAL TABLET			
00002223775	NORPROLAC	FEI	\$ 1.7177

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

RALOXIFENE HCL

Osteoporosis:

"For the treatment of osteoporosis in patients with a 20% or greater 10-year fracture risk who have documented intolerance to alendronate 70 mg or risedronate 35 mg. Special authorization may be granted for 6 months."

"Requests for other osteoporosis medications covered via special authorization will not be considered until 6 months after the last dose of denosumab 60 mg/syr injection syringe."

"Requests for other osteoporosis medications covered via special authorization will not be considered until 12 months after the last dose of zoledronic acid 0.05 mg/ml injection."

Note: The fracture risk can be determined by the World Health Organization's fracture risk assessment tool, FRAX, or the most recent (2010) version of the Canadian Association of Radiologists and Osteoporosis Canada (CAROC) table.

All requests for raloxifene hydrochloride for Osteoporosis must be completed using the Alendronate/Raloxifene/Risedronate for Osteoporosis Special Authorization Request Form (ABC 60043).

The following product(s) are eligible for auto-renewal for the treatment of osteoporosis.

60 MG ORAL TABLET

00002358840	ACT RALOXIFENE	APH	\$	0.4583
00002279215	APO-RALOXIFENE	APX	\$	0.4583
00002239028	EVISTA	LIL	\$	1.9593

RIBAVIRIN

200 MG ORAL TABLET

00002439212	IBAVYR	PPH	\$	11.5373
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For use within an Alberta Drug Benefit List (ADBL) funded combination therapy regimen for the treatment of chronic hepatitis C according to specific eligibility criteria corresponding to the regimen in which it is being administered. Use of ribavirin outside of an ADBL hepatitis C funded regimen will not be reimbursed.

(Refer to Section 3 of the Alberta Drug Benefit List for specific eligibility criteria corresponding to the regimen in which ribavirin is being administered for the treatment of Chronic Hepatitis C.)

400 MG ORAL TABLET

00002425890	IBAVYR	PPH	\$	23.0746
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For use within an Alberta Drug Benefit List (ADBL) funded combination therapy regimen for the treatment of chronic hepatitis C according to specific eligibility criteria corresponding to the regimen in which it is being administered. Use of ribavirin outside of an ADBL hepatitis C funded regimen will not be reimbursed.

(Refer to Section 3 of the Alberta Drug Benefit List for specific eligibility criteria corresponding to the regimen in which ribavirin is being administered for the treatment of Chronic Hepatitis C.)

600 MG ORAL TABLET

00002425904	IBAVYR	PPH	\$	34.6119
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For use within an Alberta Drug Benefit List (ADBL) funded combination therapy regimen for the treatment of chronic hepatitis C according to specific eligibility criteria corresponding to the regimen in which it is being administered. Use of ribavirin outside of an ADBL hepatitis C funded regimen will not be reimbursed.

(Refer to Section 3 of the Alberta Drug Benefit List for specific eligibility criteria corresponding to the regimen in which ribavirin is being administered for the treatment of Chronic Hepatitis C.)

ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

RIFABUTIN

(Refer to Section 1 - Restricted Benefits of the Alberta Drug Benefit List for coverage of the product when prescribed by a Specialist in Infectious Diseases or a designated prescriber.)

"For susceptible infections when prescribed in consultation with a Specialist in Infectious Diseases.

Special authorization may be granted for 6 months."*

*Special Authorization is only required when the prescriber prescribing the medication is not a Specialist in Infectious Diseases or a designated prescriber.

The following product(s) are eligible for auto-renewal.

150 MG ORAL CAPSULE				
00002063786	MYCOBUTIN	PFI	\$	5.5288

RIFAXIMIN

"For reducing the risk of recurrent Hepatic Encephalopathy (HE) (i.e. 2 or more episodes), in patients with a diagnosis of cirrhosis of the liver or presence of portal hypertension. Patients must have tried lactulose and been unable to achieve adequate control of HE recurrence with lactulose alone. Rifaximin must be used in combination with a maximal tolerated dose of lactulose.

Special authorization may be granted for 6 months."

This product is eligible for auto-renewal.

550 MG ORAL TABLET				
00002410702	ZAXINE	SLX	\$	7.9968

RILUZOLE

"For use in patients who have probable or definite diagnosis of amyotrophic lateral sclerosis (ALS) as defined by World Federation of Neurology (WFN) criteria who have a vital capacity of >60% predicted and do not have a tracheostomy for invasive ventilation. This drug must be prescribed by a Specialist in Neurology."

"Patients who previously received Rilutek and were not eligible for the Phase IV study can also be considered for coverage if they meet the special authorization criteria."

"Coverage cannot be renewed once the patient has a tracheostomy for the purpose of invasive ventilation."

50 MG ORAL TABLET				
00002352583	APO-RILUZOLE	APX	\$	3.4361
00002390299	MYLAN-RILUZOLE	MYP	\$	3.4361
00002242763	RILUTEK	SAV	\$	10.0542

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

RISANKIZUMAB

Special authorization coverage may be provided for the reduction in signs and symptoms of severe, debilitating plaque psoriasis in patients who:

- Have a total PASI of 10 or more and a DLQI of more than 10, OR
- Who have significant involvement of the face, palms of the hands, soles of the feet or genital region; AND
- Who are refractory or intolerant to:
 - Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory, OR
 - Cyclosporine (6 weeks treatment); AND
 - Phototherapy (unless restricted by geographic location)

Patients who have a contraindication to either cyclosporine or methotrexate will be required to complete an adequate trial of the other pre-requisite medication prior to potential coverage being considered.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.

'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be prescribed by a Specialist in Dermatology ("Dermatology Specialist").

Initial coverage may be approved for three doses of 150 mg (two x 75 mg syringes) of risankizumab at weeks 0, 4 and 16.

- Patients will be limited to receiving one 150 mg dose of risankizumab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of the initial coverage period.
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond three doses, the patient must meet all of the following criteria:

1) The patient must be assessed by a Dermatology Specialist after the initial three doses to determine response.

2) The Dermatology Specialist must confirm, in writing, that the patient is a 'responder' that meets the following criteria:

- Greater than or equal to 75% reduction in PASI score, OR
- Greater than or equal to 50% reduction in PASI score AND improvement of greater than or

ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

RISANKIZUMAB

equal to 5 points in the DLQI.

Following this assessment, continued coverage may be considered for one 150 mg dose of risankizumab every 12 weeks for a period of 12 months. Ongoing coverage may be considered if the patient is re-assessed by a Dermatology Specialist every 12 months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above.

PASI and DLQI scores are required for all requests for Plaque Psoriasis including those requests for patients that have significant involvement of the face, palms, soles of feet or genital region.

All requests (including renewal requests) for risankizumab for Plaque Psoriasis must be completed using the Adalimumab/Etanercept/Infliximab/Ixekizumab/Risankizumab/Secukinumab/Ustekinumab for Plaque Psoriasis Special Authorization Request Form (ABC 60030).

75 MG / SYR INJECTION SYRINGE

00002487454 SKYRIZI

ABV

\$ 2467.5000

RISEDRONATE SODIUM

Osteoporosis:

"For the treatment of osteoporosis in patients with a 20% or greater 10-year fracture risk who have documented intolerance to alendronate 70 mg or risedronate 35 mg. Special authorization may be granted for 6 months."

"Requests for other osteoporosis medications covered via special authorization will not be considered until 6 months after the last dose of denosumab 60 mg/syr injection syringe."

"Requests for other osteoporosis medications covered via special authorization will not be considered until 12 months after the last dose of zoledronic acid 0.05 mg/ml injection."

Note: The fracture risk can be determined by the World Health Organization's fracture risk assessment tool, FRAX, or the most recent (2010) version of the Canadian Association of Radiologists and Osteoporosis Canada (CAROC) table.

All requests for risedronate for Osteoporosis must be completed using the Alendronate/Raloxifene/Risedronate for Osteoporosis Special Authorization Request Form (ABC 60043).

The following product(s) are eligible for auto-renewal for the treatment of osteoporosis.

Paget's Disease:

"For the treatment of Paget's disease. Special Authorization for this criteria may be granted to a maximum of 2 months. Renewal requests may be considered following an observation period of at least 2 months."

"Coverage cannot be provided for two or more medications used in the treatment of Paget's disease when these medications are intended for use in combination or when therapy with two or more medications overlap."

5 MG ORAL TABLET

00002298376 TEVA-RISEDRONATE

TEV

\$ 1.6729

30 MG ORAL TABLET

00002298384 TEVA-RISEDRONATE

TEV

\$ 10.8388

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

RISPERIDONE

"For the management of the manifestations of schizophrenia and related psychotic disorders in patients who demonstrate a pattern of significant non-compliance that compromises therapeutic success and who possess clinical evidence of previous successful treatment with risperidone or paliperidone therapy;

AND who meet at least one of the following criteria:

- Experiences extra-pyramidal symptoms with either an oral or depot first generation antipsychotic agent that precludes the use of a first generation antipsychotic depot product; OR
- Is refractory to trials of at least two other antipsychotic therapies.

Special Authorization may be granted for six months."

All requests (including renewal requests) for risperidone prolonged release injection must be completed using the Aripiprazole/Paliperidone/Risperidone Prolonged Release Injection Special Authorization Request Form (ABC 60024).

The following product(s) are eligible for auto-renewal.

25 MG / VIAL INJECTION

00002255707	RISPERDAL CONSTA	JAI	\$	169.5900
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37.5 MG / VIAL INJECTION

00002255723	RISPERDAL CONSTA	JAI	\$	254.3600
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50 MG / VIAL INJECTION

00002255758	RISPERDAL CONSTA	JAI	\$	339.1500
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**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

RITUXIMAB

Granulomatosis with Polyangiitis (GPA) or Microscopic Polyangiitis (MPA)

"For use in combination with glucocorticoids for the induction of remission of severely active granulomatosis with polyangiitis (GPA, also known as Wegener's granulomatosis) or microscopic polyangiitis (MPA) in adult patients who have:

- Severe active disease that is life- or organ-threatening. The organ(s) and how the organ(s) is (are) threatened must be specified; AND
- A positive serum assay for either proteinase 3-ANCA (anti-neutrophil cytoplasmic antibody) or myeloperoxidase-ANCA. A copy of the lab report must be provided; AND
- Cyclophosphamide cannot be used for ONE of the following reasons:
 - a) The patient has failed a minimum of six intravenous pulses of cyclophosphamide; OR
 - b) The patient has failed three months of oral cyclophosphamide therapy; OR
 - c) The patient has a severe intolerance or an allergy to cyclophosphamide; OR
 - d) Cyclophosphamide is contraindicated; OR
 - e) The patient has received a cumulative lifetime dose of at least 25 grams of cyclophosphamide.

- Coverage may be approved for a maximum of 375 mg per square metre of body surface area weekly for 4 weeks.
- Patients will be limited to receiving two doses of rituximab per prescription at their pharmacy.
- For relapse following a remission, coverage may be provided for patients who experience a flare of severe active disease that is life- or organ-threatening; or, who experience worsening symptoms in 2 or more organs even if not life-threatening. Note: For relapse following a rituximab-induced remission, additional coverage may be approved no sooner than 6 months after previous rituximab treatment."

All requests (including renewal requests) for Rituxan for Granulomatosis with Polyangiitis (GPA) or Microscopic Polyangiitis (MPA) must be completed using the Rituxan for Granulomatosis with Polyangiitis/Microscopic Polyangiitis Special Authorization Request Form (ABC 60018).

Rheumatoid Arthritis

"Special authorization coverage may be provided for use in combination with methotrexate for the reduction in signs and symptoms of severely active Rheumatoid Arthritis (RA) in adult patients (18 years of age or older) who are refractory or intolerant to:

at least FOUR of the following, where at least one of which must be a minimum 12-week trial of an anti-tumor necrosis factor therapy

- Actemra (tocilizumab)
- Brenzys (etanercept)
- Cimzia (certolizumab pegol)
- Erelzi (etanercept)
- Inflectra (infliximab)
- Kevzara (sarilumab)
- Orencia (abatacept)
- Renflexis (infliximab)
- Simponi (golimumab)
- Xeljanz (tofacitinib)

AND

- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- Methotrexate with other disease modifying anti-rheumatic agent(s) (minimum 4 month trial). [e.g., methotrexate with hydroxychloroquine or methotrexate with sulfasalazine]; AND
- Leflunomide (minimum 10 week trial at 20 mg daily).

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

RITUXIMAB

specified above.

'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for a dose of 1000 mg of rituximab administered at 0 and 2 weeks (total of 2 - 1000 mg doses).
- Patients will be limited to receiving one dose of rituximab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another (with the exception of anakinra) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients will not be permitted to switch from anakinra to other biologic agents except under exceptional circumstances.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For coverage for an additional two-dose course of therapy, the patient must meet the following criteria:

- 1) The patient must be assessed by an RA Specialist after each course of therapy, between 16 and 24 weeks after receiving the initial dose of each course of therapy, to determine response.
- 2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:

- An improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place] following the initial course of rituximab; AND
- An improvement of 0.22 in HAQ score [reported to two (2) decimal places] following the initial course of rituximab.

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above, AND

- 3) The patient must have residual disease or disease activity returning to a level above a DAS28 score of 2.6.

Subsequent courses of therapy cannot be considered prior to 24 weeks elapsing from the initial dose of the previous course of therapy."

All requests (including renewal requests) for rituximab for Rheumatoid Arthritis must be completed using the Rituximab for Rheumatoid Arthritis Special Authorization Request Form (ABC 60046).

10 MG / ML INJECTION

00002241927 RITUXAN

HLR

\$

48.2308

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

**RIVAROXABAN
NON-VALVULAR ATRIAL FIBRILLATION**

SPECIAL AUTHORIZATION (step therapy approval process)

FIRST-LINE DRUG PRODUCT(S): WARFARIN

Coverage

Members of Alberta Government Sponsored Drug Plans who are at-risk with non-valvular atrial fibrillation (AF) who require the Drug Products for the prevention of stroke and systemic embolism AND in whom one of the following is also present:

- Inadequate Anticoagulation following a Reasonable Trial on Warfarin; OR
- Anticoagulation with warfarin is contraindicated or not possible due to inability to regularly monitor via International Normalized Ratio (INR) testing (i.e. no access to INR testing services at a laboratory, clinic, pharmacy, and at home).

At-risk patients with atrial fibrillation are defined as those with a CHADS2 score of greater than or equal to 1. Although the ROCKET-AF trial included patients with higher CHADS2 scores (greater than or equal to 2), other landmark studies with the other newer oral anticoagulants demonstrated a therapeutic benefit in patients with a CHADS2 score of 1. Coverage may be considered for an antiplatelet regimen or oral anticoagulation for patients with a CHADS2 score of 1.

Exclusion from Coverage:

- Patients with impaired renal function (creatinine clearance or estimated glomerular filtration rate <30 mL/min) OR
- Greater than or equal to 75 years of age and without Documented Stable Renal Function; OR
- hemodynamically significant rheumatic valvular heart disease, especially mitral stenosis; OR
- prosthetic heart valves.

Definitions:

- Documented Stable Renal Function is defined as creatinine clearance or estimated glomerular filtration rate that is maintained for at least 3 months (i.e. 30-49 mL/min for 15 mg once daily dosing or greater than or equal to 50 mL/Min for 20 mg once daily dosing).
- Inadequate anticoagulation is defined as INR testing results that are outside the desired INR range for at least 35% of the tests during the monitoring period (i.e. adequate anticoagulation is defined as INR test results that are within the desired INR range for at least 65% of the tests during the monitoring period).
- Reasonable Trial on Warfarin is defined as at least 2 months of therapy.

OTHER CRITERIA:

- Since renal impairment can increase bleeding risk, renal function should be regularly monitored. Other factors that increase bleeding risk should also be assessed and monitored (see Drug Product monograph).
- Patients starting the Drug Product should have ready access to appropriate medical services to manage a major bleeding event.
- There is currently no data to support that the Drug Product provides adequate anticoagulation in patients with rheumatic valvular disease or those with prosthetic heart valves, so Drug Product is not recommended in these populations.

Special Authorization may be granted for 24 months.

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

RIVAROXABAN

UP - First-line therapy ineffective
UQ - First-line therapy not tolerated

VENOUS THROMBOEMBOLIC EVENTS

SPECIAL AUTHORIZATION

COVERAGE:

"For the treatment of deep vein thrombosis (DVT) or pulmonary embolism (PE).

OTHER CRITERIA:

The recommended dose of rivaroxaban for patients initiating DVT or PE treatment is 15 mg twice daily for 3 weeks, followed by 20 mg once daily.

Drug plan coverage for rivaroxaban is an alternative to heparin/warfarin for up to 6 months. When used for greater than 6 months, rivaroxaban is more costly than heparin/warfarin. As such, patients with an intended duration of therapy greater than 6 months should be considered for initiation on heparin/warfarin.

Special authorization may be granted for up to 6 months."

All requests for rivaroxaban must be completed using the Apixaban/Dabigatran/Edoxaban/Rivaroxaban Special Authorization Request Form (ABC 60019).

15 MG ORAL TABLET

00002378604	XARELTO	BAI	\$	2.8700
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**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

**RIVAROXABAN
NON-VALVULAR ATRIAL FIBRILLATION**

SPECIAL AUTHORIZATION (step therapy approval process)

FIRST-LINE DRUG PRODUCT(S): WARFARIN

Coverage

Members of Alberta Government Sponsored Drug Plans who are at-risk with non-valvular atrial fibrillation (AF) who require the Drug Products for the prevention of stroke and systemic embolism AND in whom one of the following is also present:

- Inadequate Anticoagulation following a Reasonable Trial on Warfarin; OR
- Anticoagulation with warfarin is contraindicated or not possible due to inability to regularly monitor via International Normalized Ratio (INR) testing (i.e. no access to INR testing services at a laboratory, clinic, pharmacy, and at home).

At-risk patients with atrial fibrillation are defined as those with a CHADS2 score of greater than or equal to 1. Although the ROCKET-AF trial included patients with higher CHADS2 scores (greater than or equal to 2), other landmark studies with the other newer oral anticoagulants demonstrated a therapeutic benefit in patients with a CHADS2 score of 1. Coverage may be considered for an antiplatelet regimen or oral anticoagulation for patients with a CHADS2 score of 1.

Exclusion from Coverage:

- Patients with impaired renal function (creatinine clearance or estimated glomerular filtration rate <30 mL/min) OR
- Greater than or equal to 75 years of age and without Documented Stable Renal Function; OR
- hemodynamically significant rheumatic valvular heart disease, especially mitral stenosis; OR
- prosthetic heart valves.

Definitions:

- Documented Stable Renal Function is defined as creatinine clearance or estimated glomerular filtration rate that is maintained for at least 3 months (i.e. 30-49 mL/min for 15 mg once daily dosing or greater than or equal to 50 mL/Min for 20 mg once daily dosing).
- Inadequate anticoagulation is defined as INR testing results that are outside the desired INR range for at least 35% of the tests during the monitoring period (i.e. adequate anticoagulation is defined as INR test results that are within the desired INR range for at least 65% of the tests during the monitoring period).
- Reasonable Trial on Warfarin is defined as at least 2 months of therapy.

OTHER CRITERIA:

- Since renal impairment can increase bleeding risk, renal function should be regularly monitored. Other factors that increase bleeding risk should also be assessed and monitored (see Drug Product monograph).
- Patients starting the Drug Product should have ready access to appropriate medical services to manage a major bleeding event.
- There is currently no data to support that the Drug Product provides adequate anticoagulation in patients with rheumatic valvular disease or those with prosthetic heart valves, so Drug Product is not recommended in these populations.

Special Authorization may be granted for 24 months.

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

RIVAROXABAN

UP - First-line therapy ineffective
UQ - First-line therapy not tolerated

VENOUS THROMBOEMBOLIC EVENTS

SPECIAL AUTHORIZATION

COVERAGE:

"For the treatment of deep vein thrombosis (DVT) or pulmonary embolism (PE).

OTHER CRITERIA:

The recommended dose of rivaroxaban for patients initiating DVT or PE treatment is 15 mg twice daily for 3 weeks, followed by 20 mg once daily.

Drug plan coverage for rivaroxaban is an alternative to heparin/warfarin for up to 6 months. When used for greater than 6 months, rivaroxaban is more costly than heparin/warfarin. As such, patients with an intended duration of therapy greater than 6 months should be considered for initiation on heparin/warfarin.

Special authorization may be granted for up to 6 months."

All requests for rivaroxaban must be completed using the Apixaban/Dabigatran/Edoxaban/Rivaroxaban Special Authorization Request Form (ABC 60019).

20 MG ORAL TABLET

00002378612	XARELTO	BAI	\$	2.8700
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**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

RIVASTIGMINE HYDROGEN TARTRATE

"For the treatment of Alzheimer's disease in patients with an MMSE (Mini Mental State Exam) score between 10-26 and/or an InterRAI-Cognitive Performance Scale score between 1-4.

Coverage cannot be provided for two or more medications used in the treatment of Alzheimer's disease (donepezil, galantamine, rivastigmine) when these medications are intended for use in combination.

Special authorization coverage may be granted for a maximum of 24 months per request.

For each request, an updated MMSE score or InterRAI-Cognitive Performance Scale score and the date on which the exam was administered must be provided.

Renewal requests may be considered for patients where the updated MMSE score is 10 or higher or the InterRAI-Cognitive Performance Scale is 4 or lower while on this drug."

All requests (including renewal requests) for rivastigmine hydrogen tartrate must be completed using the Donepezil/Galantamine/Rivastigmine Special Authorization Request Form (ABC 60034).

1.5 MG (BASE) ORAL CAPSULE

00002336715	APO-RIVASTIGMINE	APX	\$	0.6514
00002485362	JAMP RIVASTIGMINE	JPC	\$	0.6514
00002401614	MED-RIVASTIGMINE	GMP	\$	0.6514
00002324563	SANDOZ RIVASTIGMINE	SDZ	\$	0.6514
00002242115	EXELON	NOV	\$	2.8425

3 MG (BASE) ORAL CAPSULE

00002336723	APO-RIVASTIGMINE	APX	\$	0.6514
00002485370	JAMP RIVASTIGMINE	JPC	\$	0.6514
00002401622	MED-RIVASTIGMINE	GMP	\$	0.6514
00002324571	SANDOZ RIVASTIGMINE	SDZ	\$	0.6514
00002242116	EXELON	NOV	\$	2.8425

4.5 MG (BASE) ORAL CAPSULE

00002336731	APO-RIVASTIGMINE	APX	\$	0.6514
00002485389	JAMP RIVASTIGMINE	JPC	\$	0.6514
00002401630	MED-RIVASTIGMINE	GMP	\$	0.6514
00002324598	SANDOZ RIVASTIGMINE	SDZ	\$	0.6514
00002242117	EXELON	NOV	\$	2.8425

6 MG (BASE) ORAL CAPSULE

00002336758	APO-RIVASTIGMINE	APX	\$	0.6514
00002485397	JAMP RIVASTIGMINE	JPC	\$	0.6514
00002401649	MED-RIVASTIGMINE	GMP	\$	0.6514
00002324601	SANDOZ RIVASTIGMINE	SDZ	\$	0.6514
00002242118	EXELON	NOV	\$	2.8425

2 MG / ML (BASE) ORAL SOLUTION

00002245240	EXELON	NOV	\$	1.5000
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**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

RIZATRIPTAN BENZOATE

(Refer to 28:32.28 of the Alberta Drug Benefit List for coverage of patients 18 to 64 years of age inclusive.)

"For the treatment of acute migraine attacks in patients 65 years of age and older where other standard therapy has failed."

"For the treatment of acute migraine attacks in patients 65 years of age and older who have been using rizatriptan benzoate prior to turning 65."

"Special authorization for both criteria may be granted for 24 months."

In order to comply with the first criteria, information is required regarding previous medications utilized and the patient's response to therapy.

The following product(s) are eligible for auto-renewal.

5 MG (BASE)	ORAL TABLET			
00002393468	APO-RIZATRIPTAN	APX	\$	3.7050
00002380455	JAMP-RIZATRIPTAN	JPC	\$	3.7050
00002429233	JAMP-RIZATRIPTAN IR	JPC	\$	3.7050
10 MG (BASE)	ORAL TABLET			
00002381702	ACT RIZATRIPTAN	APH	\$	3.7050
00002393476	APO-RIZATRIPTAN	APX	\$	3.7050
00002441144	AURO-RIZATRIPTAN	AUR	\$	3.7050
00002380463	JAMP-RIZATRIPTAN	JPC	\$	3.7050
00002429241	JAMP-RIZATRIPTAN IR	JPC	\$	3.7050
00002379678	MAR-RIZATRIPTAN	MAR	\$	3.7050
00002240521	MAXALT	MFC	\$	16.5163
5 MG (BASE)	ORAL DISINTEGRATING TABLET			
00002483270	ACCEL-RIZATRIPTAN ODT	ACP	\$	2.9633
00002458764	CCP-RIZATRIPTAN ODT	CEL	\$	3.7050
00002465086	JAMP-RIZATRIPTAN ODT	JPC	\$	3.7050
00002462788	MAR-RIZATRIPTAN ODT	MAR	\$	3.7050
00002379198	MYLAN-RIZATRIPTAN ODT	MYP	\$	3.7050
00002436604	NAT-RIZATRIPTAN ODT	NTP	\$	3.7050
00002393360	PMS-RIZATRIPTAN RDT	PMS	\$	3.7050
00002442906	RIZATRIPTAN ODT	SNS	\$	3.7050
00002446111	RIZATRIPTAN ODT	SIV	\$	3.7050
00002351870	SANDOZ RIZATRIPTAN ODT	SDZ	\$	3.7050
00002396661	TEVA-RIZATRIPTAN ODT	TEV	\$	3.7050
00002240518	MAXALT RPD	MFC	\$	16.5163
10 MG (BASE)	ORAL DISINTEGRATING TABLET			
00002483289	ACCEL-RIZATRIPTAN ODT	ACP	\$	2.9633
00002458772	CCP-RIZATRIPTAN ODT	CEL	\$	3.7050
00002465094	JAMP-RIZATRIPTAN ODT	JPC	\$	3.7050
00002462796	MAR-RIZATRIPTAN ODT	MAR	\$	3.7050
00002379201	MYLAN-RIZATRIPTAN ODT	MYP	\$	3.7050
00002436612	NAT-RIZATRIPTAN ODT	NTP	\$	3.7050
00002393379	PMS-RIZATRIPTAN RDT	PMS	\$	3.7050
00002442914	RIZATRIPTAN ODT	SNS	\$	3.7050
00002446138	RIZATRIPTAN ODT	SIV	\$	3.7050
00002351889	SANDOZ RIZATRIPTAN ODT	SDZ	\$	3.7050
00002396688	TEVA-RIZATRIPTAN ODT	TEV	\$	3.7050
00002240519	MAXALT RPD	MFC	\$	16.5163

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

ROSIGLITAZONE MALEATE

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

FIRST-LINE DRUG PRODUCT(S): METFORMIN

"For the treatment of Type 2 diabetes in patients who have an inadequate response to a sufficient trial (i.e. a minimum of 6 months) of metformin or who are intolerant to metformin (e.g. dermatologic reactions) or for whom the product is contraindicated."

Special authorization may be granted for 24 months.

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

UP - First-line therapy ineffective

UQ - First-line therapy not tolerated

2 MG (BASE) ORAL TABLET				
00002403366	ROSIGLITAZONE	AAP	\$	1.0316
00002241112	AVANDIA	GSK	\$	1.4665
4 MG (BASE) ORAL TABLET				
00002403374	ROSIGLITAZONE	AAP	\$	1.6188
00002241113	AVANDIA	GSK	\$	2.3037
8 MG (BASE) ORAL TABLET				
00002403382	ROSIGLITAZONE	AAP	\$	2.3150
00002241114	AVANDIA	GSK	\$	3.2944

ROTIGOTINE

"For adjunctive therapy to levodopa for the treatment of patients with advanced stage Parkinson's disease (APD).

Special authorization may be granted for six months."

This product is eligible for auto-renewal.

2 MG/24HR TRANSDERMAL PATCH				
00002403900	NEUPRO	UCB	\$	3.5400
4 MG/24HR TRANSDERMAL PATCH				
00002403927	NEUPRO	UCB	\$	6.5000
6 MG/24HR TRANSDERMAL PATCH				
00002403935	NEUPRO	UCB	\$	7.2700
8 MG/24HR TRANSDERMAL PATCH				
00002403943	NEUPRO	UCB	\$	7.2700

ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

RUFINAMIDE

"For the treatment of seizures associated with Lennox-Gastaut Syndrome (LGS) in patients who meet the following criteria:

- are currently taking two or more anti-epileptic drugs (AEDs) without optimal seizure control;
- AND
- have failed or demonstrated intolerance to adequate trials of both lamotrigine AND topiramate;
- AND
- therapy must be initiated by a Neurologist.

Special authorization may be granted for six months."

This product is eligible for auto-renewal.

100 MG ORAL TABLET				
00002369613	BANZEL	EIS	\$	0.7433
200 MG ORAL TABLET				
00002369621	BANZEL	EIS	\$	1.4867
400 MG ORAL TABLET				
00002369648	BANZEL	EIS	\$	3.2393

SACUBITRIL/ VALSARTAN

"For the treatment of heart failure (HF) in patients with the following criteria:

- 1) reduced left ventricular ejection fraction (LVEF) (< 40%)
And
- 2) New York Heart Association (NYHA) class II or III HF symptoms despite at least FOUR weeks of treatment with:
 - a stable dose of an angiotensin-converting enzyme inhibitor (ACEI) or an angiotensin II receptor antagonist (ARB)
 - in combination with a beta-blocker and other recommended therapies, including an aldosterone antagonist (if tolerable)And
- 3) who have Plasma B-type natriuretic peptide (BNP) \geq 150 pg/mL or N-terminal prohormone B-type natriuretic peptide (NT-proBNP) \geq 600 pg/mL; or
 - if the patient has been hospitalized for HF within the past 12 months and has plasma BNP \geq 100 pg/mL or NT-proBNP \geq 400 pg/mL levels

For coverage, this drug must be initiated by a Specialist in Cardiology or Internal Medicine, and the initial request must be completed by the Specialist.

Special authorization may be granted for six months."

This product is eligible for auto-renewal.

All requests (including renewal requests) for sacubitril+valsartan must be completed using the Eplerenone/Ivabradine/Sacubitril+Valsartan Special Authorization Request Form (ABC 60050).

24.3 MG * 25.7 MG ORAL TABLET				
00002446928	ENTRESTO	NOV	\$	3.8010
48.6 MG * 51.4 MG ORAL TABLET				
00002446936	ENTRESTO	NOV	\$	3.8010
97.2 MG * 102.8 MG ORAL TABLET				
00002446944	ENTRESTO	NOV	\$	3.8010

ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

SALMETEROL XINAFOATE/ FLUTICASONE PROPIONATE

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

ASTHMA

FIRST-LINE DRUG PRODUCT(S): INHALED CORTICOSTEROID (ICS)

"For the treatment of asthma in patients uncontrolled on inhaled steroid therapy."

"Special authorization may be granted for 24 months."

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

UP - First-line therapy ineffective

All requests for salmeterol xinafoate + fluticasone propionate must be completed using the Long-Acting Fixed-Dose Combination Products for Asthma/COPD Special Authorization Request Form (ABC 60025).

25 MCG / DOSE (BASE)	* 125 MCG / DOSE	INHALATION	METERED DOSE AEROSOL		
00002245126	ADVAIR 125		GSK	\$	0.8666

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

ASTHMA

FIRST-LINE DRUG PRODUCT(S): INHALED CORTICOSTEROID (ICS)

"For the treatment of asthma in patients uncontrolled on inhaled steroid therapy."

"Special authorization may be granted for 24 months."

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

UP - First-line therapy ineffective

All requests for salmeterol xinafoate + fluticasone propionate must be completed using the Long-Acting Fixed-Dose Combination Products for Asthma/COPD Special Authorization Request Form (ABC 60025).

25 MCG / DOSE (BASE)	* 250 MCG / DOSE	INHALATION	METERED DOSE AEROSOL		
00002245127	ADVAIR 250		GSK	\$	1.2302

ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

SALMETEROL XINAFOATE/ FLUTICASONE PROPIONATE

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

ASTHMA

FIRST-LINE DRUG PRODUCT(S): INHALED CORTICOSTEROID (ICS)

"For the treatment of asthma in patients uncontrolled on inhaled steroid therapy."

"Special authorization may be granted for 24 months."

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

UP - First-line therapy ineffective

All requests for salmeterol xinafoate + fluticasone propionate must be completed using the Long-Acting Fixed-Dose Combination Products for Asthma/COPD Special Authorization Request Form (ABC 60025).

50 MCG / DOSE (BASE)	* 100 MCG / DOSE	INHALATION	METERED INHALATION POWDER		
00002240835	ADVAIR 100 DISKUS		GSK	\$	1.4478

ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

SALMETEROL XINAFOATE/ FLUTICASONE PROPIONATE

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

ASTHMA

FIRST-LINE DRUG PRODUCT(S): INHALED CORTICOSTEROID (ICS)

"For the treatment of asthma in patients uncontrolled on inhaled steroid therapy."

CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD)

FIRST-LINE DRUG PRODUCT(S): LONG-ACTING BRONCHODILATOR (I.E., LONG-ACTING BETA-2 AGONIST [LABA] OR LONG-ACTING MUSCARINIC ANTAGONIST [LAMA])

"For the long-term maintenance treatment of airflow obstruction in patients with moderate to severe (i.e., FEV1 < 80% predicted) chronic obstructive pulmonary disease (COPD), who have an inadequate response to a long-acting bronchodilator (long-acting beta-2 agonist [LABA] or long-acting muscarinic antagonist [LAMA])."

"For the long-term maintenance treatment of airflow obstruction in patients with severe (i.e., FEV1 < 50% predicted) chronic obstructive pulmonary disease (COPD)."

"Special authorization may be granted for 24 months."

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

UP - First-line therapy ineffective

All requests for salmeterol xinafoate + fluticasone propionate must be completed using the Long-Acting Fixed-Dose Combination Products for Asthma/COPD Special Authorization Request Form (ABC 60025).

50 MCG / DOSE (BASE)	* 250 MCG / DOSE	INHALATION	METERED INHALATION POWDER		
00002240836	ADVAIR 250 DISKUS		GSK	\$	1.7331

ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

SALMETEROL XINAFOATE/ FLUTICASONE PROPIONATE

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

ASTHMA

FIRST-LINE DRUG PRODUCT(S): INHALED CORTICOSTEROID (ICS)

"For the treatment of asthma in patients uncontrolled on inhaled steroid therapy."

CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD)

FIRST-LINE DRUG PRODUCT(S): LONG-ACTING BRONCHODILATOR (I.E., LONG-ACTING BETA-2 AGONIST [LABA] OR LONG-ACTING MUSCARINIC ANTAGONIST [LAMA])

"For the long-term maintenance treatment of airflow obstruction in patients with moderate to severe (i.e., FEV1 < 80% predicted) chronic obstructive pulmonary disease (COPD), who have an inadequate response to a long-acting bronchodilator (long-acting beta-2 agonist [LABA] or long-acting muscarinic antagonist [LAMA])."

"For the long-term maintenance treatment of airflow obstruction in patients with severe (i.e., FEV1 < 50% predicted) chronic obstructive pulmonary disease (COPD)."

"Special authorization may be granted for 24 months."

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

UP - First-line therapy ineffective

All requests for salmeterol xinafoate + fluticasone propionate must be completed using the Long-Acting Fixed-Dose Combination Products for Asthma/COPD Special Authorization Request Form (ABC 60025).

50 MCG / DOSE (BASE)	* 500 MCG / DOSE	INHALATION	METERED INHALATION POWDER		
00002240837	ADVAIR 500 DISKUS		GSK	\$	2.4604

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

SARILUMAB

Rheumatoid Arthritis

"Special authorization coverage may be provided for use in combination with methotrexate for the reduction in signs and symptoms of severely active Rheumatoid Arthritis (RA) in adult patients (18 years of age or older) who are refractory or intolerant to:

- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- Methotrexate with other disease modifying anti-rheumatic agent(s) (minimum 4 month trial) [e.g., methotrexate with hydroxychloroquine or methotrexate with sulfasalazine]; AND
- Leflunomide (minimum 10 week trial at 20 mg daily)

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.

'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

Special authorization coverage of this agent may be provided for use as monotherapy in adult patients for whom methotrexate is contraindicated and/or for those patients who have experienced serious adverse effects.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

Initial coverage may be approved for up to 200 mg of sarilumab given subcutaneously every 2 weeks for 12 weeks.

- Patients will be limited to receiving a one-month supply of sarilumab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another (with the exception of anakinra) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients will not be permitted to switch from anakinra to other biologic agents except under exceptional circumstances.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond 12 weeks, the patient must meet the following criteria:

- 1) The patient must be assessed by an RA Specialist after 12 weeks to determine response.
- 2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:

- ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND

- An improvement of 0.22 in HAQ score [reported to two (2) decimal places].

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be approved for one subcutaneous dose of up to 200 mg every 2 weeks for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:

- 1) The patient has been assessed by an RA Specialist to determine response;
- 2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:

- confirmation of maintenance of ACR20, OR

- maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.

- 3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

SARILUMAB

requests.

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above."

All requests (including renewal requests) for sarilumab for Rheumatoid Arthritis must be completed using the Abatacept/Adalimumab/Anakinra/Certolizumab/Etanercept/Golimumab/Infliximab/Sarilumab/Tocilizumab/Tofacitinib for Rheumatoid Arthritis Special Authorization Request Form (ABC 60027).

150 MG / SYR INJECTION			
00002472961	KEVZARA (PREFILLED PEN)	SAV	\$ 737.5800
200 MG / SYR INJECTION			
00002472988	KEVZARA (PREFILLED PEN)	SAV	\$ 737.5800
150 MG / SYR INJECTION SYRINGE			
00002460521	KEVZARA	SAV	\$ 737.5800
200 MG / SYR INJECTION SYRINGE			
00002460548	KEVZARA	SAV	\$ 737.5800

SAXAGLIPTIN HCL

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

FIRST-LINE DRUG PRODUCT(S): METFORMIN
SECOND-LINE DRUG PRODUCT(S): SULFONYLUREAS
AND WHERE INSULIN IS NOT AN OPTION

As add-on therapy for the treatment of Type 2 diabetes in patients with intolerance to and/or inadequate glycemic control on:

- a sufficient trial (i.e. a minimum of 6 months) of metformin, AND
- a sulfonylurea, AND
- for whom insulin is not an option.

Or, for whom these products are contraindicated.

Special authorization may be granted for 24 months.

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

- UP - First-line therapy ineffective
- UQ - First-line therapy not tolerated
- CA - Prior adverse reaction
- CB - Previous treatment failure
- CJ - Product is not effective

All requests for saxagliptin must be completed using the DPP-4/SGLT2 Inhibitors/GLP-1 Receptor Agonist Special Authorization Request Form (ABC 60012).

2.5 MG ORAL TABLET			
00002375842	ONGLYZA	AZC	\$ 2.4910
5 MG (BASE) ORAL TABLET			
00002333554	ONGLYZA	AZC	\$ 2.9540

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

SAXAGLIPTIN HCL/ METFORMIN HCL

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

FIRST-LINE DRUG PRODUCT(S): METFORMIN
SECOND-LINE DRUG PRODUCT(S): SULFONYLUREAS
AND WHERE INSULIN IS NOT AN OPTION

As add-on therapy for the treatment of Type 2 diabetes in patients with intolerance to and/or inadequate glycemic control on:

- a sufficient trial (i.e. a minimum of 6 months) of metformin, AND
- a sulfonylurea, AND
- for whom insulin is not an option.

Or, for whom these products are contraindicated.

Special authorization may be granted for 24 months.

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

- UP - First-line therapy ineffective
- UQ - First-line therapy not tolerated
- CA - Prior adverse reaction
- CB - Previous treatment failure
- CJ - Product is not effective

All requests for saxagliptin+metformin must be completed using the DPP-4/SGLT2 Inhibitors/GLP-1 Receptor Agonist Special Authorization Request Form (ABC 60012).

2.5 MG (BASE) * 500 MG ORAL TABLET			
00002389169	KOMBOGLYZE	AZC	\$ 1.2700
2.5 MG (BASE) * 850 MG ORAL TABLET			
00002389177	KOMBOGLYZE	AZC	\$ 1.2700
2.5 MG (BASE) * 1,000 MG ORAL TABLET			
00002389185	KOMBOGLYZE	AZC	\$ 1.2700

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

SECUKINUMAB

Plaque Psoriasis

"Special authorization coverage may be provided for the reduction in signs and symptoms of severe, debilitating plaque psoriasis in patients who:

- Have a total PASI of 10 or more and a DLQI of more than 10, OR
- Who have significant involvement of the face, palms of the hands, soles of the feet or genital region; AND
- Who are refractory or intolerant to:
 - Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory, OR
 - Cyclosporine (6 weeks treatment); AND
 - Phototherapy (unless restricted by geographic location)

Patients who have a contraindication to either cyclosporine or methotrexate will be required to complete an adequate trial of the other pre-requisite medication prior to potential coverage being considered.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.

'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be prescribed by a Specialist in Dermatology ("Dermatology Specialist").

Initial coverage may be approved for 12 weeks as follows:

- Four weekly doses of 300 mg of secukinumab at weeks 0, 1, 2 and 3, followed by monthly dosing at weeks 4, 8 and 12.
- Patients will be limited to receiving two doses of secukinumab per prescription at their pharmacy during the initial 3 weeks, then one dose per prescription thereafter. Each 300 mg dose is provided as two subcutaneous injections of 150 mg.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of the initial coverage period.
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond seven doses, the patient must meet all of the following criteria:

- 1) The patient must be assessed by a Dermatology Specialist after the initial seven doses to determine response.
- 2) The Dermatology Specialist must confirm, in writing, that the patient is a 'responder' that meets the following criteria:
 - Greater than or equal to 75% reduction in PASI score, OR
 - Greater than or equal to 50% reduction in PASI score AND improvement of greater than or equal to 5 points in the DLQI.

Following this assessment, continued coverage may be considered for one 300 mg dose of secukinumab every month for a period of 12 months. Ongoing coverage may be considered if the patient is re-assessed by a Dermatology Specialist every 12 months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above."

PASI and DLQI scores are required for all requests for Plaque Psoriasis including those requests for patients that have significant involvement of the face, palms, soles of feet or genital region.

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

SECUKINUMAB

All requests (including renewal requests) for secukinumab for Plaque Psoriasis must be completed using the Adalimumab/Etanercept/Infliximab/Ixekizumab/Risankizumab/Secukinumab/Ustekinumab for Plaque Psoriasis Special Authorization Request Form (ABC 60030).

Psoriatic Arthritis

"Special authorization coverage may be provided for use in combination with methotrexate for reducing signs and symptoms and inhibiting the progression of structural damage of active arthritis in adult patients (18 years of age or older) with moderate to severe polyarticular psoriatic arthritis (PsA) or pauciarticular PsA with involvement of knee or hip joint who are refractory or intolerant to:

- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- An adequate trial of another disease modifying anti-rheumatic agent(s) (minimum 4 month trial).

Special authorization coverage of this agent may be provided for use as monotherapy in adult patients for whom methotrexate is contraindicated and/or for those patients who have experienced serious adverse effects.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.

'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

Initial coverage may be approved for 16 weeks as follows:

- Four weekly doses of 150 mg of secukinumab at weeks 0, 1, 2 and 3, followed by monthly dosing at weeks 4, 8, 12 and 16. A dose of 300 mg (given as 2 subcutaneous injections of 150 mg each) may be considered for anti-TNF alpha inadequate responders.
- Patients will be limited to receiving two doses of secukinumab per prescription at their pharmacy during the initial 3 weeks, then one dose per prescription thereafter.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond eight doses, the patient must meet the following criteria:

- 1) The patient must be assessed by an RA Specialist after the initial eight doses to determine response.
- 2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
 - ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND
 - An improvement of 0.22 in HAQ score [reported to two (2) decimal places].

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be considered for one 150 mg (or 300 mg for anti-TNF alpha inadequate responders) dose of secukinumab every month for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:

- 1) The patient has been assessed by an RA Specialist to determine response;

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

SECUKINUMAB

2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:

- Confirmation of maintenance of ACR20, or
- Maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.

3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above."

All requests (including renewal requests) for secukinumab for Psoriatic Arthritis must be completed using the Adalimumab/Certolizumab/Etanercept/Golimumab/Infliximab/Ixekizumab/Secukinumab for Psoriatic Arthritis Special Authorization Request Form (ABC 60029).

Ankylosing Spondylitis

"Special authorization coverage may be provided for the reduction in the signs and symptoms of severely active Ankylosing Spondylitis, as defined by the Modified New York criteria for Ankylosing Spondylitis, in adult patients (18 years of age or older) who have active disease as demonstrated by:

- a BASDAI greater than or equal to 4 units, demonstrated on 2 occasions at least 8 weeks apart AND
- a Spinal Pain VAS of greater than or equal to 4 cm (on a 0-10 cm scale), demonstrated on 2 occasions at least 8 weeks apart AND
- who are refractory or intolerant to treatment with 2 or more NSAIDS each taken for a minimum of 4 weeks at maximum tolerated or recommended doses.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.

'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist"). Initial coverage may be approved for 16 weeks as follows:

- Four weekly doses of 150 mg of secukinumab at weeks 0, 1, 2 and 3, followed by monthly dosing at weeks 4, 8, 12 and 16.
- Patients will be limited to receiving two doses of secukinumab per prescription at their pharmacy during the initial 3 weeks, then one dose per prescription thereafter.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond eight doses, the patient must meet the following criteria:

- 1) The patient must be assessed by an RA Specialist after the initial eight doses to determine response.
- 2) The RA Specialist must confirm, in writing, that the patient is a 'responder' that meets the following criteria:
 - Reduction of the BASDAI score by at least 50% of the pre-treatment value or by 2 or more units, AND
 - Reduction of the Spinal Pain VAS by 2 cm or more.

Following this assessment, continued coverage may be considered for one 150 mg dose of secukinumab every month for a period of 12 months. Ongoing coverage may be considered if

ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

SECUKINUMAB

the patient is re-assessed by an RA Specialist every 12 months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above."

All requests (including renewal requests) for secukinumab for Ankylosing Spondylitis must be completed using the Adalimumab/Certolizumab/Etanercept/Golimumab/Infliximab/Secukinumab for Ankylosing Spondylitis Special Authorization Request Form (ABC 60028).

150 MG / ML INJECTION SYRINGE

00002438070 COSENTYX NOV \$ 850.7100

SEMAGLUTIDE

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

FIRST-LINE DRUG PRODUCT(S): METFORMIN
SECOND-LINE DRUG PRODUCT(S): SULFONYLUREAS
AND WHERE INSULIN IS NOT AN OPTION

As add-on therapy for the treatment of Type 2 diabetes in patients with intolerance to and/or inadequate glycemic control on:

- a sufficient trial (i.e. a minimum of 6 months) of metformin, AND
- a sulfonylurea, AND
- for whom insulin is not an option.

Or, for whom these products are contraindicated

Special authorization may be granted for 24 months.

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

- UP - First-line therapy ineffective
- UQ - First-line therapy not tolerated
- CA - Prior adverse reaction
- CB - Previous treatment failure
- CJ - Product is not effective

All requests for semaglutide must be completed using the DPP-4/SGLT2 Inhibitors/GLP-1 Receptor Agonist Special Authorization Request Form (ABC 60012).

1.34 MG / ML INJECTION

00002471469 OZEMPIC NNA \$ 66.2533
 00002471477 OZEMPIC NNA \$ 132.5067

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

SILTUXIMAB

"For the treatment of multicentric Castleman's disease (MCD) in patients who are human immunodeficiency virus (HIV) negative and human herpes virus-8 (HHV-8) negative and who have an ECOG performance status of less than or equal to 2.

Initial coverage may be approved for a period of 6 months.

Continued coverage may be approved for a period of 12 months for patients who continue to meet initial coverage criteria.

Coverage for siltuximab will be provided for one intravenous dose of 11 mg/kg every 3 weeks. Patients will be limited to receiving one dose of siltuximab per prescription at their pharmacy."

100 MG / VIAL INJECTION			
00002435128 SYLVANT	JAI	\$	697.7000
400 MG / VIAL INJECTION			
00002435136 SYLVANT	JAI	\$	2790.8000

SITAGLIPTIN PHOSPHATE MONOHYDRATE

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

FIRST-LINE DRUG PRODUCT(S): METFORMIN
SECOND-LINE DRUG PRODUCT(S): SULFONYLUREAS
AND WHERE INSULIN IS NOT AN OPTION

As add-on therapy for the treatment of Type 2 diabetes in patients with intolerance to and/or inadequate glycemic control on:

- a sufficient trial (i.e. a minimum of 6 months) of metformin, AND
- a sulfonylurea, AND
- for whom insulin is not an option.

Or, for whom these products are contraindicated.

Special authorization may be granted for 24 months.

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

- UP - First-line therapy ineffective
- UQ - First-line therapy not tolerated
- CA - Prior adverse reaction
- CB - Previous treatment failure
- CJ - Product is not effective

All requests for sitagliptin must be completed using the DPP-4/SGLT2 Inhibitors/GLP-1 Receptor Agonist Special Authorization Request Form (ABC 60012).

25 MG ORAL TABLET			
00002388839 JANUVIA	MFC	\$	3.1566
50 MG ORAL TABLET			
00002388847 JANUVIA	MFC	\$	3.1566
100 MG ORAL TABLET			
00002303922 JANUVIA	MFC	\$	3.1566

ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

SITAGLIPTIN PHOSPHATE MONOHYDRATE/ METFORMIN HCL

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

FIRST-LINE DRUG PRODUCT(S): METFORMIN
SECOND-LINE DRUG PRODUCT(S): SULFONYLUREAS
AND WHERE INSULIN IS NOT AN OPTION

As add-on therapy for the treatment of Type 2 diabetes in patients with intolerance to and/or inadequate glycemic control on:

- a sufficient trial (i.e. a minimum of 6 months) of metformin, AND
- a sulfonylurea, AND
- for whom insulin is not an option.

Or, for whom these products are contraindicated.

Special authorization may be granted for 24 months.

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

- UP - First-line therapy ineffective
- UQ - First-line therapy not tolerated
- CA - Prior adverse reaction
- CB - Previous treatment failure
- CJ - Product is not effective

All requests for sitagliptin+metformin must be completed using the DPP-4/SGLT2 Inhibitors/GLP-1 Receptor Agonist Special Authorization Request Form (ABC 60012).

50 MG (BASE) * 500 MG ORAL TABLET			
00002333856 JANUMET	MFC	\$	1.7106
50 MG (BASE) * 850 MG ORAL TABLET			
00002333864 JANUMET	MFC	\$	1.7106
50 MG (BASE) * 1,000 MG ORAL TABLET			
00002333872 JANUMET	MFC	\$	1.7106
50 MG (BASE) * 500 MG ORAL EXTENDED-RELEASE TABLET			
00002416786 JANUMET XR	MFC	\$	1.7066
50 MG (BASE) * 1,000 MG ORAL EXTENDED-RELEASE TABLET			
00002416794 JANUMET XR	MFC	\$	1.7066
100 MG (BASE) * 1,000 MG ORAL EXTENDED-RELEASE TABLET			
00002416808 JANUMET XR	MFC	\$	3.4133

ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

SODIUM PHENYLBUTYRATE

"As adjunctive therapy in the chronic management of urea cycle disorders (UCDs) involving deficiencies of carbamoyl phosphate synthetase 1, ornithine transcarbamylase, or argininosuccinate synthetase, in patients with neonatal-onset presentation, and patients with late-onset disease who have a history of hyperammonemic encephalopathy.

For coverage, this drug must be prescribed by or in consultation with a metabolic or genetic physician. The diagnosis must be confirmed by blood, enzymatic, biochemical, or genetic testing.

Special authorization may be granted for 12 months."

The following product(s) are eligible for auto-renewal.

483 MG / G ORAL GRANULE				
00002436663	PHEBURANE	MDK	\$	9.2690

ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

SOFOSBUVIR

"For use as combination therapy with ribavirin or daclatasvir for treatment-naive or treatment-experienced (1) adult patients with chronic hepatitis C (CHC) infection who meet all of the following criteria:

I) Prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist (except on a case-by-case basis, in geographic areas where access to these specialties is not available);

AND

II) Laboratory confirmed hepatitis C genotype 2 or genotype 3;

AND

III) Laboratory confirmed quantitative HCV RNA value within the last 6 months;

AND

IV) Fibrosis (2) stage of F0 or greater (Metavir scale or equivalent).

Duration of therapy reimbursed:

- Treatment-naive or treatment experienced genotype 2, without cirrhosis or with compensated cirrhosis (3): 12 weeks in combination with ribavirin

- Treatment-naive or treatment-experienced genotype 3, without cirrhosis: 12 weeks in combination with daclatasvir

- Treatment-naive or treatment-experienced genotype 3, without cirrhosis or with compensated cirrhosis (3), or with decompensated cirrhosis (4), or post-liver transplant: 24 weeks in combination with ribavirin

Exclusion criteria:

- Patients currently being treated with another HCV antiviral agent

- Retreatment for failure or re-infection in patients who have received an adequate prior course of an HCV direct-acting antiviral drug regimen may be considered on an exceptional case-by-case basis

- Combination therapy with elbasvir/grazoprevir will not be considered

Notes:

1. Treatment-experienced are those who failed prior therapy with an interferon-based regimen, including regimens containing an HCV protease inhibitor.

2. Fibrosis score test is optional. Acceptable methods include liver biopsy, transient elastography (FibroScan), fibrotest and serum biomarker panels (such as AST-to-Platelet Ratio Index or Fibrosis-4 score) either alone or in combination.

3. Compensated cirrhosis is defined as cirrhosis with Child-Turcotte-Pugh A (i.e. score 5 to 6) and d

4. Decompensated cirrhosis is defined as cirrhosis with Child-Turcotte-Pugh B or C (i.e. score 7 or above).

5. Health care professionals are advised to refer to the product monograph and prescribing guidelines for appropriate use of the drug product, including use in special populations."

All requests for sofosbuvir must be completed using the Antivirals for Chronic Hepatitis C Special Authorization Request Form (ABC 60022).

400 MG ORAL TABLET

00002418355

SOVALDI

GIL

\$

654.7619

ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

SOFOSBUVIR/ LEDIPASVIR

"For treatment-naive or treatment-experienced (1) adult patients with chronic hepatitis C (CHC) infection who meet all of the following criteria:

I) Prescribed by or in consultation with a hepatologist, gastroenterologist or infectious disease specialist (except on a case-by-case basis, in geographic areas where access to these specialties is not available);

AND

II) Laboratory confirmed hepatitis C genotype 1;

AND

III) Laboratory confirmed quantitative HCV RNA value within the last 6 months;

AND

IV) Fibrosis (2) stage of F0 or greater (Metavir scale or equivalent).

Duration of therapy reimbursed:

- Treatment-naive, without cirrhosis, recent quantitative hepatitis C viral load less than 6 M IU/mL: 8 weeks or 12 weeks (3)

- Treatment-naive, without cirrhosis, viral load greater than or equal to 6 M IU/mL: 12 weeks

- Treatment-naive, with compensated cirrhosis (4): 12 weeks

- Treatment-experienced, without cirrhosis: 12 weeks

- Treatment-naive or treatment-experienced with decompensated cirrhosis (5): 12 weeks in combination with ribavirin

- Treatment-naive or treatment-experienced liver transplant recipients, without cirrhosis or with compensated cirrhosis (4): 12 weeks in combination with ribavirin

- Treatment-experienced, with compensated cirrhosis (4): 24 weeks

Exclusion criteria:

- Patients currently being treated with another HCV antiviral agent

- Retreatment for failure or re-infection in patients who have received an adequate prior course of an HCV direct-acting antiviral drug regimen may be considered on an exceptional case-by-case basis

Notes:

1. Treatment-experienced are those who failed prior therapy with an interferon-based regimen, including regimens containing an HCV protease inhibitor.

2. Fibrosis score test is optional. Acceptable methods include liver biopsy, transient elastography (FibroScan), fibrotest and serum biomarker panels (such as AST-to-Platelet Ratio Index or Fibrosis-4 score) either alone or in combination.

3. For this population cohort, evidence has shown that the SVR rates with 8-week and 12-week treatment regimens are similar. Treatment regimens of up to 12 weeks are recognized by Health Canada as an approved treatment option. 12-week treatment regimens may be considered for patients with advanced liver fibrosis.

4. Compensated cirrhosis is defined as cirrhosis with Child-Turcotte-Pugh A (i.e. score 5 to 6).

5. Decompensated cirrhosis is defined as cirrhosis with Child-Turcotte-Pugh B or C (i.e. score 7 or above).

6. Health care professionals are advised to refer to the product monograph and prescribing guidelines for appropriate use of the drug product, including use in special populations."

All requests for sofosbuvir/ledipasvir must be completed using the Antivirals for Chronic Hepatitis C Special Authorization Request Form (ABC 60022).

400 MG * 90 MG ORAL TABLET

00002432226 HARVONI

GIL

\$ 797.6190

ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

SOFOSBUVIR/ VELPATASVIR

"For treatment-naive or treatment-experienced (1) adult patients with chronic hepatitis C (CHC) infection who meet all of the following criteria:

I) Prescribed by or in consultation with a hepatologist, gastroenterologist or infectious disease specialist (except on a case-by-case basis, in geographic areas where access to these specialties is not available);

AND

II) Laboratory confirmed hepatitis C genotype (2) 1, 2, 3, 4, 5, 6 or mixed genotypes;

AND

III) Laboratory confirmed quantitative HCV RNA value within the last 6 months;

AND

IV) Fibrosis (3) stage of F0 or greater (Metavir scale or equivalent).

Duration of therapy reimbursed:

- Treatment-naive or treatment-experienced, without cirrhosis or with compensated cirrhosis (4): 12 weeks

- Treatment-naive or treatment-experienced, with decompensated cirrhosis (5): 12 weeks in combination with ribavirin

Exclusion criteria:

- Patients currently being treated with another HCV antiviral agent

- Retreatment for failure or re-infection in patients who have received an adequate prior course of an HCV direct-acting antiviral drug regimen may be considered on an exceptional case-by-case basis

Notes:

1. Treatment-experienced is defined as those who failed prior therapy with an interferon-based regimen, including regimens containing an HCV protease inhibitor.

2. HCV genotype testing is optional.

3. Fibrosis score test is optional. Acceptable methods include liver biopsy, transient elastography (FibroScan), fibrotest and serum biomarker panels (such as AST-to-Platelet Ratio Index or Fibrosis-4 score) either alone or in combination.

4. Compensated cirrhosis is defined as cirrhosis with Child-Turcotte-Pugh A (i.e. score 5 to 6).

5. Decompensated cirrhosis is defined as cirrhosis with Child-Turcotte-Pugh B or C (i.e. score 7 or above).

6. Health care professionals are advised to refer to the product monograph and prescribing guidelines for appropriate use of the drug product, including use in special populations."

All requests for sofosbuvir/velpatasvir must be completed using the Antivirals for Chronic Hepatitis C Special Authorization Request Form (ABC 60022).

400 MG * 100 MG ORAL TABLET

00002456370 EPCLUSA

GIL

\$ 714.2857

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

SOFOSBUVIR/ VELPATASVIR/ VOXILAPREVIR

"For treatment-experienced (1) adult patients with chronic hepatitis C (CHC) infection who meet all of the following criteria:

I) Prescribed by or in consultation with a hepatologist, gastroenterologist or infectious disease specialist (except on a case-by-case basis, in geographic areas where access to these specialties is not available);

AND

II) Laboratory confirmed hepatitis C genotype (2) 1, 2, 3, 4, 5, 6 or mixed genotypes and have previously been treated with a CHC antiviral drug regimen containing a non-structural protein 5A (NS5A) inhibitor;

OR

Laboratory confirmed hepatitis C genotype 1, 2, 3, 4 and have previously been treated with a CHC antiviral drug regimen containing sofosbuvir without an NS5A inhibitor;

AND

III) Laboratory confirmed quantitative HCV RNA value within the last 6 months;

AND

IV) Fibrosis (3) stage of F0 or greater (Metavir scale or equivalent).

Duration of therapy reimbursed:

- Treatment-experienced, without cirrhosis or with compensated cirrhosis (4): 12 weeks

Exclusion criteria:

- Patients currently being treated with another HCV antiviral agent

Notes:

1. Treatment-experienced is defined as those who have previously been treated with a CHC antiviral drug regimen.
2. HCV genotype testing is optional for patients previously treated with a CHC antiviral drug regimen containing a non-structural protein 5A (NS5A) inhibitor.
3. Fibrosis score test is optional. Acceptable methods include liver biopsy, transient elastography (FibroScan), fibrotest and serum biomarker panels (such as AST-to-Platelet Ratio Index or Fibrosis-4 score) either alone or in combination.
4. Compensated cirrhosis is defined as cirrhosis with Child-Turcotte-Pugh A (i.e. score 5 to 6).
5. Health care professionals are advised to refer to the product monograph and prescribing guidelines for appropriate use of the drug product, including use in special populations."

All requests for sofosbuvir/velpatasvir/voxilaprevir must be completed using the Antivirals for Chronic Hepatitis C Special Authorization Request Form (ABC 60022).

400 MG * 100 MG * 100 MG ORAL TABLET

00002467542	VOSEVI	GIL	\$ 714.2857
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SOMATROPIN

"For replacement of endogenous growth hormone in adults with severe growth hormone deficiency. Information is required regarding the results of either a diagnostic insulin tolerance test or a glucagon stimulation test. Growth hormone values less than 3 mcg/litre are indicative of severe growth hormone deficiency.

Special authorization may be granted for 6 months."

The following product(s) are eligible for auto-renewal.

0.6 MG / SYR INJECTION

00002401762	GENOTROPIN MINIQUICK	PFI	\$ 16.7400
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0.8 MG / SYR INJECTION

00002401770	GENOTROPIN MINIQUICK	PFI	\$ 22.3200
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1 MG / SYR INJECTION

00002401789	GENOTROPIN MINIQUICK	PFI	\$ 27.9000
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1.2 MG / SYR INJECTION

00002401797	GENOTROPIN MINIQUICK	PFI	\$ 33.4800
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**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

SOMATROPIN

1.4 MG / SYR INJECTION			
00002401800	GENOTROPIN MINIQUICK	PFI	\$ 39.0600
1.6 MG / SYR INJECTION			
00002401819	GENOTROPIN MINIQUICK	PFI	\$ 44.6400
1.8 MG / SYR INJECTION			
00002401827	GENOTROPIN MINIQUICK	PFI	\$ 50.2200
2 MG / SYR INJECTION			
00002401835	GENOTROPIN MINIQUICK	PFI	\$ 55.8000
5.3 MG / SYR INJECTION			
00002401703	GENOTROPIN GOQUICK	PFI	\$ 147.8700
12 MG / SYR INJECTION			
00002401711	GENOTROPIN GOQUICK	PFI	\$ 334.8000

SOMATROPIN

"For replacement of endogenous growth hormone in adults with severe growth hormone deficiency. Information is required regarding the results of either a diagnostic insulin tolerance test or a glucagon stimulation test. Growth hormone values less than 3 mcg/litre are indicative of severe growth hormone deficiency.

Special authorization may be granted for 6 months."

The following product(s) are eligible for auto-renewal.

6 MG / VIAL INJECTION			
00002243077	HUMATROPE	LIL	\$ 280.0200
12 MG / VIAL INJECTION			
00002243078	HUMATROPE	LIL	\$ 560.0400

SOMATROPIN R-DNA ORIGIN

"For replacement of endogenous growth hormone in adults with severe growth hormone deficiency. Information is required regarding the results of either a diagnostic insulin tolerance test or a glucagon stimulation test. Growth hormone values less than 3 mcg/litre are indicative of severe growth hormone deficiency.

Special authorization may be granted for 6 months."

The following product(s) are eligible for auto-renewal.

3.3 MG / ML INJECTION			
00002325063	OMNITROPE	SDZ	\$ 103.8667
5 MG / VIAL INJECTION			
00002237971	SAIZEN	SRO	\$ 220.7828
5.83 MG / ML INJECTION			
00002350122	SAIZEN	SRO	\$ 264.9150
6.7 MG / ML INJECTION			
00002325071	OMNITROPE	SDZ	\$ 207.7333
8 MG / ML INJECTION			
<input checked="" type="checkbox"/>	00002350130	SAIZEN (1.5 ML)	SRO \$ 353.2200
<input checked="" type="checkbox"/>	00002350149	SAIZEN (2.5 ML)	SRO \$ 353.2200

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

STIRIPENTOL

"For use in combination with clobazam and valproate as adjunctive therapy of refractory generalized tonic-clonic seizures in patients with severe myoclonic epilepsy in infancy (Dravet Syndrome), whose seizures are not adequately controlled with clobazam and valproate alone.

This medication must be prescribed in consultation with a Neurologist.

Special authorization may be granted for 6 months."

Each of these products is eligible for auto-renewal.

250 MG ORAL CAPSULE				
00002398958	DIACOMIT	BCF	\$	5.8984
500 MG ORAL CAPSULE				
00002398966	DIACOMIT	BCF	\$	11.7783
250 MG ORAL POWDER PACKET				
00002398974	DIACOMIT	BCF	\$	5.8984

SUMATRIPTAN HEMISULFATE

(Refer to 28:32.28 of the Alberta Drug Benefit List for coverage of patients 18 to 64 years of age inclusive.)

"For the treatment of acute migraine attacks in patients 65 years of age and older where other standard therapy has failed."

"For the treatment of acute migraine attacks in patients 65 years of age and older who have been using sumatriptan prior to turning 65."

"Special authorization for both criteria may be granted for 24 months."

In order to comply with the first criteria, information is required regarding previous medications utilized and the patient's response to therapy.

The following product(s) are eligible for auto-renewal.

5 MG / DOSE (BASE)	NASAL UNIT DOSE SPRAY			
00002230418	IMITREX	GSK	\$	15.9450
20 MG / DOSE (BASE)	NASAL UNIT DOSE SPRAY			
00002230420	IMITREX	GSK	\$	16.4050

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

SUMATRIPTAN SUCCINATE

(Refer to 28:32.28 of the Alberta Drug Benefit List for coverage of patients 18 to 64 years of age inclusive.)

"For the treatment of acute migraine attacks in patients 65 years of age and older where other standard therapy has failed."

"For the treatment of acute migraine attacks in patients 65 years of age and older who have been using sumatriptan prior to turning 65."

"Special authorization for both criteria may be granted for 24 months."

In order to comply with the first criteria, information is required regarding previous medications utilized and the patient's response to therapy.

The following product(s) are eligible for auto-renewal.

50 MG (BASE) ORAL TABLET				
00002268388	APO-SUMATRIPTAN	APX	\$	2.7732
00002268914	MYLAN-SUMATRIPTAN	MYP	\$	2.7732
00002256436	PMS-SUMATRIPTAN	PMS	\$	2.7732
00002263025	SANDOZ SUMATRIPTAN	SDZ	\$	2.7732
00002286521	SUMATRIPTAN	SNS	\$	2.7732
00002385570	SUMATRIPTAN DF	SIV	\$	2.7732
00002286823	TEVA-SUMATRIPTAN DF	TEV	\$	2.7732
00002212153	IMITREX DF	GSK	\$	16.1771
100 MG (BASE) ORAL TABLET				
00002268396	APO-SUMATRIPTAN	APX	\$	3.0549
00002268922	MYLAN-SUMATRIPTAN	MYP	\$	3.0549
00002256444	PMS-SUMATRIPTAN	PMS	\$	3.0549
00002263033	SANDOZ SUMATRIPTAN	SDZ	\$	3.0549
00002286548	SUMATRIPTAN	SNS	\$	3.0549
00002385589	SUMATRIPTAN DF	SIV	\$	3.0549
00002239367	TEVA-SUMATRIPTAN	TEV	\$	3.0549
00002286831	TEVA-SUMATRIPTAN DF	TEV	\$	3.0549
00002212161	IMITREX DF	GSK	\$	17.8209
6 MG / SYR (BASE) INJECTION SYRINGE				
00002361698	TARO-SUMATRIPTAN (0.5 ML)	TAR	\$	36.1888
00002212188	IMITREX (0.5 ML)	GSK	\$	48.1450

ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

TACROLIMUS

"For use in patients 2 to 15 years of age inclusive with atopic dermatitis who are unable to tolerate or have failed topical steroid therapy."

"For use in patients 2 to 15 years of age inclusive with atopic dermatitis who require ongoing use of potent (Class 3 or higher) topical steroids."

"For use in patients 16 years of age and older with atopic dermatitis affecting face and flexures who are unable to tolerate or have failed topical steroid therapy."

"For use in patients 16 years of age and older with atopic dermatitis who require ongoing use of potent (Class 3 or higher) topical steroids over greater than 30 % of body surface area."

"Special authorization for all criteria may be granted for 6 months."

Information is required regarding the patient's diagnosis, previous medications utilized (including specific topical steroids) and the patient's response to therapy. In order to comply with the third criterion, information is also required regarding the area(s) affected. In order to comply with the fourth criterion, information is also required regarding the percentage body surface area affected.

The following product(s) are eligible for auto-renewal.

All requests for tacrolimus topical ointment must be completed using the Tacrolimus Topical Ointment Special Authorization Request Form (ABC 60047).

0.03 % TOPICAL OINTMENT

00002244149	PROTOPIC	LEO	\$	2.2774
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"For use in patients 16 years of age and older with atopic dermatitis affecting face and flexures who are unable to tolerate or have failed topical steroid therapy."

"For use in patients 16 years of age and older with atopic dermatitis who require ongoing use of potent (Class 3 or higher) topical steroids over greater than 30 % of body surface area."

"Special authorization for all criteria may be granted for 6 months."

Information is required regarding the patient's diagnosis, previous medications utilized (including specific topical steroids) and the patient's response to therapy. In order to comply with the first criterion, information is also required regarding the area(s) affected. In order to comply with the second criterion, information is also required regarding the percentage body surface area affected.

The following product(s) are eligible for auto-renewal.

All requests for tacrolimus topical ointment must be completed using the Tacrolimus Topical Ointment Special Authorization Request Form (ABC 60047).

0.1 % TOPICAL OINTMENT

00002244148	PROTOPIC	LEO	\$	2.4177
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**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

TALIGLUCERASE ALFA

For long-term enzyme replacement therapy (ERT) for pediatric and adult patients with type 1 Gaucher disease (GD) when the following criteria are met:

1. The diagnosis of GD must have been established by the demonstration of specific deficiency of glucocerebrosidase (GCase) in tissue or cultured skin fibroblasts, or by demonstration of the presence, in tissue or peripheral blood leukocytes, of mutations in the GCase gene known to result in severe enzyme deficiency.
2. Other potentially confounding diagnoses, such as Hodgkin disease or other storage disorders, must have been ruled out. The symptoms experienced by the patient should be shown to be attributable to GD and not some other condition that might mimic it. A trial of therapy would normally be considered in situations of uncertainty only if the symptoms were accompanied by objective evidence (hematological or imaging changes consistent with complaints).
3. The patient should not have any GD-related or other medical condition that might reasonably be expected to compromise their response to treatment. In some patients with GD, secondary pathologic changes, such as avascular necrosis of bone, may already have occurred that would not be expected to respond to enzyme replacement. In such patients, reversal of the pathology is unlikely. Treatment of patients with significant secondary pathology would be directed at preventing further progression of the disease. In these cases, the extent to which symptoms, such as bone pain, are due to active progression of the disease, rather than the secondary pathology, may only be established by a trial of therapy.
4. Treatment should be provided under the care of a specialist with experience in the diagnosis and management of GD.
5. None of the following exclusion criteria apply:
 - a. The presence of any GD-related condition that might reasonably be expected to compromise a response to therapy
 - b. The presence of another medical condition that might reasonably be expected to compromise a response to therapy
 - c. Asymptomatic GD
 - d. The presence of primary neurological disease due to GD
6. Patients must have the following baseline parameters assessed prior to initiating therapy on taliglucerase alfa:
 - Hemoglobin level and platelet count
 - Presence of splenic infarction, bone crises, radiographic or MRI evidence of incipient destruction of any major joint, spontaneous fractures, chronic bone pain, major joint replacement, liver synthetic dysfunction, symptomatic hepatosplenomegaly, progressive pulmonary disease due to GD, or growth failure in children.
7. The patient is unable to receive ERT with velaglucerase alfa, including:
 - a. Rare cases of severe allergic reactions or hypersensitivity to velaglucerase alfa.
 - b. Patients who are sub-optimally responsive despite maximum doses of velaglucerase alfa for at least 12 months.
 - c. Patients unable to receive velaglucerase alfa for medical reasons.

Notes:

- Pregnancy is not considered a contraindication to ERT.
- Patients to be considered for reimbursement of drug costs for ERT must be willing to participate in the long term evaluation of the efficacy of treatment by periodic medical assessment. Failure to comply with recommended medical assessment and investigations may result in withdrawal of financial support of drug therapy.

Initial coverage may be approved at a dosage of up to 60 units/kg every 2 weeks for a period of 6 months.

Ongoing coverage may be considered for up to 60 units/kg every 2 weeks for a period of 6 months at a time during the first 2 years of treatment, and thereafter for 12-month periods, only if

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

TALIGLUCERASE ALFA

the following criteria are met:

- The patient demonstrates all of the following expected treatment outcomes, where applicable:
 1. For patients with baseline hemoglobin <85% of lower limit of age- and sex-appropriate normal: Increase hemoglobin levels to >110 g/L for women and children and >120 g/L for men
 2. For patients with a baseline platelet count <50 x 10⁹/L on two separate occasions at least one month apart:
 - a. Increase platelet count to level sufficient to prevent spontaneous bleeding
 - b. Normalization of platelet count in splenectomized patients
 - c. In patients with intact spleen, an increase of at least 1.5X in baseline platelet count
 3. For patients with a prior splenic infarct at baseline:
 - a. Reduction of spleen volume by at least 50%
 - b. Prevention of further splenic infarcts
 4. Prevention of bone crises
 5. For patients with radiographic or MRI evidence of incipient destruction of any major joint at baseline: Improvement in imaging parameters (either MRI, QCSI2, or BMD)
 6. Prevention of spontaneous fractures
 7. Reduced bone pain in patients with chronic bone pain at baseline
 8. No major joint replacement surgery
 9. Improvement in liver function in patients with liver synthetic dysfunction at baseline
 10. For patients with symptomatic hepatosplenomegaly at baseline:
 - a. Reduction of spleen volume by at least 50%
 - b. Reduction in liver volume by at least 30%
 11. For patients with progressive pulmonary disease due to GD at baseline:
 - c. Improvement in pulmonary hypertension
 - d. Improvement in oxygenation
 - e. Reversal of hepatopulmonary syndrome
 12. For children with growth failure at baseline: Return to normal range on height percentiles
- Treatment should be discontinued if the above treatment outcomes have not been demonstrated, as evidenced by readings consistent over the previous 12-month period at the maximum dosage of 60 units/kg every 2 weeks.

Patients will be limited to receiving a one-month supply of taliglucerase alfa per prescription at their pharmacy.

Coverage cannot be provided for taliglucerase alfa when this medication is intended for use in combination with other ERT.

Patients will not be permitted to switch back to a previously trialed ERT if they were deemed sub-optimally responsive despite maximum doses.

The dosage of taliglucerase alfa prescribed would depend on the severity of the disease and would be at the discretion of the specialist. The efficacy of treatment should be re-evaluated every 6 months and dosage adjustments made as appropriate. If there has been insufficient response to treatment after 6 months on a lower dose, the dosage may be increased to a maximum of 60 units/kg every 2 weeks. In the event of severe drug reaction, treatment may have to be discontinued. ERT has been shown to be well tolerated with minimal toxicity reported.

All requests for Taliglucerase Alfa must be completed using the Velaglucerase Alfa/Taliglucerase Alfa for Gaucher Disease Special Authorization Request Form (ABC 60070).

200 UNIT / VIAL INJECTION

00002425637 ELELYSO

PFI

\$ 648.3600

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

TEDUGLUTIDE

"Special authorization coverage may be provided for the treatment of adult patients (18 years of age or older) with short bowel syndrome (SBS) if all of the following criteria are met:

- SBS is a result of major intestinal resection (e.g., due to injury, volvulus, vascular disease, cancer, Crohn's Disease), and
- Resection has resulted in dependency on parenteral nutrition (PN) for at least 12 months, and
- PN is required at least three times weekly to meet caloric, fluid or electrolyte needs due to ongoing malabsorption, and
- PN frequency and volume have been stable for at least one month.

For coverage, the drug must be initiated and monitored by a specialist in gastroenterology or an internal medicine specialist with an interest in gastroenterology on a case-by-case basis, in geographic areas where access to this specialty is not available ('Specialist').

Initial coverage may be approved for up to 24 weeks of 0.05 mg/kg/day administered subcutaneously once daily.

- Patients will be limited to receiving a four week supply of teduglutide per prescription at their pharmacy.

For continued coverage beyond 24 weeks, the patient must meet the following criteria:

- 1) The patient must be assessed by the Specialist between weeks 20 and 24, after initiation of therapy to determine response.
- 2) The Specialist must confirm in writing that the patient is a 'responder' as demonstrated by:
 - at least a 20% reduction in weekly PN volume from baseline.

Following this assessment, continued coverage may be provided for 0.05 mg/kg/day administered subcutaneously once daily for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:

- 1) The patient has been assessed by the Specialist to determine response;
- 2) The Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
 - confirmation of maintenance of at least a 20% reduction in weekly PN volume from baseline."

5 MG / VIAL INJECTION

00002445727	REVESTIVE	SHB	\$	904.0000
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**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

TERIFLUNOMIDE

Relapsing Remitting Multiple Sclerosis (RRMS):

Special authorization coverage may be provided for the reduction of the frequency and severity of clinical relapses and reduction of the number and volume of active brain lesions, identified on MRI scans, in ambulatory patients with relapsing remitting multiple sclerosis.

Coverage

For coverage, this drug must be prescribed by a registered MS Neurologist. A current assessment must be completed by a registered MS Neurologist at every request.

To register to become an MS Neurologist please complete the Registration for MS Neurologist Status Form (ABC 60002).

Initial Coverage

- 1) The registered MS Neurologist must confirm a diagnosis of RRMS;
- 2) The patient must have active disease which is defined as at least two relapses* of MS during the previous two years or in the two years prior to starting an MS disease modifying therapy (DMT).

*A relapse is defined as the appearance of new symptoms or worsening of old symptoms, lasting at least 48 hours in the absence of fever, not associated with withdrawal from steroids. Onset of clinical relapses must be separated by a period of at least one month. At least one definite gadolinium-enhancing T1 MRI lesion (not questionable faint enhancement) obtained at least 90 days after initiation of the DMT and at least 90 days before or after a relapse may substitute for one clinical relapse.

- 3) The patient must be ambulatory with or without aid (The registered MS Neurologist must provide a current updated Expanded Disability Status Scale (EDSS) score less than or equal to 6.5).

Coverage may be approved for up to 12 months. Patients will be limited to receiving a one-month supply of teriflunomide per prescription at their pharmacy for the first 12 months of coverage.

Continued Coverage

For continued coverage beyond the initial coverage period, the patient must meet the following criteria:

- 1) The patient must be assessed by a registered MS Neurologist;
- 2) The registered MS Neurologist must confirm a diagnosis of RRMS;
- 3) The registered MS Neurologist must provide a current updated EDSS score. The patient must not have an EDSS score of 7.0 or above sustained for one year or more.

Coverage of this drug may be considered in a patient with a sustained EDSS score of 7.0 or above in exceptional circumstances. For MS DMT coverage to be considered, details of the exceptional circumstance must be provided in a letter from the registered MS Neurologist and accompany the Special Authorization Request Form.

Continued coverage may be approved for up to 12 months. Patients may receive up to 100 days' supply of teriflunomide per prescription at their pharmacy.

Restarting After an Interruption in Therapy Greater Than 12 Months

In order to be eligible for coverage, after an interruption in therapy greater than 12 months, the

ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

TERIFLUNOMIDE

patient must meet the following criteria:

- 1) At least one relapse* per 12 month period; or
- 2) At least two relapses* during the previous 24 month period.

All requests (including renewal requests) for teriflunomide must be completed using the Dimethyl Fumarate/Glatiramer Acetate/Interferon Beta-1a/Ocrelizumab/Peginterferon Beta-1a/Teriflunomide for RRMS/Interferon Beta-1b for SPMS or RRMS Special Authorization Request Form (ABC 60001).

14 MG ORAL TABLET				
00002416328	AUBAGIO	GZM	\$	58.3114

TESTOSTERONE

"For use in males for the treatment of congenital and acquired primary and secondary hypogonadism."

"Coverage cannot be considered when used for the treatment of androgen decline in the aging male (ADAM)."

"Special authorization may be granted for 6 months."

The following product(s) are eligible for auto-renewal.

12.2 MG TRANSDERMAL PATCH				
00002239653	ANDRODERM (2.5 MG/DAY)	ALL	\$	2.2217
24.3 MG TRANSDERMAL PATCH				
00002245972	ANDRODERM (5 MG/DAY)	ALL	\$	4.4433

TESTOSTERONE UNDECANOATE

"For use in males for the treatment of congenital and acquired primary and secondary hypogonadism."

"Coverage cannot be considered when used for the treatment of androgen decline in the aging male (ADAM)."

"Special authorization may be granted for 6 months."

The following product(s) are eligible for auto-renewal.

40 MG ORAL CAPSULE				
00002322498	PMS-TESTOSTERONE	PMS	\$	0.4700
00002421186	TARO-TESTOSTERONE	TAR	\$	0.4700

ALBERTA DRUG BENEFIT LIST
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TETRABENAZINE

"For the treatment of hyperkinetic movement disorders when prescribed by specialists in Neurology, Psychiatry, or Geriatric Medicine.

Special authorization may be granted for 6 months."

The following product(s) are eligible for auto-renewal.

25 MG ORAL TABLET

00002407590	APO-TETRABENAZINE	APX	\$	3.3746
00002402424	PMS-TETRABENAZINE	PMS	\$	3.3746
00002410338	TETRABENAZINE	STM	\$	3.3746
00002199270	NITOMAN	VCL	\$	7.4995

TICAGRELOR

(Refer to 20:12.18 of the Alberta Drug Benefit List for coverage of ticagrelor when prescribed by a specialist in Cardiology, Cardiac Surgery, Cardiovascular & Thoracic Surgery, Internal Medicine or General Surgery.)

For the treatment of Acute Coronary Syndrome, defined as unstable angina or myocardial infarction, when initiated in hospital in consultation with a Specialist in Cardiology, Cardiac Surgery, Cardiovascular & Thoracic Surgery, Internal Medicine or General Surgery. Treatment must be in combination with low dose ASA. Special authorization may be granted for 6 months.*

*Special Authorization is only required when the initiating prescriber is not a Specialist in Cardiology, Cardiac Surgery, Cardiovascular & Thoracic Surgery, Internal Medicine or General Surgery.

The following product(s) are eligible for auto-renewal.

90 MG ORAL TABLET

00002368544	BRILINTA	AZC	\$	1.5620
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ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

**TIOTROPIUM BROMIDE MONOHYDRATE/ OLODATEROL
HYDROCHLORIDE**

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD)

FIRST-LINE DRUG PRODUCT(S): LONG-ACTING BRONCHODILATOR (I.E., LONG-ACTING BETA-2 AGONIST [LABA] OR LONG-ACTING MUSCARINIC ANTAGONIST [LAMA])

"For the long-term maintenance treatment of airflow obstruction in patients with moderate to severe (i.e., FEV1 < 80% predicted) chronic obstructive pulmonary disease (COPD), who have an inadequate response to a long-acting bronchodilator (long-acting beta-2 agonist [LABA] or long-acting muscarinic antagonist [LAMA])."

"For the long-term maintenance treatment of airflow obstruction in patients with severe (i.e., FEV1 < 50% predicted) chronic obstructive pulmonary disease (COPD)."

"Special authorization may be granted for 24 months."

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

UP - First-line therapy ineffective

All requests for tiotropium bromide monohydrate + olodaterol hydrochloride must be completed using the Long-Acting Fixed-Dose Combination Products for Asthma/COPD Special Authorization Request Form (ABC 60025).

2.5 MCG / DOSE * 2.5 MCG / DOSE	INHALATION SOLUTION			
00002441888	INSPIOLTO RESPIMAT	BOE	\$	1.0576

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

TOCILIZUMAB

Rheumatoid Arthritis:

"Special authorization coverage may be provided for use in combination with methotrexate for the reduction in signs and symptoms of severely active Rheumatoid Arthritis (RA) in adult patients (18 years of age or older) who are refractory or intolerant to:

- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- Methotrexate with other disease modifying anti-rheumatic agent(s) (minimum 4-month trial). [e.g., methotrexate with hydroxychloroquine or methotrexate with sulfasalazine]; AND
- Leflunomide (minimum 10 week trial at 20 mg daily)

Special authorization coverage of this agent may be provided for use as monotherapy in adult patients for whom methotrexate is contraindicated and/or for those patients who have experienced serious adverse effects.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.

'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for 16 weeks as follows:
 - Tocilizumab intravenous infusion: one dose of 4 mg/kg or 8 mg/kg (up to a maximum of 800 mg per dose) of tocilizumab administered at 0, 4, 8, 12 and 16 weeks (total of 5 doses). Patients will be limited to receiving one dose of intravenous tocilizumab per prescription at their pharmacy.
 - Tocilizumab subcutaneous injection: for patients weighing less than 100 kg, initial coverage may be approved for one 162 mg dose of tocilizumab administered every other week, up to weekly based on clinical response. For patients weighing 100 kg or more, initial coverage may be approved for one 162 mg dose of tocilizumab administered every week. Patients will be limited to receiving a one-month supply of subcutaneous tocilizumab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another (with the exception of anakinra) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients will not be permitted to switch from anakinra to other biologic agents except under exceptional circumstances.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond the initial 16 weeks, the patient must meet the following criteria:

- 1) The patient must be assessed by an RA Specialist after 16 weeks, but no longer than 20 weeks after treatment to determine response.
- 2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

TOCILIZUMAB

the following criteria:

- ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND

- An improvement of 0.22 in HAQ score [reported to two (2) decimal places].

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be approved for a period of 12 months. Coverage for tocilizumab will be provided for one intravenous dose of 4 mg/kg to 8 mg/kg (up to a maximum of 800 mg per dose) every 4 weeks, or one 162 mg subcutaneous dose administered every one to two weeks (based on weight and clinical response). Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:

1) The patient has been assessed by an RA Specialist to determine response;

2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:

- Confirmation of maintenance of ACR20, OR

- Maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.

3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above."

All requests (including renewal requests) for tocilizumab for Rheumatoid Arthritis must be

completed using the

Abatacept/Adalimumab/Anakinra/Certolizumab/Etanercept/Golimumab/Infliximab/Sarilumab/Tocilizumab/Tofacitinib for Rheumatoid Arthritis Special Authorization Request Form (ABC 60027).

Systemic Juvenile Idiopathic Arthritis:

"Special authorization coverage may be provided for the treatment of active systemic juvenile idiopathic arthritis (sJIA) in patients 2 years of age and older when all of the following conditions are met:

- the patient has a diagnosis of systemic JIA with fever (greater than 38 degrees

Celsius) for at least two weeks and at least one of the following: rash of systemic JIA; serositis; lymphadenopathy; hepatomegaly; splenomegaly; AND

- the physician has ruled out other potential etiologies; AND

- the patient is refractory to one or more non-steroidal anti-inflammatory drugs (NSAIDs) and one or more systemic corticosteroids.

"Refractory" is defined as one or more of the following: lack of effect, serious adverse effects or contraindications to treatments as defined in the product monographs.

For coverage, this drug must be prescribed by a prescriber affiliated with a Pediatric Rheumatology Clinic in Edmonton or Calgary (Pediatric RA Specialist).

- Coverage may be approved for one dose of 12 mg/kg for patient weight less than 30 kg or 8 mg/kg for patient weight greater than or equal to 30 kg to a maximum of 800 mg, administered every two weeks for 12 weeks.

- Patients will be limited to receiving one month of tocilizumab per prescription at their pharmacy.

For continued coverage beyond 12 weeks, the patient must meet the following criteria:

1) The patient must be assessed by a Pediatric RA Specialist after 12 weeks, but no longer than 16 weeks after, treatment with this biologic agent to determine response.

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

TOCILIZUMAB

2) The Pediatric RA Specialist must confirm in writing that the patient is a responder as demonstrated by JIA ACR30 response and/or absence of fever and/or reduction in inflammatory markers [e.g., C-reactive protein (CRP) concentration of less than 15 mg/L or reduction in erythrocyte sedimentation rate (ESR)].

Following this assessment, continued coverage may be approved for one dose of 12 mg/kg for patient weight less than 30 kg or 8 mg/kg for patient weight greater than or equal to 30 kg to a maximum of 800 mg, administered every two weeks, for a maximum of twelve months. After twelve months, in order to be considered for continued coverage, the patient must meet the following criteria:

- 1) The patient has been re-assessed every 12 months by a Pediatric RA Specialist to determine response, AND
- 2) The Pediatric RA Specialist must confirm in writing that the patient has maintained a response to therapy."

All requests (including renewal requests) for tocilizumab for Systemic Juvenile Idiopathic Arthritis must be completed using the Tocilizumab for Systemic Juvenile Idiopathic Arthritis Special Authorization Request Form (ABC 60048).

Polyarticular Juvenile Idiopathic Arthritis:

"Special authorization coverage may be provided for the reduction in signs and symptoms of severely active polyarticular juvenile idiopathic arthritis (pJIA) in patients 2 years of age and older who:

- Have 5 or more active joints (defined by either swelling or limitation of motion plus pain and/or tenderness), AND
- Are refractory to one or more disease modifying anti-rheumatic agents (DMARDs) conventionally used in children (minimum three month trial).

"Refractory" is defined as one or more of the following: lack of effect, serious adverse effects (e.g., leukopenia, hepatitis) or contraindications to treatments as defined in the product monographs.

For coverage, this drug must be prescribed by a prescriber affiliated with a Pediatric Rheumatology Clinic in Edmonton or Calgary (Pediatric Rheumatology Specialist).

- Coverage may be approved for 10 mg/kg/dose for patients less than 30 kg, or 8 mg/kg/dose for patients 30 kg or greater every 4 weeks.
- Patients will be limited to receiving a one-month supply of tocilizumab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another (with the exception of abatacept) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients will not be permitted to switch from abatacept to other biologic agents except under exceptional circumstances.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage of this agent beyond 12 weeks, the patient must meet the following criteria:

- 1) The patient must be assessed by a Pediatric Rheumatology Specialist after 12 weeks, but no longer than 16 weeks after, treatment with this biologic agent to determine response.
- 2) The Pediatric Rheumatology Specialist must confirm in writing that the patient is a responder that meets the following criteria (ACR Pedi 30):
 - 30% improvement from baseline in at least three of the following six response

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

TOCILIZUMAB

variables, with worsening of 30% or more in no more than one of the six variables. The variables include:

- i. global assessment of the severity of the disease by the Pediatric Rheumatology Specialist,
- ii. global assessment of overall well-being by the patient or parent,
- iii. number of active joints (joints with swelling not due to deformity or joints with limitation of motion with pain tenderness or both),
- iv. number of joints with limitation of motion,
- v. functional ability based on CHAQ scores,
- vi. ESR or CRP

3) Data from all of the six variables comprising the ACR Pedi 30 and the CHAQ scores must be reported in each request.

Following this assessment, continued coverage may be approved for 10 mg/kg/dose for patients less than 30 kg, or 8 mg/kg/dose for patients 30 kg or greater every 4 weeks, for a maximum of twelve months. After twelve months, in order to be considered for continued coverage, the patient must be re-assessed every twelve months by a Pediatric Rheumatology Specialist and must meet the following criteria:

- 1) The patient has been assessed by a Pediatric Rheumatology Specialist to determine response, and
- 2) The Pediatric Rheumatology Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by maintenance of the ACR Pedi 30,
- 3) Data from all of the six variables comprising the ACR Pedi 30 and the CHAQ scores must be reported in each request.

Once a child with pJIA has had two disease-free years, it is common clinical practice for drug treatment to be stopped."

All requests (including renewal requests) for tocilizumab for Polyarticular Juvenile Idiopathic Arthritis must be completed using the Adalimumab/Etanercept/Tocilizumab for Polyarticular Juvenile Idiopathic Arthritis Special Authorization Request Form (ABC 60011).

80 MG / VIAL INJECTION

00002350092 ACTEMRA (4 ML)

HLR

\$ 182.8000

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

TOCILIZUMAB

Rheumatoid Arthritis:

"Special authorization coverage may be provided for use in combination with methotrexate for the reduction in signs and symptoms of severely active Rheumatoid Arthritis (RA) in adult patients (18 years of age or older) who are refractory or intolerant to:

- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- Methotrexate with other disease modifying anti-rheumatic agent(s) (minimum 4-month trial). [e.g., methotrexate with hydroxychloroquine or methotrexate with sulfasalazine]; AND
- Leflunomide (minimum 10 week trial at 20 mg daily)

Special authorization coverage of this agent may be provided for use as monotherapy in adult patients for whom methotrexate is contraindicated and/or for those patients who have experienced serious adverse effects.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.

'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for 16 weeks as follows:
 - Tocilizumab intravenous infusion: one dose of 4 mg/kg or 8 mg/kg (up to a maximum of 800 mg per dose) of tocilizumab administered at 0, 4, 8, 12 and 16 weeks (total of 5 doses). Patients will be limited to receiving one dose of intravenous tocilizumab per prescription at their pharmacy.
 - Tocilizumab subcutaneous injection: for patients weighing less than 100 kg, initial coverage may be approved for one 162 mg dose of tocilizumab administered every other week, up to weekly based on clinical response. For patients weighing 100 kg or more, initial coverage may be approved for one 162 mg dose of tocilizumab administered every week. Patients will be limited to receiving a one-month supply of subcutaneous tocilizumab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another (with the exception of anakinra) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients will not be permitted to switch from anakinra to other biologic agents except under exceptional circumstances.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond the initial 16 weeks, the patient must meet the following criteria:

- 1) The patient must be assessed by an RA Specialist after 16 weeks, but no longer than 20 weeks after treatment to determine response.
- 2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

TOCILIZUMAB

the following criteria:

- ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND

- An improvement of 0.22 in HAQ score [reported to two (2) decimal places].

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be approved for a period of 12 months. Coverage for tocilizumab will be provided for one intravenous dose of 4 mg/kg to 8 mg/kg (up to a maximum of 800 mg per dose) every 4 weeks, or one 162 mg subcutaneous dose administered every one to two weeks (based on weight and clinical response). Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:

1) The patient has been assessed by an RA Specialist to determine response;

2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:

- Confirmation of maintenance of ACR20, OR

- Maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.

3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above."

All requests (including renewal requests) for tocilizumab for Rheumatoid Arthritis must be

completed using the

Abatacept/Adalimumab/Anakinra/Certolizumab/Etanercept/Golimumab/Infliximab/Sarilumab/Tocilizumab/Tofacitinib for Rheumatoid Arthritis Special Authorization Request Form (ABC 60027).

Systemic Juvenile Idiopathic Arthritis:

"Special authorization coverage may be provided for the treatment of active systemic juvenile idiopathic arthritis (sJIA) in patients 2 years of age and older when all of the following conditions are met:

- the patient has a diagnosis of systemic JIA with fever (greater than 38 degrees Celsius) for at least two weeks and at least one of the following: rash of systemic JIA; serositis; lymphadenopathy; hepatomegaly; splenomegaly; AND

- the physician has ruled out other potential etiologies; AND

- the patient is refractory to one or more non-steroidal anti-inflammatory drugs (NSAIDs) and one or more systemic corticosteroids.

"Refractory" is defined as one or more of the following: lack of effect, serious adverse effects or contraindications to treatments as defined in the product monographs.

For coverage, this drug must be prescribed by a prescriber affiliated with a Pediatric Rheumatology Clinic in Edmonton or Calgary (Pediatric RA Specialist).

- Coverage may be approved for one dose of 12 mg/kg for patient weight less than 30 kg or 8 mg/kg for patient weight greater than or equal to 30 kg to a maximum of 800 mg, administered every two weeks for 12 weeks.

- Patients will be limited to receiving one month of tocilizumab per prescription at their pharmacy.

For continued coverage beyond 12 weeks, the patient must meet the following criteria:

1) The patient must be assessed by a Pediatric RA Specialist after 12 weeks, but no longer than 16 weeks after, treatment with this biologic agent to determine response.

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

TOCILIZUMAB

2) The Pediatric RA Specialist must confirm in writing that the patient is a responder as demonstrated by JIA ACR30 response and/or absence of fever and/or reduction in inflammatory markers [e.g., C-reactive protein (CRP) concentration of less than 15 mg/L or reduction in erythrocyte sedimentation rate (ESR)].

Following this assessment, continued coverage may be approved for one dose of 12 mg/kg for patient weight less than 30 kg or 8 mg/kg for patient weight greater than or equal to 30 kg to a maximum of 800 mg, administered every two weeks, for a maximum of twelve months. After twelve months, in order to be considered for continued coverage, the patient must meet the following criteria:

- 1) The patient has been re-assessed every 12 months by a Pediatric RA Specialist to determine response, AND
- 2) The Pediatric RA Specialist must confirm in writing that the patient has maintained a response to therapy."

All requests (including renewal requests) for tocilizumab for Systemic Juvenile Idiopathic Arthritis must be completed using the Tocilizumab for Systemic Juvenile Idiopathic Arthritis Special Authorization Request Form (ABC 60048).

Polyarticular Juvenile Idiopathic Arthritis:

"Special authorization coverage may be provided for the reduction in signs and symptoms of severely active polyarticular juvenile idiopathic arthritis (pJIA) in patients 2 years of age and older who:

- Have 5 or more active joints (defined by either swelling or limitation of motion plus pain and/or tenderness), AND
- Are refractory to one or more disease modifying anti-rheumatic agents (DMARDs) conventionally used in children (minimum three month trial).

"Refractory" is defined as one or more of the following: lack of effect, serious adverse effects (e.g., leukopenia, hepatitis) or contraindications to treatments as defined in the product monographs.

For coverage, this drug must be prescribed by a prescriber affiliated with a Pediatric Rheumatology Clinic in Edmonton or Calgary (Pediatric Rheumatology Specialist).

- Coverage may be approved for 10 mg/kg/dose for patients less than 30 kg, or 8 mg/kg/dose for patients 30 kg or greater every 4 weeks.
- Patients will be limited to receiving a one-month supply of tocilizumab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another (with the exception of abatacept) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients will not be permitted to switch from abatacept to other biologic agents except under exceptional circumstances.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage of this agent beyond 12 weeks, the patient must meet the following criteria:

- 1) The patient must be assessed by a Pediatric Rheumatology Specialist after 12 weeks, but no longer than 16 weeks after, treatment with this biologic agent to determine response.
- 2) The Pediatric Rheumatology Specialist must confirm in writing that the patient is a responder that meets the following criteria (ACR Pedi 30):
 - 30% improvement from baseline in at least three of the following six response

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

TOCILIZUMAB

variables, with worsening of 30% or more in no more than one of the six variables. The variables include:

- i. global assessment of the severity of the disease by the Pediatric Rheumatology Specialist,
- ii. global assessment of overall well-being by the patient or parent,
- iii. number of active joints (joints with swelling not due to deformity or joints with limitation of motion with pain tenderness or both),
- iv. number of joints with limitation of motion,
- v. functional ability based on CHAQ scores,
- vi. ESR or CRP

3) Data from all of the six variables comprising the ACR Pedi 30 and the CHAQ scores must be reported in each request.

Following this assessment, continued coverage may be approved for 10 mg/kg/dose for patients less than 30 kg, or 8 mg/kg/dose for patients 30 kg or greater every 4 weeks, for a maximum of twelve months. After twelve months, in order to be considered for continued coverage, the patient must be re-assessed every twelve months by a Pediatric Rheumatology Specialist and must meet the following criteria:

- 1) The patient has been assessed by a Pediatric Rheumatology Specialist to determine response, and
- 2) The Pediatric Rheumatology Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by maintenance of the ACR Pedi 30,
- 3) Data from all of the six variables comprising the ACR Pedi 30 and the CHAQ scores must be reported in each request.

Once a child with pJIA has had two disease-free years, it is common clinical practice for drug treatment to be stopped."

All requests (including renewal requests) for tocilizumab for Polyarticular Juvenile Idiopathic Arthritis must be completed using the Adalimumab/Etanercept/Tocilizumab for Polyarticular Juvenile Idiopathic Arthritis Special Authorization Request Form (ABC 60011).

200 MG / VIAL INJECTION

00002350106	ACTEMRA (10 ML)	HLR	\$	457.0000
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**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

TOCILIZUMAB

Rheumatoid Arthritis:

"Special authorization coverage may be provided for use in combination with methotrexate for the reduction in signs and symptoms of severely active Rheumatoid Arthritis (RA) in adult patients (18 years of age or older) who are refractory or intolerant to:

- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- Methotrexate with other disease modifying anti-rheumatic agent(s) (minimum 4-month trial). [e.g., methotrexate with hydroxychloroquine or methotrexate with sulfasalazine]; AND
- Leflunomide (minimum 10 week trial at 20 mg daily)

Special authorization coverage of this agent may be provided for use as monotherapy in adult patients for whom methotrexate is contraindicated and/or for those patients who have experienced serious adverse effects.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.

'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for 16 weeks as follows:
 - Tocilizumab intravenous infusion: one dose of 4 mg/kg or 8 mg/kg (up to a maximum of 800 mg per dose) of tocilizumab administered at 0, 4, 8, 12 and 16 weeks (total of 5 doses). Patients will be limited to receiving one dose of intravenous tocilizumab per prescription at their pharmacy.
 - Tocilizumab subcutaneous injection: for patients weighing less than 100 kg, initial coverage may be approved for one 162 mg dose of tocilizumab administered every other week, up to weekly based on clinical response. For patients weighing 100 kg or more, initial coverage may be approved for one 162 mg dose of tocilizumab administered every week. Patients will be limited to receiving a one-month supply of subcutaneous tocilizumab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another (with the exception of anakinra) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients will not be permitted to switch from anakinra to other biologic agents except under exceptional circumstances.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond the initial 16 weeks, the patient must meet the following criteria:

- 1) The patient must be assessed by an RA Specialist after 16 weeks, but no longer than 20 weeks after treatment to determine response.
- 2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

TOCILIZUMAB

the following criteria:

- ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND

- An improvement of 0.22 in HAQ score [reported to two (2) decimal places].

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be approved for a period of 12 months. Coverage for tocilizumab will be provided for one intravenous dose of 4 mg/kg to 8 mg/kg (up to a maximum of 800 mg per dose) every 4 weeks, or one 162 mg subcutaneous dose administered every one to two weeks (based on weight and clinical response). Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:

1) The patient has been assessed by an RA Specialist to determine response;

2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:

- Confirmation of maintenance of ACR20, OR

- Maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.

3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above."

All requests (including renewal requests) for tocilizumab for Rheumatoid Arthritis must be

completed using the

Abatacept/Adalimumab/Anakinra/Certolizumab/Etanercept/Golimumab/Infliximab/Sarilumab/Tocilizumab for Rheumatoid Arthritis Special Authorization Request Form (ABC 60027).

Systemic Juvenile Idiopathic Arthritis:

"Special authorization coverage may be provided for the treatment of active systemic juvenile idiopathic arthritis (sJIA) in patients 2 years of age and older when all of the following conditions are met:

- the patient has a diagnosis of systemic JIA with fever (greater than 38 degrees Celsius) for at least two weeks and at least one of the following: rash of systemic JIA; serositis; lymphadenopathy; hepatomegaly; splenomegaly; AND

- the physician has ruled out other potential etiologies; AND

- the patient is refractory to one or more non-steroidal anti-inflammatory drugs (NSAIDs) and one or more systemic corticosteroids.

"Refractory" is defined as one or more of the following: lack of effect, serious adverse effects or contraindications to treatments as defined in the product monographs.

For coverage, this drug must be prescribed by a prescriber affiliated with a Pediatric Rheumatology Clinic in Edmonton or Calgary (Pediatric RA Specialist).

- Coverage may be approved for one dose of 12 mg/kg for patient weight less than 30 kg or 8 mg/kg for patient weight greater than or equal to 30 kg to a maximum of 800 mg, administered every two weeks for 12 weeks.

- Patients will be limited to receiving one month of tocilizumab per prescription at their pharmacy.

For continued coverage beyond 12 weeks, the patient must meet the following criteria:

1) The patient must be assessed by a Pediatric RA Specialist after 12 weeks, but no longer than 16 weeks after, treatment with this biologic agent to determine response.

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

TOCILIZUMAB

2) The Pediatric RA Specialist must confirm in writing that the patient is a responder as demonstrated by JIA ACR30 response and/or absence of fever and/or reduction in inflammatory markers [e.g., C-reactive protein (CRP) concentration of less than 15 mg/L or reduction in erythrocyte sedimentation rate (ESR)].

Following this assessment, continued coverage may be approved for one dose of 12 mg/kg for patient weight less than 30 kg or 8 mg/kg for patient weight greater than or equal to 30 kg to a maximum of 800 mg, administered every two weeks, for a maximum of twelve months. After twelve months, in order to be considered for continued coverage, the patient must meet the following criteria:

- 1) The patient has been re-assessed every 12 months by a Pediatric RA Specialist to determine response, AND
- 2) The Pediatric RA Specialist must confirm in writing that the patient has maintained a response to therapy."

All requests (including renewal requests) for tocilizumab for Systemic Juvenile Idiopathic Arthritis must be completed using the Tocilizumab for Systemic Juvenile Idiopathic Arthritis Special Authorization Request Form (ABC 60048).

400 MG / VIAL INJECTION

00002350114	ACTEMRA (20 ML)	HLR	\$	914.0000
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ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

TOCILIZUMAB

Rheumatoid Arthritis

"Special authorization coverage may be provided for use in combination with methotrexate for the reduction in signs and symptoms of severely active Rheumatoid Arthritis (RA) in adult patients (18 years of age or older) who are refractory or intolerant to:

- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- Methotrexate with other disease modifying anti-rheumatic agent(s) (minimum 4-month trial). [e.g., methotrexate with hydroxychloroquine or methotrexate with sulfasalazine]; AND
- Leflunomide (minimum 10 week trial at 20 mg daily)

Special authorization coverage of this agent may be provided for use as monotherapy in adult patients for whom methotrexate is contraindicated and/or for those patients who have experienced serious adverse effects.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.

'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for 16 weeks as follows:
 - Tocilizumab intravenous infusion: one dose of 4 mg/kg or 8 mg/kg (up to a maximum of 800 mg per dose) of tocilizumab administered at 0, 4, 8, 12 and 16 weeks (total of 5 doses). Patients will be limited to receiving one dose of intravenous tocilizumab per prescription at their pharmacy.
 - Tocilizumab subcutaneous injection: for patients weighing less than 100 kg, initial coverage may be approved for one 162 mg dose of tocilizumab administered every other week, up to weekly based on clinical response. For patients weighing 100 kg or more, initial coverage may be approved for one 162 mg dose of tocilizumab administered every week. Patients will be limited to receiving a one-month supply of subcutaneous tocilizumab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another (with the exception of anakinra) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients will not be permitted to switch from anakinra to other biologic agents except under exceptional circumstances.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond the initial 16 weeks, the patient must meet the following criteria:

- 1) The patient must be assessed by an RA Specialist after 16 weeks, but no longer than 20 weeks after treatment to determine response.
- 2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
 - ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND
 - An improvement of 0.22 in HAQ score [reported to two (2) decimal places].

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

TOCILIZUMAB

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be approved for a period of 12 months. Coverage for tocilizumab will be provided for one intravenous dose of 4 mg/kg to 8 mg/kg (up to a maximum of 800 mg per dose) every 4 weeks, or one 162 mg subcutaneous dose administered every one to two weeks (based on weight and clinical response). Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:

- 1) The patient has been assessed by an RA Specialist to determine response;
- 2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
 - Confirmation of maintenance of ACR20, OR
 - Maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.
- 3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above."

All requests (including renewal requests) for tocilizumab for Rheumatoid Arthritis must be completed using the Abatacept/Adalimumab/Anakinra/Certolizumab/Etanercept/Golimumab/Infliximab/Sarilumab/Tocilizumab/Tofacitinib for Rheumatoid Arthritis Special Authorization Request Form (ABC 60027).

Giant Cell Arteritis

"Special authorization coverage may be provided for use in combination with glucocorticoids for the treatment of giant cell arteritis (GCA) in adult patients.

For coverage, this drug must be initiated in consultation with a Specialist in Internal Medicine, Rheumatology or Neurology.

Initial coverage may be approved for 12 weeks as follows:

- Coverage may be approved for one 162 mg subcutaneous dose of tocilizumab administered every week.
- As an interim measure, coverage will be provided for additional doses up to week 16, to allow time to determine whether the patient meets criteria for continued coverage below.
- Patients will be limited to receiving a one-month supply of subcutaneous tocilizumab per prescription at their pharmacy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond the initial 12 weeks, the patient must meet the following criteria:

- 1) The patient must be assessed after 12 weeks, but no longer than 16 weeks after treatment to determine response; AND
 - 2) The patient must be a 'responder' that meets the following criteria:
 - Patient has achieved remission which is defined as the absence of flare* AND normalization of C-reactive protein (CRP) to <1 mg/dL.
- *Flare is defined as the recurrence of signs or symptoms of GCA and/or erythrocyte sedimentation rate (ESR) greater or equal to 30 mm/hr attributable to GCA.

Following this assessment, continued coverage may be approved for one 162 mg subcutaneous dose administered every week for a period of 36 weeks.

Duration of therapy with tocilizumab will be limited to 52 weeks per treatment course. Re-treatment may be considered for patients who experience a disease flare after treatment discontinuation."

ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

TOCILIZUMAB

All requests (including renewal requests) for tocilizumab for Giant Cell Arteritis must be completed using the Tocilizumab for Giant Cell Arteritis Special Authorization Request Form (ABC 60066).

162 MG / SYR INJECTION SYRINGE

00002424770	ACTEMRA (0.9 ML SYRINGE)	HLR	\$	358.9050
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**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

TOFACITINIB CITRATE

Rheumatoid Arthritis:

"Special authorization coverage may be provided for use in combination with methotrexate for the reduction in signs and symptoms of severely active Rheumatoid Arthritis (RA) in adult patients (18 years of age or older) who are refractory or intolerant to:

- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- Methotrexate with other disease modifying anti-rheumatic agent(s) (minimum 4 month trial) [e.g., methotrexate with hydroxychloroquine or methotrexate with sulfasalazine]; AND
- Leflunomide (minimum 10 week trial at 20 mg daily).

Special authorization coverage of this agent may be provided for use as monotherapy in adult patients for whom methotrexate is contraindicated and/or for those patients who have experienced serious adverse effects.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.

'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for three months as follows:
- Tofacitinib 5 mg tablet: one tablet twice daily.
- Tofacitinib 11 mg extended-release tablet: one tablet daily.
- Patients will be limited to receiving a one-month supply of tofacitinib per prescription at their pharmacy.
- Patients will not be permitted to switch back to tofacitinib if they were deemed unresponsive to therapy.

For continued coverage beyond three months, the patient must meet the following criteria:

- 1) The patient must be assessed by an RA Specialist after the initial three months to determine response.
- 2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
 - ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND
 - An improvement of 0.22 in HAQ score [reported to two (2) decimal places].

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be approved for 5 mg twice daily or 11 mg once daily for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:

- 1) The patient has been assessed by an RA Specialist to determine response;
- 2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
 - confirmation of maintenance of ACR20, or
 - maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.
- 3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Coverage cannot be provided for tofacitinib when intended for use in combination with a biologic agent."

ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

TOFACITINIB CITRATE

All requests (including renewal requests) for tofacitinib for Rheumatoid Arthritis must be completed using the Abatacept/Adalimumab/Anakinra/Certolizumab/Etanercept/Golimumab/Infliximab/Sarilumab/Tocilizumab/Tofacitinib for Rheumatoid Arthritis Special Authorization Request Form (ABC 60027).

5 MG (BASE)	ORAL TABLET			
00002423898	XELJANZ	PFI	\$	24.5098

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

TOFACITINIB CITRATE

"Special authorization coverage may be provided for use in combination with methotrexate for the reduction in signs and symptoms of severely active Rheumatoid Arthritis (RA) in adult patients (18 years of age or older) who are refractory or intolerant to:

- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- Methotrexate with other disease modifying anti-rheumatic agent(s) (minimum 4 month trial) [e.g., methotrexate with hydroxychloroquine or methotrexate with sulfasalazine]; AND
- Leflunomide (minimum 10 week trial at 20 mg daily).

Special authorization coverage of this agent may be provided for use as monotherapy in adult patients for whom methotrexate is contraindicated and/or for those patients who have experienced serious adverse effects.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.

'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for three months as follows:
- Tofacitinib 5 mg tablet: one tablet twice daily.
- Tofacitinib 11 mg extended-release tablet: one tablet daily.
- Patients will be limited to receiving a one-month supply of tofacitinib per prescription at their pharmacy.
- Patients will not be permitted to switch back to tofacitinib if they were deemed unresponsive to therapy.

For continued coverage beyond three months, the patient must meet the following criteria:

- 1) The patient must be assessed by an RA Specialist after the initial three months to determine response.
- 2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:

- ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND
- An improvement of 0.22 in HAQ score [reported to two (2) decimal places].

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be approved for 5 mg twice daily or 11 mg once daily for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:

- 1) The patient has been assessed by an RA Specialist to determine response;
- 2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
 - confirmation of maintenance of ACR20, or
 - maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.
- 3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

TOFACITINIB CITRATE

Coverage cannot be provided for tofacitinib when intended for use in combination with a biologic agent."

All requests (including renewal requests) for tofacitinib for Rheumatoid Arthritis must be completed using the Abatacept/Adalimumab/Anakinra/Certolizumab/Etanercept/Golimumab/Infliximab/Sarilumab/Tocilizumab/Tofacitinib for Rheumatoid Arthritis Special Authorization Request Form (ABC 60027).

11 MG (BASE)	ORAL EXTENDED-RELEASE TABLET			
00002470608	XELJANZ XR	PFI	\$	49.0197

TRETINOIN

"For the treatment of severe acne as defined by scarring acne.

Special authorization may be granted for 6 months."

The following product(s) are eligible for auto-renewal.

0.025 % TOPICAL GEL				
00001926470	VITAMIN A ACID	VCL	\$	0.3429
0.05 % TOPICAL GEL				
00001926489	VITAMIN A ACID	VCL	\$	0.3429
0.01 % TOPICAL CREAM				
00000657204	STIEVA-A	GSK	\$	0.3084
0.025 % TOPICAL CREAM				
00000578576	STIEVA-A	GSK	\$	0.3084
0.05 % TOPICAL CREAM				
00000518182	STIEVA-A	GSK	\$	0.2060
0.01 % TOPICAL GEL				
00001926462	VITAMIN A ACID	VCL	\$	0.3429

TROSPIUM CHLORIDE

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

FIRST-LINE DRUG PRODUCT(S): SOLIFENACIN OR TOLTERODINE LA

"For patients who have failed on or are intolerant to solifenacin or tolterodine LA."

"Special authorization may be granted for 24 months."

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

UP - First-line therapy ineffective

UQ - First-line therapy not tolerated

20 MG ORAL TABLET				
00002488353	MAR-TROSPIUM	MAR	\$	0.6108
00002275066	TROSEC	SUN	\$	0.7820

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

UMECLIDINIUM BROMIDE/ VILANTEROL TRIFENATATE

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD)

FIRST-LINE DRUG PRODUCT(S): LONG-ACTING BRONCHODILATOR (I.E., LONG-ACTING BETA-2 AGONIST [LABA] OR LONG-ACTING MUSCARINIC ANTAGONIST [LAMA])

"For the long-term maintenance treatment of airflow obstruction in patients with moderate to severe (i.e., FEV1 < 80% predicted) chronic obstructive pulmonary disease (COPD), who have an inadequate response to a long-acting bronchodilator (long-acting beta-2 agonist [LABA] or long-acting muscarinic antagonist [LAMA])."

"For the long-term maintenance treatment of airflow obstruction in patients with severe (i.e., FEV1 < 50% predicted) chronic obstructive pulmonary disease (COPD)."

"Special authorization may be granted for 24 months."

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

UP - First-line therapy ineffective

All requests for umeclidinium bromide + vilanterol trifenate must be completed using the Long-Acting Fixed-Dose Combination Products for Asthma/COPD Special Authorization Request Form (ABC 60025).

62.5 MCG / DOSE (BASE) * 25 MCG / DOSE (BASE)	INHALATION	METERED INHALATION POWDER	
00002418401 ANORO ELLIPTA		GSK	\$ 2.8350

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

USTEKINUMAB

Plaque Psoriasis

"Special authorization coverage may be provided for the reduction in signs and symptoms of severe, debilitating plaque psoriasis in patients who:

- Have a total PASI of 10 or more and a DLQI of more than 10, OR
- Who have significant involvement of the face, palms of the hands, soles of the feet or genital region; AND
- Who are refractory to or intolerant to:
at least THREE of the following:
 - Cosentyx (secukinumab)
 - Inflectra (infliximab)
 - Renflexis (infliximab)
 - Skyrizi (risankizumab)
 - Taltz (ixekizumab)

AND

- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory, OR
- Cyclosporine (6 weeks treatment); AND
- Phototherapy (unless restricted by geographic location)

Patients who have a contraindication to either cyclosporine or methotrexate will be required to complete an adequate trial of the other pre-requisite medication prior to potential coverage being considered.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.

'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be prescribed by a Specialist in Dermatology ("Dermatology Specialist").

- Initial coverage may be approved for three doses of 45 mg (90 mg for patients weighing greater than 100 kg) at weeks 0, 4 and 16.
- Patients will be limited to receiving one dose per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage, the patient must meet all of the following criteria:

- 1) The patient must be assessed by a Dermatology Specialist after the initial 16 weeks of therapy to determine response.
- 2) The Dermatology Specialist must confirm, in writing, that the patient is a 'responder' that meets the following criteria:
 - Greater than or equal to 75% reduction in PASI score, OR
 - Greater than or equal to 50% reduction in PASI score AND improvement of greater than or equal to 5 points in the DLQI.

Following this assessment, continued coverage may be considered for 45 mg (90 mg for patients weighing greater than 100 kg) every 12 weeks for a period of 12 months. Ongoing coverage may be considered if the patient is re-assessed by a Dermatology Specialist every 12

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

USTEKINUMAB

months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above."

PASI and DLQI scores are required for all requests for Plaque Psoriasis including those requests for patients that have significant involvement of the face, palms, soles of feet or genital region.

All requests (including renewal requests) for ustekinumab for Plaque Psoriasis must be completed using the Adalimumab/Etanercept/Infliximab/Ixekizumab/Risankizumab/Secukinumab/Ustekinumab for Plaque Psoriasis Special Authorization Request Form (ABC 60030).

45 MG INJECTION VIAL OR SYRINGE				
00002320673	STELARA (0.5 ML VIAL OR SYRINGE)	JAI	\$	4465.5800
<i>For this product - pricing has been established on a per vial or syringe basis.</i>				
90 MG / SYR INJECTION SYRINGE				
00002320681	STELARA (1.0 ML SYRINGE)	JAI	\$	4465.5800

VARENICLINE TARTRATE

For subsequent prescriptions, patients may obtain this product via special authorization with the following criteria for coverage:

"For use in patients 18 years of age and older for smoking cessation treatment in conjunction with smoking cessation counseling.

Special authorization coverage may be granted for a maximum of 24 weeks of therapy per year."

This product is not eligible for auto-renewal.

0.5 MG (BASE) ORAL TABLET				
00002419882	APO-VARENICLINE	APX	\$	0.9237
00002426226	TEVA-VARENICLINE	TEV	\$	0.9237
00002291177	CHAMPIX	PFI	\$	1.9116
1 MG (BASE) ORAL TABLET				
00002419890	APO-VARENICLINE	APX	\$	0.9235
00002426234	TEVA-VARENICLINE	TEV	\$	0.9235
00002291185	CHAMPIX	PFI	\$	1.9077

VARENICLINE TARTRATE/ VARENICLINE TARTRATE

For subsequent prescriptions, patients may obtain this product via special authorization with the following criteria for coverage:

"For use in patients 18 years of age and older for smoking cessation treatment in conjunction with smoking cessation counseling.

Special authorization coverage may be granted for a maximum of 24 weeks of therapy per year."

This product is not eligible for auto-renewal.

0.5 MG * 1 MG ORAL TABLET				
00002435675	APO-VARENICLINE (STARTER PACK)	APX	\$	0.9203
00002426781	TEVA-VARENICLINE (STARTER PACK)	TEV	\$	0.9203
00002298309	CHAMPIX (STARTER PACK)	PFI	\$	1.9013

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

VEDOLIZUMAB

Moderately to Severely Active Crohn's Disease

"Special authorization coverage may be approved for coverage of vedolizumab for the reduction in signs and symptoms and induction and maintenance of clinical remission of Moderately to Severely Active Crohn's Disease in patients who meet the following criteria:

- vedolizumab must be prescribed by a Specialist in Gastroenterology or a physician appropriately trained by the University of Alberta or the University of Calgary and recognized as a prescriber by Alberta Blue Cross for coverage for the treatment of Moderately to Severely Active Crohn's Disease patients ('Specialist').
- Patients must be 18 years of age or older to be considered for coverage of vedolizumab.
- Patients will be limited to receiving one dose of vedolizumab per prescription at their pharmacy.
- Patients may be allowed to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy (both primary loss of response and secondary loss of response) or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

Prior to initiation of vedolizumab therapy for New Patients:

'New Patients' are patients who have never been treated with vedolizumab by any health care provider.

Moderately to Severely Active Crohn's Disease:

Prior to initiation of vedolizumab therapy, New Patients must have a current Modified (without the physical exam) Harvey Bradshaw Index score of greater than or equal to 7 (New Patient's Baseline Score), AND be Refractory.

Refractory is defined as one or more of the following:

- 1) Serious adverse effects or reactions to the treatments specified below; OR
- 2) Contraindications (as defined in product monographs) to the treatments specified below; OR
- 3) Previous documented lack of effect at doses and for duration of all treatments specified below:
 - a) mesalamine: minimum of 3 grams/day for a minimum of 6 weeks; AND refractory to, or dependent on, glucocorticoids: following at least one tapering dosing schedule of 40 mg/day, tapering by 5 mg each week to 20 mg, then tapering by 2.5 mg each week to zero, or similar. [Note: Patients who have used the above treatments in combination will not be required to be challenged with individual treatments as monotherapy]

AND

b) Immunosuppressive therapy as follows:

- Azathioprine: minimum of 2 mg/kg/day for a minimum of 3 months; OR
- 6-mercaptopurine: minimum of 1 mg/kg/day for a minimum of 3 months; OR
- Methotrexate: minimum of 15 mg/week for a minimum of 3 months.

OR

- Immunosuppressive therapy discontinued at less than 3 months due to serious adverse effects or reactions.

Applications for coverage must include information regarding the dosages and duration of trial of each treatment the patient received, a description of any adverse effects, reactions, contraindications and/or lack of effect, as well as any other information requested by Alberta Blue Cross.

Coverage Criteria for Moderately to Severely Active Crohn's Disease

- New Patients must meet the criteria above prior to being considered for approval.
- All approvals are also subject to the following applicable criteria.

Induction Dosing for New Patients:

- Coverage for Induction Dosing may only be approved for New Patients (those who have never

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

VEDOLIZUMAB

been treated with vedolizumab by any health care provider).

- 'Induction Dosing' means a maximum of one 300 mg dose of vedolizumab per New Patient at 0, 2 and 6 weeks (for a maximum total of three doses).
- New Patients are eligible to receive Induction Dosing only once, after which time the Maintenance Dosing for New Patients and Continued Coverage for Maintenance Dosing criteria will apply.

Maintenance Dosing:

'Maintenance Dosing' means one 300 mg dose of vedolizumab per patient every eight (8) weeks for a period of 12 months to:

- New Patients following the completion of Induction Dosing; OR
- Existing Patients, who are patients that are being treated, or have previously been treated, with vedolizumab.

Maintenance Dosing for New Patients after Completion of Induction Dosing:

- The New Patient must be assessed by a Specialist between weeks 10 and 14 after the initiation of Induction Dosing to determine response by obtaining a Modified Harvey Bradshaw Index score for patients with Moderately to Severely Active Crohn's Disease; AND
- The Specialist must confirm the Modified Harvey Bradshaw Index score shows a decrease from the New Patient's Baseline Score of greater than or equal to 3 points for patients with Moderately to Severely Active Crohn's.

Maintenance Dosing for Existing Patients:

- The patient must be assessed by a Specialist at least 4 to 8 weeks after the day the last dose of vedolizumab was administered to the patient and prior to administration of the next dose to obtain: a Modified Harvey Bradshaw Index Score (Existing Patient's Baseline Score) for Moderately to Severely Active Crohn's; AND
- these measures must be provided to Alberta Blue Cross for assessment for continued coverage for maintenance dosing.

Continued Coverage for Maintenance Dosing:

-Continued coverage may be considered for one 300 mg dose of vedolizumab per patient provided no more often than every 8 weeks for a period of 12 months, if the following criteria are met at the end of each 12 month period:

- The New Patient or the Existing Patient must be assessed by a Specialist at least 4 to 6 weeks after the day the last dose of vedolizumab was administered to the patient and prior to the administration of the next dose to obtain a Modified Harvey Bradshaw Index Score for Moderately to Severely Active Crohn's; AND
- For New Patients: The Specialist must confirm that the patient has maintained a greater than or equal to 3 point decrease from the New Patient's Baseline Score for Moderately to Severely Active Crohn's; OR
- For Existing Patients: The Specialist must confirm that the patient has maintained the Existing Patient's Baseline Score."

All requests (including renewal requests) for vedolizumab for Moderately to Severely Active Crohn's Disease must be completed using the Adalimumab/Vedolizumab for Crohn's/Infliximab for Crohn's/Fistulizing Crohn's Special Authorization Request Form (ABC 60031).

Ulcerative Colitis

"Special authorization coverage may be provided for the reduction in signs and symptoms and induction and maintenance of clinical remission of Ulcerative Colitis in adult patients (18 years of age or older) with active disease (characterized by a partial Mayo score >4 prior to initiation of biologic therapy) and who are refractory or intolerant to:

- mesalamine: minimum of 4 grams/day for a minimum of 4 weeks

AND

- corticosteroids (failure to respond to prednisone 40 mg daily for 2 weeks, or; steroid dependent

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

VEDOLIZUMAB

i.e. failure to taper off steroids without recurrence of disease or disease requiring a second dose of steroids within 12 months of previous dose).

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.

'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

Immunosuppressive therapy as follows may also be initiated if in the clinician's judgment a trial is warranted:

- i) Azathioprine: minimum of 2 mg/kg/day for a minimum of 2 months; OR
- ii) 6-mercaptopurine: minimum of 1 mg/kg/day for a minimum of 2 months

For coverage, this drug must be prescribed by a Specialist in Gastroenterology or a physician appropriately trained by the University of Alberta or the University of Calgary and recognized as a prescriber by Alberta Blue Cross ('Specialist').

Initial coverage may be approved for three doses of 300 mg of vedolizumab at 0, 2 and 6 weeks.

- Patients will be limited to receiving a one dose of vedolizumab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond three doses, the patient must meet the following criteria:

1) The patient must be assessed by a Specialist between weeks 10 and 12 after the initiation of therapy to determine response.

2) The Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:

- a decrease in the partial Mayo score of greater than or equal to 2 points

Following this assessment, continued coverage may be approved for a dose of 300 mg every 8 weeks for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:

1) The patient has been assessed by a Specialist in Gastroenterology to determine response;

2) The Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:

- a decrease in the partial Mayo score of greater than or equal to 2 points from the score prior to initiation of vedolizumab therapy."

All requests (including renewal requests) for vedolizumab for Ulcerative Colitis must be completed using the Adalimumab/Golimumab/Infliximab/Vedolizumab for Ulcerative Colitis Special Authorization Request Form (ABC 60008).

300 MG / VIAL INJECTION

00002436841 ENTYVIO

TAK

\$ 3290.0000

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

VELAGLUCERASE ALFA

For long-term enzyme replacement therapy (ERT) for pediatric and adult patients with type 1 Gaucher disease (GD) when the following criteria are met:

1. The diagnosis of GD must have been established by the demonstration of specific deficiency of glucocerebrosidase (GCase) in tissue or cultured skin fibroblasts, or by demonstration of the presence, in tissue or peripheral blood leukocytes, of mutations in the GCase gene known to result in severe enzyme deficiency.
2. Other potentially confounding diagnoses, such as Hodgkin disease or other storage disorders, must have been ruled out. The symptoms experienced by the patient should be shown to be attributable to GD and not some other condition that might mimic it. A trial of therapy would normally be considered in situations of uncertainty only if the symptoms were accompanied by objective evidence (hematological or imaging changes consistent with complaints).
3. The patient should not have any GD-related or other medical condition that might reasonably be expected to compromise their response to treatment. In some patients with GD, secondary pathologic changes, such as avascular necrosis of bone, may already have occurred that would not be expected to respond to enzyme replacement. In such patients, reversal of the pathology is unlikely. Treatment of patients with significant secondary pathology would be directed at preventing further progression of the disease. In these cases, the extent to which symptoms, such as bone pain, are due to active progression of the disease, rather than the secondary pathology, may only be established by a trial of therapy.
4. Treatment should be provided under the care of a specialist with experience in the diagnosis and management of GD.
5. None of the following exclusion criteria apply:
 - a. The presence of any GD-related condition that might reasonably be expected to compromise a response to therapy
 - b. The presence of another medical condition that might reasonably be expected to compromise a response to therapy
 - c. Asymptomatic GD
 - d. The presence of primary neurological disease due to GD
6. Patients must have the following baseline parameters assessed prior to initiating therapy on velaglycerase alfa:
 - a. Hemoglobin level and platelet count
 - b. Presence of splenic infarction, bone crises, radiographic or MRI evidence of incipient destruction of any major joint, spontaneous fractures, chronic bone pain, major joint replacement, liver synthetic dysfunction, symptomatic hepatosplenomegaly, progressive pulmonary disease due to GD, or growth failure in children.

Notes:

- Pregnancy is not considered a contraindication to ERT.
- Patients to be considered for reimbursement of drug costs for ERT must be willing to participate in the long term evaluation of the efficacy of treatment by periodic medical assessment. Failure to comply with recommended medical assessment and investigations may result in withdrawal of financial support of drug therapy.

Initial coverage may be approved at a dosage of up to 60 units/kg every 2 weeks for a period of 6 months.

Ongoing coverage may be considered for up to 60 units/kg every 2 weeks for a period of 6 months at a time during the first 2 years of treatment, and thereafter for 12-month periods, only if the following criteria are met:

- The patient demonstrates all of the following expected treatment outcomes, where applicable:
 1. For patients with baseline hemoglobin <85% of lower limit of age- and sex-appropriate normal: Increase hemoglobin levels to >110 g/L for women and children and >120 g/L for men
 2. For patients with a baseline platelet count <50 x 10⁹/L on two separate occasions at least

ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

VELAGLUCERASE ALFA

one month apart:

- a. Increase platelet count to level sufficient to prevent spontaneous bleeding
- b. Normalization of platelet count in splenectomized patients
- c. In patients with intact spleen, an increase of at least 1.5X in baseline platelet count
3. For patients with a prior splenic infarct at baseline:
 - a. Reduction of spleen volume by at least 50%
 - b. Prevention of further splenic infarcts
4. Prevention of bone crises
5. For patients with radiographic or MRI evidence of incipient destruction of any major joint at baseline: Improvement in imaging parameters (either MRI, QCSI2, or BMD)
6. Prevention of spontaneous fractures
7. Reduced bone pain in patients with chronic bone pain at baseline
8. Optimize surgical outcome for major joint replacement surgery where required at baseline. No new major joint replacement surgery thereafter.
9. Improvement in liver function in patients with liver synthetic dysfunction at baseline
10. For patients with symptomatic hepatosplenomegaly at baseline:
 - a. Reduction of spleen volume by at least 50%
 - b. Reduction in liver volume by at least 30%
11. For patients with progressive pulmonary disease due to GD at baseline:
 - a. Improvement in pulmonary hypertension
 - b. Improvement in oxygenation
 - c. Reversal of hepatopulmonary syndrome
12. For children with growth failure at baseline: Return to normal range on height percentiles

- Treatment should be discontinued if the above treatment outcomes have not been demonstrated, as evidenced by readings consistent over the previous 12-month period at the maximum dosage of 60 units/kg every 2 weeks.

Patients will be limited to receiving a one-month supply of velaglucerase alfa per prescription at their pharmacy.

Coverage cannot be provided for velaglucerase alfa when this medication is intended for use in combination with other ERT.

Patients will not be permitted to switch back to a previously trialed ERT if they were deemed sub-optimally responsive despite maximum doses.

The dosage of velaglucerase alfa prescribed would depend on the severity of the disease and would be at the discretion of the specialist. The efficacy of treatment should be re-evaluated every 6 months and dosage adjustments made as appropriate. If there has been insufficient response to treatment after 6 months on a lower dose, the dosage may be increased to a maximum of 60 units/kg every 2 weeks. In the event of severe drug reaction, treatment may have to be discontinued. ERT has been shown to be well tolerated with minimal toxicity reported.

All requests for Velaglucerase Alfa must be completed using the Velaglucerase Alfa/Taliglucerase Alfa for Gaucher Disease Special Authorization Request Form (ABC 60070).

400 UNIT / VIAL INJECTION

00002357119 VPRIV

SHG

\$ 1955.0000

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

VORICONAZOLE

(Refer to Section 1 - Restricted Benefits of the Alberta Drug Benefit List for coverage of the product when prescribed by a Specialist in Infectious Diseases or a designated prescriber.)

"For the treatment of invasive aspergillosis for post-hospital discharge only."*

"For treatment of culture proven invasive candidiasis with documented resistance to fluconazole."*

"This medication must be prescribed in consultation with a specialist in Infectious Diseases."

*Special Authorization is only required when the prescriber prescribing the medication is not a Specialist in Infectious Diseases or a designated prescriber.

50 MG ORAL TABLET

00002399245	SANDOZ VORICONAZOLE	SDZ	\$	6.7818
00002396866	TEVA-VORICONAZOLE	TEV	\$	6.7818
00002256460	VFEND	PFI	\$	13.3516

200 MG ORAL TABLET

00002399253	SANDOZ VORICONAZOLE	SDZ	\$	26.4807
00002396874	TEVA-VORICONAZOLE	TEV	\$	26.4807
00002256479	VFEND	PFI	\$	53.3843

40 MG / ML ORAL SUSPENSION

00002279991	VFEND	PFI	\$	10.5318
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200 MG / VIAL INJECTION

00002477696	VORICONAZOLE INJECTION	JPC	\$	136.5800
00002256487	VFEND	PFI	\$	160.0204

ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

ZOLEDRONIC ACID

Osteoporosis:

"For the treatment of osteoporosis in patients who have:

A high 10-year risk (i.e., greater than 20%) of experiencing a major osteoporotic fracture,

OR

A moderate 10-year fracture risk (10-20%) and have experienced a prior fragility fracture;

AND

at least one of the following:

1) For whom oral bisphosphonates are contraindicated due to an abnormality of the esophagus which delays esophageal emptying;

OR

2) Who have demonstrated persistent severe gastrointestinal intolerance to a course of therapy with either alendronate or risedronate;

OR

3) Who had an unsatisfactory response (defined as a fragility fracture despite adhering to oral alendronate or risedronate treatment fully for 1 year and evidence of a decline in BMD below pre-treatment baseline level).

Note: The fracture risk can be determined by the World Health Organization's fracture risk assessment tool, FRAX, or the most recent (2010) version of the Canadian Association of Radiologists and Osteoporosis Canada (CAROC) table.

Special Authorization may be granted for 12 months.

-Patients will be limited to receiving one dose of zoledronic acid per prescription at their pharmacy.

-Coverage cannot be provided for two or more osteoporosis medications (alendronate, denosumab, raloxifene, risedronate, zoledronic acid) when these medications are intended for use as combination therapy.

-Requests for other osteoporosis medications covered via special authorization will not be considered until 6 months after the last dose of denosumab 60 mg/syr injection syringe.

-Requests for other osteoporosis medications covered via special authorization will not be considered until 12 months after the last dose of zoledronic acid 0.05 mg/ml injection."

-This product is eligible for auto-renewal for the treatment of osteoporosis.

All requests for zoledronic acid for osteoporosis must be completed using the Denosumab/Zoledronic Acid for Osteoporosis Special Authorization Request Form (ABC 60007).

Paget's Disease:

"For the treatment of Paget's disease. Special Authorization for this criterion may be granted for one dose per 12 month period."

"Coverage cannot be provided for two or more medications used in the treatment of

**ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

ZOLEDRONIC ACID

Paget's disease when these medications are intended for use in combination or when therapy with two or more medications overlap."

0.05 MG / ML INJECTION

00002415100	TARO-ZOLEDRONIC ACID	TAR	\$	3.3540
00002422433	ZOLEDRONIC ACID	DRL	\$	3.3540
00002269198	ACLASTA	NOV	\$	7.3329

"For the treatment of tumor-induced hypercalcemia in patients with documented evidence of intolerance or lack of response to clodronate or pamidronate.

For the prevention of skeletal-related events in patients with metastatic castration-resistant prostate cancer (CRPC) with one or more bony metastases.

Special authorization may be granted for 6 months."

The following product(s) are eligible for auto-renewal.

0.8 MG / ML INJECTION

00002482525	JAMP-ZOLEDRONIC ACID	JPC	\$	38.7856
00002415186	TARO-ZOLEDRONIC ACID CONCENTRATE	TAR	\$	38.7856
00002407639	ZOLEDRONIC ACID	TEV	\$	38.7856
00002444739	ZOLEDRONIC ACID	MDA	\$	38.7856
00002401606	ZOLEDRONIC ACID - Z	SDZ	\$	38.7856
00002422425	ZOLEDRONIC ACID CONCENTRATE	DRL	\$	38.7856
00002472805	ZOLEDRONIC ACID FOR INJECTION	MAR	\$	38.7856
00002248296	ZOMETA CONCENTRATE	NOV	\$	119.8460

ZOLMITRIPTAN

(Refer to 28:32.28 of the Alberta Drug Benefit List for coverage of patients 18 to 64 years of age inclusive.)

"For the treatment of acute migraine attacks in patients 65 years of age and older where other standard therapy has failed."

"For the treatment of acute migraine attacks in patients 65 years of age and older who have been using zolmitriptan prior to turning 65."

"Special authorization for both criteria may be granted for 24 months."

In order to comply with the first criteria, information is required regarding previous medications utilized and the patient's response to therapy.

The following product(s) are eligible for auto-renewal.

2.5 MG ORAL TABLET

00002458780	CCP-ZOLMITRIPTAN	CEL	\$	3.5375
00002421623	JAMP-ZOLMITRIPTAN	JPC	\$	3.5375
00002419521	MINT-ZOLMITRIPTAN	MPI	\$	3.5375
00002421534	NAT-ZOLMITRIPTAN	NTP	\$	3.5375
00002324229	PMS-ZOLMITRIPTAN	PMS	\$	3.5375
00002362988	SANDOZ ZOLMITRIPTAN	SDZ	\$	3.5375
00002313960	TEVA-ZOLMITRIPTAN	TEV	\$	3.5375
00002238660	ZOMIG	AZC	\$	14.9600

2.5 MG ORAL DISPERSIBLE TABLET

00002428237	JAMP-ZOLMITRIPTAN ODT	JPC	\$	1.7532
00002428474	SEPTA-ZOLMITRIPTAN-ODT	SEP	\$	1.7532
00002243045	ZOMIG RAPIMELT	AZC	\$	14.9600

ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

ZOLMITRIPTAN

5 MG / DOSE NASAL UNIT DOSE SPRAY

00002248993 ZOMIG

AZC

\$ 14.9600
