

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 and Wellness-sponsored drug programs. (For Alberta Human Services and Alberta Seniors (AISH) 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 and Wellness 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 Health and Wellness 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).

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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 and Wellness 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.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.

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

Criteria for Coverage

Wording that appears within quotation marks (“ ”) in this section is the official special authorization criteria, as recommended by the Alberta Health and Wellness Expert Committee on Drug Evaluation and Therapeutics, and approved by the Minister of Health and Wellness. 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	ABB
75 MG	ORAL TABLET	
DIN N/A*	CYLERT	ABB

**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.

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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 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.
- 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 between 12 and 16 weeks of receiving the initial dose.

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 dose of up to 1000 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;

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 abatacept for Rheumatoid Arthritis must be completed using the Abatacept/Adalimumab/Anakinra/Etanercept/Golimumab/Infliximab/Tocilizumab for Rheumatoid Arthritis Special Authorization Request Form (ABC 30902).

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 (JIA) 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 (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.

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 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 (JRA30):
 - 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 JRA30 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 JRA30 variables for JIA 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)."

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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 Juvenile Idiopathic Arthritis must be completed using the Abatacept for Juvenile Idiopathic Arthritis Special Authorization Request Form (ABC 31291).

250 MG / VIAL (BASE)	INJECTION		
00002282097	ORENCIA	BMS	\$ 460.9097

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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 who agrees to and continues to actively and consistently participate in the Alberta Post-Marketing Study ("Study") as required by Alberta Health and Wellness or its agent, throughout the special authorization approval period ("RA Specialist"). The patient must also provide all consents and authorizations required to permit the RA Specialist to actively and consistently participate in the Study. Special authorization approval for the patient may be revoked if the RA Specialist does not continually, actively and consistently participate in the Study.

- 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:

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- 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/Etanercept/Golimumab/Infliximab/Tocilizumab for Rheumatoid Arthritis Special Authorization Request Form (ABC 30902).

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 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 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:

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- 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/Etanercept/Golimumab/Infliximab for Psoriatic Arthritis Special Authorization Request Form (ABC 30964).

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 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.

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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."

All requests (including renewal requests) for adalimumab for Ankylosing Spondylitis must be completed using the Adalimumab/Etanercept/Golimumab/Infliximab for Ankylosing Spondylitis Special Authorization Request Form (ABC 31195).

Moderately to Severely 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.
- 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,

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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 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

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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 for Crohn's/Infliximab for Crohn's/Fistulizing Crohn's Special Authorization Request Form (ABC 31200).

Plaque Psoriasis:

"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:

- 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

ALBERTA HEALTH AND WELLNESS DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

ADALIMUMAB

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."

All requests (including renewal requests) for adalimumab for Plaque Psoriasis must be completed using the Adalimumab/Etanercept/Infliximab/Ustekinumab for Plaque Psoriasis Special Authorization Request Form (ABC 31192).

40 MG / SYR INJECTION SYRINGE

00002258595 HUMIRA

ABB

\$ 729.4200

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

ALENDRONATE SODIUM

"For the treatment of osteoporosis in patients who have documented hip, vertebral or other fractures. Special authorization may be granted for 6 months."

"For the treatment of osteoporosis in patients with documented evidence of intolerance or lack of response to etidronate (i.e. demonstrated as a > 2% loss in bone mineral density in one year). Special authorization for this criteria may be granted for 6 months."

"Coverage cannot be provided for two or more osteoporosis medications (alendronate, calcitonin, denosumab, etidronate, raloxifene, risedronate) 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."

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

All requests for alendronate sodium for Osteoporosis must be completed using the Alendronate/Raloxifene/Risedronate/Synthetic Calcitonin Salmon for Osteoporosis Special Authorization Request Form (ABC 31086).

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

10 MG ORAL TABLET

00002248728	APO-ALENDRONATE	APX	\$	0.6911
00002288087	SANDOZ ALENDRONATE	SDZ	\$	0.6911
00002247373	TEVA-ALENDRONATE	TEV	\$	0.6911

40 MG ORAL TABLET

00002258102	CO ALENDRONATE	COB	\$	2.6097
00002201038	FOSAMAX	MFC	\$	4.0743

70 MG ORAL TABLET

00002352966	ALENDRONATE	SNS	\$	3.5835
00002299712	ALENDRONATE-FC	MEL	\$	3.5835
00002248730	APO-ALENDRONATE	APX	\$	3.5835
00002258110	CO ALENDRONATE	COB	\$	3.5835
00002286335	MYLAN-ALENDRONATE	MYP	\$	3.5835
00002284006	PMS-ALENDRONATE-FC	PMS	\$	3.5835
00002275279	RATIO-ALENDRONATE	RPH	\$	3.5835
00002288109	SANDOZ ALENDRONATE	SDZ	\$	3.5835
00002261715	TEVA-ALENDRONATE	TEV	\$	3.5835
00002245329	FOSAMAX	MFC	\$	10.2385

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

ALENDRONATE SODIUM/ VITAMIN D3

"For the treatment of osteoporosis in patients who have documented hip, vertebral or other fractures."

"For the treatment of osteoporosis in patients with documented evidence of intolerance or lack of response to etidronate (i.e. demonstrated as a > 2% loss in bone mineral density in one year)."

"Coverage cannot be provided for two or more osteoporosis medications (alendronate, calcitonin, denosumab, etidronate, raloxifene, risedronate) 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."

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

All requests for alendronate sodium/vitamin D3 must be completed using the Alendronate/Raloxifene/Risedronate/Synthetic Calcitonin Salmon for Osteoporosis Special Authorization Request Form (ABC 31086).

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

70 MG * 5,600 UNIT	ORAL TABLET			
00002314940	FOSAVANCE	MFC	\$	4.5533

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"

10 MG	ORAL SUSTAINED-RELEASE TABLET			
00002315866	APO-ALFUZOSIN	APX	\$	0.4966
00002314282	NOVO-ALFUZOSIN PR	TEV	\$	0.4966
00002304678	SANDOZ ALFUZOSIN	SDZ	\$	0.4966
00002245565	XATRAL	SAV	\$	1.0251

AMPICILLIN

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

250 MG	ORAL CAPSULE			
00000020877	NOVO-AMPICILLIN	TEV	\$	0.3657
500 MG	ORAL CAPSULE			
00000020885	NOVO-AMPICILLIN	TEV	\$	0.7091

**ALBERTA HEALTH AND WELLNESS 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 who agrees to and continues to actively and consistently participate in the Alberta Post-Marketing Study ("Study") as required by Alberta Health and Wellness or its agent, throughout the special authorization approval period ("RA Specialist"). The patient must also provide all consents and authorizations required to permit the RA Specialist to actively and consistently participate in the Study. Special authorization approval for the patient may be revoked if the RA Specialist does not continually, actively and consistently participate in the Study.

- 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;

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

ANAKINRA

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 anakinra must be completed using the Abatacept/Adalimumab/Anakinra/Etanercept/Golimumab/Infliximab/ Tocilizumab for Rheumatoid Arthritis Special Authorization Request Form (ABC 30902).

100 MG / SYR INJECTION SYRINGE

00002245913	KINERET	BVM	\$	47.9010
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AZITHROMYCIN

"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."

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

600 MG ORAL TABLET

00002330911	AZITHROMYCIN	SNS	\$	6.0000
00002256088	CO AZITHROMYCIN	COB	\$	6.0000
00002261642	PMS-AZITHROMYCIN	PMS	\$	6.0000
00002231143	ZITHROMAX	PFI	\$	12.0693

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 tobramycin and inhaled aztreonam are intended for use in combination."

"Special authorization may be granted for 6 months."

75 MG / VIAL INHALATION POWDER FOR SOLUTION

00002329840	CAYSTON	GIL	\$	48.1564
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ALBERTA HEALTH AND WELLNESS DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

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.

10 % TOPICAL (ALCOHOL) GEL				
0000263699	PANOXYL 10	GSK	\$	0.1462
20 % TOPICAL (ALCOHOL) GEL				
00000373036	PANOXYL 20	GSK	\$	0.1905

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	AZC	\$	1.5860

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	\$	7.8200
1 MG / ML (BASE) INJECTION				
00002225166	SUPREFACT	SAV	\$	11.1436
6.3 MG (BASE) INJECTION IMPLANT				
00002228955	SUPREFACT DEPOT	SAV	\$	756.8100

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."

0.5 MG ORAL TABLET				
00002301407	CO CABERGOLINE	COB	\$	8.8550
00002242471	DOSTINEX	PAL	\$	13.6901

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

CASPOFUNGIN

"For esophageal candidiasis in patients who are intolerant to fluconazole and itraconazole, or who have failed both agents 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."

50 MG / VIAL INJECTION			
00002244265	CANCIDAS	MFC	\$ 222.0000
70 MG / VIAL INJECTION			
00002244266	CANCIDAS	MFC	\$ 222.0000

CEFADROXIL

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

500 MG ORAL CAPSULE			
00002240774	APO-CEFADROXIL	APX	\$ 0.8421
00002235134	NOVO-CEFADROXIL	TEV	\$ 0.8421

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 31140).

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

100 MG ORAL CAPSULE			
00002239941	CELEBREX	PFI	\$ 0.6828
200 MG ORAL CAPSULE			
00002239942	CELEBREX	PFI	\$ 1.3659

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 % (BASE) * 5 % TOPICAL GEL			
<input checked="" type="checkbox"/>	00002248472	BENZACLIN	VCL \$ 0.8918
<input checked="" type="checkbox"/>	00002243158	CLINDOXYL	GSK \$ 0.9064

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

CLOPIDOGREL BISULFATE

(Refer to 20:12.18 of the Alberta Health and Wellness Drug Benefit List for one month of coverage, following the first intravascular stent placement, when prescribed by a Specialist in Cardiology, Cardiac Surgery, Cardiovascular & Thoracic Surgery, or General Surgery.)

"For the prevention of thrombosis, for one month, when prescribed following intravascular bare metal stent placement. Patients who have received one month of coverage via the Limited Restricted Benefit will not be eligible for additional coverage under this criterion." **

"For the prevention of thrombosis, for up to 12 months, when prescribed following intravascular drug eluting stent (DES) placement. Patients who have received one month of coverage via the Limited Restricted Benefit may be eligible for an additional 11 months of coverage (i.e., up to 12 months of coverage) following the submission of a special authorization request." **

"For the prevention of cerebrovascular (e.g. stroke, TIA) and non-cerebrovascular ischemic events in patients who have a contraindication to ASA. Special authorization for this criterion may be granted for 24 months."

"For use in patients who have experienced a non-cerebrovascular ischemic event while on ASA. Special authorization for this criterion may be granted for 24 months."

"For use in patients who have experienced a cerebrovascular ischemic event (e.g. stroke, TIA) while on dipyridamole/ASA (Aggrenox) or for whom dipyridamole/ASA (Aggrenox) is contraindicated. Special authorization for this criterion may be granted for 24 months."

"Coverage will not be considered when clopidogrel and dipyridamole/ASA are intended for use in combination."

** Special Authorization for post-stent coverage is required when the prescriber prescribing the medication is not a designated prescriber, for treatment after repeat stents, or for continued coverage of up to 12 months following intravascular drug eluting stent (DES) placement.

In order to comply with the first and second criteria, information is required regarding the date, type of stent, and stenting procedure. In order to comply with the third criterion, information is required as to why ASA cannot be used. In order to comply with the fourth criterion, information is required regarding the type of ischemic event experienced while on ASA. In order to comply with the fifth criterion, information is required regarding the type of ischemic event experienced while on dipyridamole/ASA (Aggrenox) and/or why dipyridamole/ASA (Aggrenox) cannot be used.

All requests for clopidogrel bisulfate must be completed using the Clopidogrel Special Authorization Request Form (ABC 30786).

75 MG (BASE)	ORAL	TABLET			
00002252767	APO-CLOPIDOGREL	APX	\$	0.9279	
00002303027	CO CLOPIDOGREL	COB	\$	0.9279	
00002351536	MYLAN-CLOPIDOGREL	MYP	\$	0.9279	
00002348004	PMS-CLOPIDOGREL	PMS	\$	0.9279	
00002359316	SANDOZ CLOPIDOGREL	SDZ	\$	0.9279	
00002293161	TEVA-CLOPIDOGREL	TEV	\$	0.9279	
00002238682	PLAVIX	SAV	\$	2.6512	

**ALBERTA HEALTH AND WELLNESS 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	\$ 0.6238
25 MG ORAL CAPSULE			
00002247073	SANDOZ CYCLOSPORINE	SDZ	\$ 1.3050
00002150689	NEORAL	NOV	\$ 1.4500
50 MG ORAL CAPSULE			
00002247074	SANDOZ CYCLOSPORINE	SDZ	\$ 2.5450
00002150662	NEORAL	NOV	\$ 2.8270
100 MG ORAL CAPSULE			
00002242821	SANDOZ CYCLOSPORINE	SDZ	\$ 5.0900
00002150670	NEORAL	NOV	\$ 5.6560
100 MG / ML ORAL SOLUTION			
00002244324	APO-CYCLOSPORINE	APX	\$ 3.7708
00002150697	NEORAL	NOV	\$ 5.0276

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	\$ 1.4339
00002245898	CYPROTERONE	AAP	\$ 1.5141
100 MG / ML INJECTION			
00000704423	ANDROCUR DEPOT	PMS	\$ 26.8130

ALBERTA HEALTH AND WELLNESS 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.

110 MG ORAL CAPSULE			
00002312441 PRADAX	BOE	\$	1.6000
150 MG ORAL CAPSULE			
00002358808 PRADAX	BOE	\$	1.6000

DANAPAROID SODIUM

"For the treatment of patients with heparin-induced thrombocytopenia."

1,250 UNIT / ML INJECTION			
00002129043 ORGARAN	MFC	\$	33.7083

**ALBERTA HEALTH AND WELLNESS 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 (<100 g/L). Hemoglobin levels should be maintained within 100 - 110 g/L. According to current practice guidelines patients' iron status should be monitored regularly, and wherever possible patients should be iron replete as demonstrated by serum ferritin > 100 mcg/L and transferrin saturation > 20%."

"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 of Aranesp should be reduced by about 25%."

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 first criterion, renewal requests may be considered if the patient's hemoglobin is < 120 g/L while on Aranesp.

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

All requests for darbepoetin must be completed using the Darbepoetin/Epoetin Special Authorization Request Form (ABC 30888).

10 MCG / SYR INJECTION SYRINGE			
00002246354	ARANESP (0.4 ML SYRINGE)	AMG	\$ 26.8000
20 MCG / SYR INJECTION SYRINGE			
00002246355	ARANESP (0.5 ML SYRINGE)	AMG	\$ 53.6000
100 MCG / ML INJECTION SYRINGE			
00002246357	ARANESP (0.3/ 0.4/ 0.5 ML SYR)	AMG	\$ 268.0000
	<i>For this product - pricing has been established on a per millilitre basis.</i>		
200 MCG / ML INJECTION SYRINGE			
00002246358	ARANESP (0.3/ 0.4/ 0.5/ 0.65 ML SYR)	AMG	\$ 536.0000
	<i>For this product - pricing has been established on a per millilitre basis.</i>		
500 MCG / ML INJECTION SYRINGE			
00002246360	ARANESP (0.3/0.4/0.6/1.0 ML SYR)	AMG	\$ 1444.1900
	<i>For this product - pricing has been established on a per millilitre basis.</i>		

DARIFENACIN HYDROBROMIDE

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

FIRST-LINE DRUG PRODUCT(S): OXYBUTYNIN

"For patients who are intolerant to oxybutynin.

Special authorization may be granted for 24 months."

7.5 MG (BASE) ORAL EXTENDED-RELEASE TABLET			
00002273217	ENABLEX	NOV	\$ 1.5023
15 MG (BASE) ORAL EXTENDED-RELEASE TABLET			
00002273225	ENABLEX	NOV	\$ 1.5023

ALBERTA HEALTH AND WELLNESS 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."

125 MG ORAL DISPERSIBLE TABLET FOR SUSPENSION			
00002287420 EXJADE	NOV	\$	10.1348
250 MG ORAL DISPERSIBLE TABLET FOR SUSPENSION			
00002287439 EXJADE	NOV	\$	20.2696
500 MG ORAL DISPERSIBLE TABLET FOR SUSPENSION			
00002287447 EXJADE	NOV	\$	40.5400

DENOSUMAB

"For the treatment of postmenopausal osteoporosis in women for whom oral bisphosphonates are

contraindicated due to hypersensitivity OR an endoscopically or radiographically confirmed untreatable abnormality of the esophagus which delays esophageal emptying (e.g., stricture or achalasia), AND who have at least two of the following:

- Age greater than or equal to 75 years
- A prior fragility fracture
- A bone mineral density (BMD) T-score of less than or equal to -2.5

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, calcitonin, denosumab, etidronate, raloxifene, risedronate) when these medications are intended for use as combination therapy.

All requests for denosumab must be completed using the Denosumab Special Authorization Request Form (ABC 31377).

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

60 MG / SYR INJECTION SYRINGE			
00002343541 PROLIA	AMG	\$	339.5700

ALBERTA HEALTH AND WELLNESS 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 30776).

5 MG ORAL TABLET

00002232043	ARICEPT	PFI	\$	4.8187
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10 MG ORAL TABLET

00002232044	ARICEPT	PFI	\$	4.8187
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DUTASTERIDE

"For the treatment of benign prostatic hyperplasia in patients who are poor surgical risks or who have enlarged prostates and have moderate to severe symptoms suggestive of obstruction.

Special authorization may be granted for 6 months"

Information is required regarding the medical condition(s) or circumstances by which this patient would be deemed a poor surgical risk.

All requests (including renewal requests) for dutasteride must be completed using the Dutasteride/Finasteride Special Authorization Request Form (ABC 31257).

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

0.5 MG ORAL CAPSULE

00002247813	AVODART	GSK	\$	1.6570
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**ALBERTA HEALTH AND WELLNESS 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 AHWDBL, 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).

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CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

ECULIZUMAB

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 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 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 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 vaccination with a quadravalent vaccine (A, C, Y and W135) at least two (2) weeks prior to receiving the first dose of eculizumab. All patients must be monitored and revaccinated according to current medical guidelines for vaccine use. Treating physicians will be required to submit confirmation of meningococcal vaccination in order for their patients to continue to be eligible for treatment with eculizumab.

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)

**ALBERTA HEALTH AND WELLNESS DRUG BENEFIT LIST
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ECULIZUMAB

months thereafter;

AND

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 vaccinated or revaccinated (meningococcal) according to current medical guidelines for vaccine use;
- Progress reports on the clinical symptoms that formed the basis of initial eligibility;
- Quality of life, through clinical narrative;
- Granulocyte 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

In addition to meeting all of the Initial Coverage Clinical Criteria or the Continued Coverage Clinical Criteria referred to above (as appropriate), the patient must not have any of the following contraindications:

- Small granulocyte clone size - a granulocyte clone size 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. DISCONTINUANCE 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.

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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 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 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 one-month 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.

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ECULIZUMAB

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 Clinical Drug Services, Alberta Blue Cross.

300 MG / VIAL INJECTION			
00002322285	SOLIRIS	API	\$ 6742.5000

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 of Eprex should be reduced by about 25%. Patients may be granted a maximum allowable dose of 40,000 IU per week."

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 Eprex."

All requests for epoetin alfa must be completed using the Darbepoetin/Epoetin Special Authorization Request Form (ABC 30888).

30,000 UNIT / SYR INJECTION SYRINGE			
00002288680	EPREX	JAI	\$ 420.9400
40,000 UNIT / SYR INJECTION SYRINGE			
00002240722	EPREX	JAI	\$ 420.9400

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EPOETIN ALFA

"For the treatment of anemia of chronic renal failure in patients with low hemoglobin (< 100 g/L). Hemoglobin levels should be maintained within 100 - 110 g/L. According to current practice guidelines patients' iron status should be monitored regularly, and wherever possible patients should be iron replete as demonstrated by serum ferritin > 100 mcg/L and transferrin saturation > 20%."

"For the treatment of anemia in AZT-treated/HIV infected patients."

"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 of Eprex should be reduced by about 25%."

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 first criterion, renewal requests may be considered if the patient's hemoglobin is < 120 g/L while on Eprex.

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

All requests for epoetin alfa must be completed using the Darbepoetin/Epoetin Special Authorization Request Form (ABC 30888).

1,000 UNIT / SYR INJECTION SYRINGE			
00002231583	EPREX (0.5 ML SYRINGE)	JAI	\$ 14.2500
2,000 UNIT / SYR INJECTION SYRINGE			
00002231584	EPREX (0.5 ML SYRINGE)	JAI	\$ 28.5000
3,000 UNIT / SYR INJECTION SYRINGE			
00002231585	EPREX (0.3 ML SYRINGE)	JAI	\$ 42.7500
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	\$ 280.6200

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

ERTAPENEM

"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."

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	\$	49.9500
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ERYTHROMYCIN/ 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.

4 % * 0.01 % TOPICAL GEL				
00002015994	STIEVAMYCIN MILD	GSK	\$	0.8302
4 % * 0.025 % TOPICAL GEL				
00001905112	STIEVAMYCIN REGULAR	GSK	\$	0.8302
4 % * 0.05 % TOPICAL GEL				
00001945262	STIEVAMYCIN FORTE	GSK	\$	0.8302

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

ETANERCEPT

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 who agrees to and continues to actively and consistently participate in the Alberta Post-Marketing Study ("Study") as required by Alberta Health and Wellness or its agent, throughout the special authorization approval period ("RA Specialist"). The patient must also provide all consents and authorizations required to permit the RA Specialist to actively and consistently participate in the Study. Special authorization approval for the patient may be revoked if the RA Specialist does not continually, actively and consistently participate in the Study.

- 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:

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ETANERCEPT

- 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/Etanercept/Golimumab/Infliximab/Tocilizumab for Rheumatoid Arthritis Special Authorization Request Form (ABC 30902).

Juvenile Idiopathic Arthritis:

- "Special authorization coverage may be provided for the reduction in signs and symptoms of severely active polyarticular juvenile idiopathic arthritis (JIA) 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 who agrees to and continues to actively and consistently participate in the Alberta Post-Marketing Study ("Study") as required by Alberta Health and Wellness and its agent, throughout the special authorization approval period (Pediatric RA Specialist). The patient or patient's guardian must also provide all consents and authorizations required to permit the Pediatric RA Specialist to actively and consistently participate in the Study. Special authorization approval for the patient may be revoked if the Pediatric RA Specialist does not continually, actively and consistently participate in the Study.

- 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 Enbrel per prescription at their pharmacy.

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 RA Specialist after 12 weeks, but no longer than 16 weeks after, treatment with this biologic agent to determine response.
- 2) The Pediatric RA Specialist must confirm in writing that the patient is a responder that meets the following criteria (JRA30):
 - 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 RA 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

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ETANERCEPT

3) Data from all of the six variables comprising the JRA30 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 RA Specialist and must meet the following criteria:

- 1) The patient has been assessed 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 as indicated by maintenance of the JRA30,
- 3) Data from all of the six variables comprising the JRA30 and the CHAQ scores must be reported in each request.

Once a child with JIA 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 Juvenile Idiopathic Arthritis must be completed using the Etanercept for Juvenile Idiopathic Arthritis Special Authorization Request Form (ABC 30948).

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 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:

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
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

ETANERCEPT

- 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/Etanercept/Golimumab/Infliximab for Psoriatic Arthritis Special Authorization Request Form (ABC 30964).

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 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.

ALBERTA HEALTH AND WELLNESS DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

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 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/Etanercept/Golimumab/Infliximab for Ankylosing Spondylitis Special Authorization Request Form (ABC 31195).

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 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

ALBERTA HEALTH AND WELLNESS DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

ETANERCEPT

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."

All requests (including renewal requests) for etanercept for Plaque Psoriasis must be completed using the Adalimumab/Etanercept/Infliximab/Ustekinumab for Plaque Psoriasis Special Authorization Request Form (ABC 31192).

25 MG / VIAL INJECTION

00002242903	ENBREL	AMG	\$ 189.4150
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50 MG / SYR INJECTION SYRINGE

00002274728	ENBREL	AMG	\$ 378.9425
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Note: 1 x 50 mg syringe is interchangeable with 2 x 25 mg vials

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 30925).

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

10 MG ORAL TABLET

00002247521	EZETROL	MFC	\$ 1.7927
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**ALBERTA HEALTH AND WELLNESS DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

FEBUXOSTAT

"For patients with symptomatic gout who have documented hypersensitivity OR severe intolerance to allopurinol, AND intolerance or lack of response to sulfinpyrazone AND probenecid.

Special authorization may be granted for 6 months."

Please note: Coverage cannot be considered for lack of response to allopurinol.

All requests for febuxostat must be completed using the Febuxostat Special Authorization Request Form (ABC 31376).

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

80 MG ORAL TABLET				
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 31169).

(Please note: The following fentanyl products are benefits not requiring special authorization for individuals approved by Alberta Health and Wellness for Palliative Care Drug Coverage. Refer to the Palliative Care Drug Benefit Supplement for additional information on this coverage.)

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

12 MCG/HR TRANSDERMAL PATCH				
00002311925	RATIO-FENTANYL	RPH	\$	2.2300
00002341379	PMS-FENTANYL MTX	PMS	\$	2.2320
00002330105	RAN-FENTANYL MATRIX	RAN	\$	2.2320
00002327112	SANDOZ FENTANYL PATCH	SDZ	\$	2.2320
25 MCG/HR TRANSDERMAL PATCH				
00002314630	NOVO-FENTANYL 25	TEV	\$	3.7188
00002341387	PMS-FENTANYL MTX	PMS	\$	3.7188
00002330113	RAN-FENTANYL MATRIX	RAN	\$	3.7188
00002282941	RATIO-FENTANYL	RPH	\$	3.7188
00002327120	SANDOZ FENTANYL PATCH	SDZ	\$	3.7188

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

FENTANYL

50 MCG/HR TRANSDERMAL PATCH

00002314649	NOVO-FENTANYL 50	TEV	\$	7.0000
00002341395	PMS-FENTANYL MTX	PMS	\$	7.0000
00002330121	RAN-FENTANYL MATRIX	RAN	\$	7.0000
00002282968	RATIO-FENTANYL	RPH	\$	7.0000
00002327147	SANDOZ FENTANYL PATCH	SDZ	\$	7.0000

75 MCG/HR TRANSDERMAL PATCH

00002314657	NOVO-FENTANYL 75	TEV	\$	9.8438
00002341409	PMS-FENTANYL MTX	PMS	\$	9.8438
00002330148	RAN-FENTANYL MATRIX	RAN	\$	9.8438
00002282976	RATIO-FENTANYL	RPH	\$	9.8438
00002327155	SANDOZ FENTANYL PATCH	SDZ	\$	9.8438

100 MCG/HR TRANSDERMAL PATCH

00002314665	NOVO-FENTANYL 100	TEV	\$	12.2500
00002341417	PMS-FENTANYL MTX	PMS	\$	12.2500
00002330156	RAN-FENTANYL MATRIX	RAN	\$	12.2500
00002282984	RATIO-FENTANYL	RPH	\$	12.2500
00002327163	SANDOZ FENTANYL PATCH	SDZ	\$	12.2500

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."

Information is required regarding previous medications utilized and the patient's response to therapy. Information should include the use of agents such as morphine and/or hydromorphone, if not contraindicated for the patient.

All requests for fentanyl citrate must be completed using the Fentanyl Special Authorization Request Form (ABC 31169).

(Please note: The following fentanyl citrate product is a benefit not requiring special authorization for individuals approved by Alberta Health and Wellness for Palliative Care Drug Coverage. Refer to the Palliative Care Drug Benefit Supplement for additional information on this coverage.)

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

0.05 MG / ML (BASE) INJECTION

00000888346	FENTANYL CITRATE	HSP	\$	1.7543
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**ALBERTA HEALTH AND WELLNESS DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

FILGRASTIM

"To decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-neoplastic drugs with curative intent. This drug product must be prescribed by the Directors of Alberta Health Services - Cancer Care "Cancer Centres" (or their designates)."

"For the reduction in the duration of neutropenia, fever, antibiotic use and hospitalization following induction and consolidation treatment for acute myeloid leukemia. This drug product must be prescribed by the Directors of Alberta Health Services - Cancer Care "Cancer Centres" (or their designates)."

"To increase neutrophil counts and to reduce the incidence and duration of infection in patients with a diagnosis of congenital, cyclic or idiopathic neutropenia. This drug product must be prescribed by the Directors of Divisions of Hematology in tertiary care centres (or their designates)."

"For the treatment of patients undergoing Peripheral Blood Progenitor Cell (PBPC) collection and therapy when prescribed by a designated prescriber."

All requests for filgrastim must be completed using the Filgrastim/Pegfilgrastim Special Authorization Request Form (ABC 31150).

Please note for the first criterion: Coverage cannot be considered for palliative patients.

0.3 MG / ML INJECTION

00001968017	NEUPOGEN	AMG	\$	186.8181
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FINASTERIDE

"For the treatment of benign prostatic hyperplasia in patients who are poor surgical risks or who have enlarged prostates and have moderate to severe symptoms suggestive of obstruction.

Special authorization may be granted for 6 months."

Information is required regarding the medical condition(s) or circumstances by which this patient would be deemed a poor surgical risk.

All requests (including renewal requests) for finasteride must be completed using the Dutasteride/Finasteride Special Authorization Request Form (ABC 31257).

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

5 MG ORAL TABLET

00002365383	APO-FINASTERIDE	APX	\$	0.6714
00002354462	CO FINASTERIDE	COB	\$	0.6714
00002355043	FINASTERIDE	AHI	\$	0.6714
00002357224	JAMP-FINASTERIDE	JPC	\$	0.6714
00002356058	MYLAN-FINASTERIDE	MYP	\$	0.6714
00002348500	NOVO-FINASTERIDE	TEV	\$	0.6714
00002310112	PMS-FINASTERIDE	PMS	\$	0.6714
00002371820	RAN-FINASTERIDE	RAN	\$	0.6714
00002306905	RATIO-FINASTERIDE	RPH	\$	0.6714
00002322579	SANDOZ FINASTERIDE	SDZ	\$	0.6714
00002010909	PROSCAR	MFC	\$	1.9182

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

FLUCONAZOLE

"For susceptible infections in immunocompromised patients (e.g. patients with AIDS, cancer, or transplant patients)."

10 MG / ML ORAL SUSPENSION				
00002024152	DIFLUCAN	PFI	\$	0.9909

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	APO-FLUTAMIDE	APX	\$	1.3530
00002230089	NOVO-FLUTAMIDE	TEV	\$	1.3530
00002230104	PMS-FLUTAMIDE	PMS	\$	1.3530
00000637726	EUFLEX	MFC	\$	1.3922

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 30776).

8 MG (BASE) ORAL EXTENDED-RELEASE CAPSULE				
00002339439	MYLAN-GALANTAMINE ER	MYP	\$	1.8906
00002316943	PAT-GALANTAMINE ER	PAT	\$	1.8906
00002377950	TEVA-GALANTAMINE ER	TEV	\$	1.8906
00002266717	REMINYL ER	JAI	\$	5.0249
16 MG (BASE) ORAL EXTENDED-RELEASE CAPSULE				
00002339447	MYLAN-GALANTAMINE ER	MYP	\$	1.8906
00002316951	PAT-GALANTAMINE ER	PAT	\$	1.8906
00002377969	TEVA-GALANTAMINE ER	TEV	\$	1.8906
00002266725	REMINYL ER	JAI	\$	5.0249
24 MG (BASE) ORAL EXTENDED-RELEASE CAPSULE				
00002339455	MYLAN-GALANTAMINE ER	MYP	\$	1.8906
00002316978	PAT-GALANTAMINE ER	PAT	\$	1.8906
00002377977	TEVA-GALANTAMINE ER	TEV	\$	1.8906
00002266733	REMINYL ER	JAI	\$	5.0249

**ALBERTA HEALTH AND WELLNESS 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/Etanercept/Golimumab/Infliximab for Ankylosing Spondylitis Special Authorization Request Form (ABC 31195).

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 to:

- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if

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

GOLIMUMAB

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 completed using the Adalimumab/Etanercept/Golimumab/Infliximab for Psoriatic Arthritis Special Authorization Request Form (ABC 30964).

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

GOLIMUMAB

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 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

ALBERTA HEALTH AND WELLNESS DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

GOLIMUMAB

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/Etanercept/Golimumab/Infliximab/Tocilizumab for Rheumatoid Arthritis Special Authorization Request Form (ABC 30902).

50 MG / SYR INJECTION SYRINGE

<input checked="" type="checkbox"/> 00002324776	SIMPONI	JAI	\$ 1447.0000
<input checked="" type="checkbox"/> 00002324784	SIMPONI	JAI	\$ 1447.0000

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	AZC	\$ 390.5000
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10.8 MG / SYR (BASE) INJECTION SYRINGE

00002225905	ZOLADEX LA	AZC	\$ 1113.0000
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ALBERTA HEALTH AND WELLNESS DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

IMIPENEM/ CILASTATIN SODIUM

"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 (i.e. Enterobacter spp., Citrobacter freundii complex, Serratia spp., Morganella spp., Providencia spp., Proteus vulgaris, Proteus penneri and some Hafnia spp.) or extended spectrum beta-lactamases where there is resistance to first-line agents (trimethoprim/sulfamethoxazole, ciprofloxacin and aminoglycosides) or
- 6) For use in other Health Canada approved indications in consultation with a specialist in Infectious Diseases."

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.

250 MG / VIAL * 250 MG / VIAL (BASE)	INJECTION			
00000717274	PRIMAXIN	MFC	\$	13.0400
500 MG / VIAL * 500 MG / VIAL (BASE)	INJECTION			
00000717282	PRIMAXIN	MFC	\$	24.3800

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 31222).

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

50 MG/G / G TOPICAL CREAM				
00002239505	ALDARA	MEP	\$	50.3370

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

INFLIXIMAB

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.

For coverage, this drug must be initiated by a Specialist in Rheumatology who agrees to and continues to actively and consistently participate in the Alberta Post-Marketing Study ("Study") as required by Alberta Health and Wellness or its agent, throughout the special authorization approval period ("RA Specialist"). The patient must also provide all consents and authorizations required to permit the RA Specialist to actively and consistently participate in the Study. Special authorization approval for the patient may be revoked if the RA Specialist does not continually, actively and consistently participate in the Study.

- 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

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

INFLIXIMAB

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/Etanercept/Golimumab/Infliximab/Tocilizumab for Rheumatoid Arthritis Special Authorization Request Form (ABC 30902).

Moderately to Severely Active Crohn's Disease and Fistulizing Crohn's Disease:

"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]

**ALBERTA HEALTH AND WELLNESS DRUG BENEFIT LIST
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.

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

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 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

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INFLIXIMAB

Disease and Fistulizing Crohn's Disease must be completed using the Adalimumab for Crohn's/Infliximab for Crohn's/Fistulizing Crohn's Disease Special Authorization Request Form (ABC 31200).

Ankylosing Spondylitis:

"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 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/Etanercept/Golimumab/Infliximab for Ankylosing Spondylitis Special Authorization Request Form (ABC 31195).

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

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CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

INFLIXIMAB

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 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 RA 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

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CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

INFLIXIMAB

using the Adalimumab/Etanercept/Golimumab/Infliximab for Psoriatic Arthritis Special Authorization Request Form (ABC 30964).

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 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."

All requests (including renewal requests) for infliximab for Plaque Psoriasis must be completed using the Adalimumab/Etanercept/Infliximab/Ustekinumab for Plaque Psoriasis Special

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INFLIXIMAB

Authorization Request Form (ABC 31192).

100 MG / VIAL INJECTION

00002244016	REMICADE	JAI	\$	940.0000
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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	\$	0.3295
00002097176	RATIO-IPRATROPIUM UDV	RPH	\$	0.3295

250 MCG / ML INHALATION UNIT DOSE SOLUTION

00002216221	MYLAN-IPRATROPIUM STERINEBS	MYP	\$	0.6590
00002231244	PMS-IPRATROPIUM (1ML)	PMS	\$	0.6590
00002231245	PMS-IPRATROPIUM (2ML)	PMS	\$	0.6590
00002097168	RATIO-IPRATROPIUM UDV	RPH	\$	0.6590

ITRACONAZOLE

"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."

10 MG / ML ORAL SOLUTION

00002231347	SPORANOX	JAI	\$	0.7830
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LACOSAMIDE

"For adjunctive therapy in adult 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.

Coverage may be granted for a maximum dose of 400 mg daily.

Special authorization may be granted for six months."

Each of these products is eligible for auto-renewal.

50 MG ORAL TABLET

00002357615	VIMPAT	UCB	\$	2.3200
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100 MG ORAL TABLET

00002357623	VIMPAT	UCB	\$	3.3200
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**ALBERTA HEALTH AND WELLNESS DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

LACOSAMIDE

150 MG ORAL TABLET			
00002357631	VIMPAT	UCB	\$ 4.3200
200 MG ORAL TABLET			
00002357658	VIMPAT	UCB	\$ 5.3200

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)	TCI	\$ 1102.0000
90 MG / SYR INJECTION SYRINGE			
00002283409	SOMATULINE AUTOGEL (0.3 ML SYRINGE)	TCI	\$ 1470.0000
120 MG / SYR INJECTION SYRINGE			
00002283417	SOMATULINE AUTOGEL (0.5 ML SYRINGE)	TCI	\$ 1840.0000

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	ABB	\$ 347.1800
5 MG / ML INJECTION			
00000727695	LUPRON	ABB	\$ 67.6464
7.5 MG / VIAL INJECTION			
00000836273	LUPRON DEPOT	ABB	\$ 387.9700
11.25 MG / VIAL INJECTION			
00002239834	LUPRON DEPOT	ABB	\$ 1034.4100
22.5 MG / VIAL INJECTION			
00002230248	LUPRON DEPOT	ABB	\$ 1071.0000

ALBERTA HEALTH AND WELLNESS DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

LEVOCARNITINE

"For the treatment of primary carnitine deficiency. Information is required regarding the ratio of acyl:free carnitine and 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 acyl:free carnitine and total plasma carnitine levels.

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

330 MG ORAL TABLET				
00002144328	CARNITOR	PPC	\$	1.3078
100 MG / ML ORAL SOLUTION				
00002144336	CARNITOR	PPC	\$	0.3961
200 MG / ML INJECTION				
00002144344	CARNITOR	PPC	\$	12.5220

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.

5 MG ORAL TABLET				
00002370921	TRAJENTA	BOE	\$	2.5500

ALBERTA HEALTH AND WELLNESS DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

LINEZOLID

"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."

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

00002243684 ZYVOXAM PFI \$ 72.1263

MEGESTROL ACETATE

"For the treatment of non-cancer indications (e.g. cachexia in HIV/AIDS patients and cancer patients) in patients who cannot swallow tablets.

Special authorization may be granted for 6 months."

(Please note: The above megestrol acetate product is a benefit not requiring special authorization for individuals approved by Alberta Health and Wellness for Palliative Care Drug Coverage. Refer to the Palliative Care Drug Benefit Supplement for additional information on this coverage.)

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

40 MG / ML ORAL SUSPENSION

00002168979 MEGACE OS BMS \$ 1.6404

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 and Wellness for Palliative Care Drug Coverage. Refer to the Palliative Care 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 \$ 1.0073

160 MG ORAL TABLET

00002195925 MEGESTROL AAP \$ 4.2630

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

MEROPENEM

- 1) "As an alternative to imipenem for severe polymicrobial infections involving gram-negative organisms resistant to first-line agents in patients with documented seizure disorder/CNS abnormality or
- 2) As an alternative agent for severe polymicrobial infections involving gram-negative organisms resistant to first-line agents and to imipenem but susceptible to meropenem or
- 3) Therapy of meningitis due to gram-negative organisms producing inducible beta-lactamases (i.e. Enterobacter spp., Citrobacter freundii complex, Serratia spp., Morganella spp., Providencia spp., Proteus vulgaris, Proteus penneri and some Hafnia spp.) or
- 4) For treatment of CNS infections due to gram-negative organisms that are resistant to third-generation cephalosporins but are susceptible to meropenem or
- 5) Therapy for infections involving multi-resistant Pseudomonas aeruginosa, where there is documented susceptibility to meropenem or
- 6) For use in other Health Canada approved indications, in consultation with a specialist in Infectious Diseases."

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

00002218488	MERREM	AZC	\$	25.2600
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1 G / VIAL INJECTION

00002218496	MERREM	AZC	\$	50.5200
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**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

0000195057	NEO-MEDROL ACNE	PFI	\$	0.2602
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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	MODAFINIL	AAP	\$	0.9990
00002239665	ALERTEC	SHB	\$	1.3174

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

MONTELUKAST SODIUM

(Refer to 48:10.24 of the Alberta Health and Wellness 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 31313).

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

10 MG (BASE)	ORAL TABLET			
00002374609	APO-MONTELUKAST	APX	\$	0.8483
00002379333	MONTELUKAST	SNS	\$	0.8483
00002368226	MYLAN-MONTELUKAST	MYP	\$	0.8483
00002373947	PMS-MONTELUKAST FC	PMS	\$	0.8483
00002328593	SANDOZ MONTELUKAST	SDZ	\$	0.8483
00002355523	TEVA-MONTELUKAST	TEV	\$	0.8483
00002238217	SINGULAIR	MFC	\$	2.4238
5 MG (BASE)	ORAL CHEWABLE TABLET			
00002377616	APO-MONTELUKAST	APX	\$	0.5776
00002379325	MONTELUKAST	SNS	\$	0.5776
00002380757	MYLAN-MONTELUKAST	MYP	\$	0.5776
00002354985	PMS-MONTELUKAST	PMS	\$	0.5776
00002330393	SANDOZ MONTELUKAST	SDZ	\$	0.5776
00002355515	TEVA-MONTELUKAST	TEV	\$	0.5776
00002238216	SINGULAIR	MFC	\$	1.6503

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

NARATRIPTAN HCL

(Refer to 28:32.28 of the Alberta Health and Wellness 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	NOVO-NARATRIPTAN	TEV	\$	8.4338
00002237820	AMERGE	GSK	\$	14.1715
2.5 MG (BASE) ORAL TABLET				
00002322323	SANDOZ NARATRIPTAN	SDZ	\$	6.1437
00002314304	NOVO-NARATRIPTAN	TEV	\$	6.1438
00002237821	AMERGE	GSK	\$	14.9372

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	\$	1.9076
00000839191	SANDOSTATIN	NOV	\$	5.0700
100 MCG / ML (BASE) INJECTION				
00002248640	OCTREOTIDE ACETATE OMEGA	OMG	\$	3.6007
00000839205	SANDOSTATIN	NOV	\$	9.5700
200 MCG / ML (BASE) INJECTION				
00002248642	OCTREOTIDE ACETATE OMEGA	OMG	\$	6.9268
00002049392	SANDOSTATIN	NOV	\$	18.4100
500 MCG / ML (BASE) INJECTION				
00002248641	OCTREOTIDE ACETATE OMEGA	OMG	\$	16.9230
00000839213	SANDOSTATIN	NOV	\$	44.9780
10 MG / VIAL (BASE) INJECTION				
00002239323	SANDOSTATIN LAR	NOV	\$	1315.7400

ALBERTA HEALTH AND WELLNESS DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

OCTREOTIDE ACETATE

20 MG / VIAL (BASE)	INJECTION		
00002239324	SANDOSTATIN LAR	NOV	\$ 1699.8900
30 MG / VIAL (BASE)	INJECTION		
00002239325	SANDOSTATIN LAR	NOV	\$ 2180.9400

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

OMALIZUMAB

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 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;
 - unscheduled physician visits resulting in 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 an unscheduled physician visit and resulted in courses (or chronic use greater than 50% of the year) of systemic corticosteroids.

Initial coverage may be approved for twenty-eight (28) weeks based on the recommended dose and dosage adjustment outlined in the Health Canada approved Product Monograph.

ALBERTA HEALTH AND WELLNESS DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

OMALIZUMAB

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 the respirologist or clinical immunologist or allergist or such other clinicians as the Minister may designate who initiated therapy. 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 use in the prior twelve (12) months 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.

150 MG / VIAL INJECTION

00002260565 XOLAIR

NOV

\$ 600.0000

OXYBUTYNIN CHLORIDE

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

FIRST-LINE DRUG PRODUCT(S): IMMEDIATE RELEASE OXYBUTYNIN

"For patients who are intolerant of immediate release oxybutynin."

"Special authorization may be granted for 24 months."

10 MG ORAL EXTENDED-RELEASE TABLET

00002273578 UROMAX

PUR

\$ 1.3655

15 MG ORAL EXTENDED-RELEASE TABLET

00002273586 UROMAX

PUR

\$ 1.4710

ALBERTA HEALTH AND WELLNESS 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 meet at least two of three 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 (Note: one trial must include a first generation antipsychotic agent); OR
- Possesses clinical evidence of previous successful treatment with risperidone or paliperidone therapy.

Special Authorization may be granted for six months."

All requests (including renewal requests) for paliperidone prolonged release injection must be completed using the Paliperidone/Risperidone Prolonged Release Injection Special Authorization Request Form (ABC 31258).

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

50 MG / SYR (BASE)	INJECTION SYRINGE			
00002354217	INVEGA SUSTENNA (0.5 ML SYR)	JAI	\$	304.1000
75 MG / SYR (BASE)	INJECTION SYRINGE			
00002354225	INVEGA SUSTENNA (0.75 ML SYR)	JAI	\$	456.1800
100 MG / SYR (BASE)	INJECTION SYRINGE			
00002354233	INVEGA SUSTENNA (1 ML SYR)	JAI	\$	456.1800
150 MG / SYR (BASE)	INJECTION SYRINGE			
00002354241	INVEGA SUSTENNA (1.5 ML SYR)	JAI	\$	608.2200

PAPAVERINE HCL

"For the relief of cerebral or peripheral ischemia with arterial spasm.

Special authorization may be granted for 6 months."

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

32.5 MG / ML INJECTION				
00000009881	PAPAVERINE HCL	SDZ	\$	1.7163

PEGFILGRASTIM

"To decrease the incidence of infection, as manifested by febrile neutropenia, in patients 18 years of age and older with non-myeloid malignancies receiving myelosuppressive antineoplastic drugs with curative intent. This drug product must be prescribed by the Directors of Alberta Health Services - Cancer Care "Cancer Centres" (or their designates)."

All requests for pegfilgrastim must be completed using the Filgrastim/Pegfilgrastim Special Authorization Request Form (ABC 31150).

Please note: Coverage cannot be considered for palliative patients.

6 MG / SYR INJECTION SYRINGE				
00002249790	NEULASTA (0.6 ML SYRINGE)	AMG	\$	2499.0000

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

PEGINTERFERON ALFA-2A

(Refer to 08:18.20 of the Alberta Health and Wellness 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 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 30944), 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:
 - Advanced fibrosis or cirrhosis.
 - Patients who have relapsed following non-pegylated interferon/ribavirin combination therapy."

In order to comply with this criterion: Confirmation of the diagnosis of chronic hepatitis C and

ALBERTA HEALTH AND WELLNESS DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

PEGINTERFERON ALFA-2A

presence of active liver disease is required. Information must include the patient's pre-treatment anti-HCV and 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. 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 30944). 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	\$ 395.8400
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**ALBERTA HEALTH AND WELLNESS DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

PEGINTERFERON ALFA-2A/ RIBAVIRIN

"For the treatment of chronic hepatitis C in patients with evidence of active liver disease.

Prior to initiation of Pegasys RBV therapy:

- To determine treatment duration and prognosis, HCV genotype testing is required for all patients.
- At least three (3) weeks before anticipated start date of therapy, please submit a Peginterferon Alfa-2a+Ribavirin/Peginterferon Alfa-2b+Ribavirin Special Authorization Request Form (ABC 30932) along with appropriate lab results to Alberta Blue Cross.

All Patients (with the Exception of Post-Liver Transplant Patients and Advanced Fibrosis or Cirrhosis Patients):

Prior to initiation of Pegasys RBV therapy:

- Genotype 1 patients and Genotype 2 or 3 patients with HIV co-infection 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):

- Genotype 1 patients and Genotype 2 or 3 patients with HIV co-infection, may receive an initial approval for 14 weeks of coverage.
- Genotype 2 or 3 patients may receive initial and maximal approval for 24 weeks of coverage. These patients will not be eligible for continued approval.
- Genotype 4, 5 and 6 patients may receive initial and maximal approval for 48 weeks of coverage. These patients will not be eligible for continued approval.

At 12 weeks of treatment:

- HCV RNA testing is required for all Genotype 1 patients and Genotype 2 or 3 patients with HIV co-infection 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 12th week serum sample for evaluation of continued coverage.

Renewal approval period (for patients meeting criteria):

- Genotype 1 patients and Genotype 2 or 3 patients with HIV co-infection who respond to therapy as measured by a negative HCV RNA status at 12 weeks, may be approved for an additional 34 weeks of coverage (i.e. total 48 weeks).
- Genotype 1 patients and Genotype 2 or 3 patients with HIV co-infection who achieve a reduction in viral load by at least 2 logs (100 fold) but do not possess negative HCV RNA status at week 12 may be approved for an additional 14 weeks of coverage. Patients should be retested for HCV RNA status at 24 weeks:
 - Patients who respond to therapy, as measured by a negative HCV RNA status at 24 weeks, may be approved for an additional 20 weeks of coverage (i.e. total 48 weeks).
 - Those who fail to demonstrate negative HCV RNA status at 24 weeks will not be eligible for continued approval.

Post-Liver Transplant Patients:

Initial Alberta Blue Cross approval periods (for patients meeting criteria):

- Genotype 1 and Genotype 2 or 3 patients may receive an initial approval for 26 weeks of coverage.
- Genotype 4, 5 and 6 patients may receive initial and maximal approval for 48 weeks of coverage. These patients will not be eligible for continued approval.

At 24 weeks of treatment:

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
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

PEGINTERFERON ALFA-2A/ RIBAVIRIN

- HCV RNA testing is required for all Genotype 1 and Genotype 2 or 3 patients at the 24th week of treatment.

Renewal approval period (for patients meeting criteria):

- Genotype 1 and Genotype 2 or 3 patients who respond to therapy as measured by a negative HCV RNA status at 24 weeks, may be approved for an additional 22 weeks of coverage (i.e. total 48 weeks).
- Those who fail to demonstrate negative HCV RNA status at 24 weeks will not be eligible for continued approval.

Advanced Fibrosis or Cirrhosis Patients:

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 ALL patients (including post-liver transplant 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:
 - Advanced fibrosis or cirrhosis.
 - Patients who have relapsed following non-pegylated interferon/ribavirin combination therapy.
 - Patients who have failed to respond to or relapsed following interferon monotherapy."

Confirmation of the diagnosis of chronic hepatitis C and presence of active liver disease is required. Information must include the patient's pre-treatment anti-HCV and serum HCV RNA (by PCR) status. Information is also required regarding whether liver enzymes (ALT/AST) are elevated, or the results of liver biopsy. All requests for peginterferon alfa-2a/ribavirin must be completed using the Peginterferon Alfa-2a+Ribavirin/Peginterferon Alfa-2b+Ribavirin Special Authorization Request Form (ABC 30932). In order to meet the requirements of provincial privacy legislation, the patient's signature must be affixed to each completed form.

180 MCG * 200 MG INJECTION SYRINGE/TABLET

00002253429 PEGASYS RBV (KIT) HLR \$ 395.8400

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

PEGINTERFERON ALFA-2B/ RIBAVIRIN

"For the treatment of chronic hepatitis C in patients with evidence of active liver disease.

Prior to initiation of Pegetron therapy:

- To determine treatment duration and prognosis, HCV genotype testing is required for all patients.
- At least three (3) weeks before anticipated start date of therapy, please submit a Peginterferon Alfa-2a+Ribavirin/Peginterferon Alfa-2b+Ribavirin Special Authorization Request Form (ABC 30932) along with appropriate lab results to Alberta Blue Cross.

All Patients (with the Exception of Post-Liver Transplant Patients and Advanced Fibrosis or Cirrhosis Patients):

Prior to initiation of Pegetron therapy:

- Genotype 1 patients and Genotype 2 or 3 patients with HIV co-infection 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):

- Genotype 1 patients and Genotype 2 or 3 patients with HIV co-infection, may receive an initial approval for 14 weeks of coverage.
- Genotype 2 or 3 patients may receive initial and maximal approval for 24 weeks of coverage. These patients will not be eligible for continued approval.
- Genotype 4, 5 and 6 patients may receive initial and maximal approval for 48 weeks of coverage. These patients will not be eligible for continued approval.

At 12 weeks of treatment:

- HCV RNA testing is required for all Genotype 1 patients and Genotype 2 or 3 patients with HIV co-infection 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 12th week serum sample for evaluation of continued coverage.

Renewal approval period (for patients meeting criteria):

- Genotype 1 patients and Genotype 2 or 3 patients with HIV co-infection who respond to therapy as measured by a negative HCV RNA status at 12 weeks, may be approved for an additional 34 weeks of coverage (i.e. total 48 weeks).
- Genotype 1 patients and Genotype 2 or 3 patients with HIV co-infection who achieve a reduction in viral load by at least 2 logs (100 fold) but do not possess negative HCV RNA status at week 12 may be approved for an additional 14 weeks of coverage. Patients should be retested for HCV RNA status at 24 weeks:
 - Patients who respond to therapy, as measured by a negative HCV RNA status at 24 weeks, may be approved for an additional 20 weeks of coverage (i.e. total 48 weeks).
 - Those who fail to demonstrate negative HCV RNA status at 24 weeks will not be eligible for continued approval.

Post-Liver Transplant Patients:

Initial Alberta Blue Cross approval periods (for patients meeting criteria):

- Genotype 1 and Genotype 2 or 3 patients may receive an initial approval for 26 weeks of coverage.
- Genotype 4, 5 and 6 patients may receive initial and maximal approval for 48 weeks of coverage. These patients will not be eligible for continued approval.

At 24 weeks of treatment:

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
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

PEGINTERFERON ALFA-2B/ RIBAVIRIN

- HCV RNA testing is required for all Genotype 1 and Genotype 2 or 3 patients at the 24th week of treatment.

Renewal approval period (for patients meeting criteria):

- Genotype 1 and Genotype 2 or 3 patients who respond to therapy as measured by a negative HCV RNA status at 24 weeks, may be approved for an additional 22 weeks of coverage (i.e. total 48 weeks).
- Those who fail to demonstrate negative HCV RNA status at 24 weeks will not be eligible for continued approval.

Advanced Fibrosis or Cirrhosis Patients:

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 ALL patients (including post-liver transplant 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:
 - Advanced fibrosis or cirrhosis.
 - Patients who have relapsed following non-pegylated interferon/ribavirin combination therapy.
 - Patients who have failed to respond to or relapsed following interferon monotherapy."

Confirmation of the diagnosis of chronic hepatitis C and presence of active liver disease is required. Information must include the patient's pre-treatment anti-HCV and serum HCV RNA (by PCR) status. Information is also required regarding whether liver enzymes (ALT/AST) are elevated, or the results of liver biopsy. All requests for peginterferon alfa-2b/ribavirin must be completed using the Peginterferon Alfa-2a+Ribavirin/Peginterferon Alfa-2b+Ribavirin Special Authorization Request Form (ABC 30932). In order to meet the requirements of provincial privacy legislation, the patient's signature must be affixed to each completed form.

50 MCG * 200 MG	INJECTION VIAL/CAPSULE		
00002246026	PEGETRON (KIT)	MFC	\$ 752.2000
150 MCG * 200 MG	INJECTION VIAL/CAPSULE		
00002246030	PEGETRON (KIT)	MFC	\$ 831.1800
80 MCG * 200 MG	INJECTION SYRINGE/CAPSULE		
00002254581	PEGETRON REDIPEN (KIT)	MFC	\$ 752.2000
100 MCG * 200 MG	INJECTION SYRINGE/CAPSULE		
00002254603	PEGETRON REDIPEN (KIT)	MFC	\$ 752.2000
120 MCG * 200 MG	INJECTION SYRINGE/CAPSULE		
00002254638	PEGETRON REDIPEN (KIT)	MFC	\$ 831.1800
150 MCG * 200 MG	INJECTION SYRINGE/CAPSULE		
00002254646	PEGETRON REDIPEN (KIT)	MFC	\$ 831.1800

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

PIOGLITAZONE HCL

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.

15 MG (BASE) ORAL TABLET				
00002303442	ACCEL PIOGLITAZONE	ACP	\$	0.8718
00002302942	APO-PIOGLITAZONE	APX	\$	0.8718
00002363232	AVA-PIOGLITAZONE	AVA	\$	0.8718
00002302861	CO PIOGLITAZONE	COB	\$	0.8718
00002326477	MINT-PIOGLITAZONE	MPI	\$	0.8718
00002298279	MYLAN-PIOGLITAZONE	MYP	\$	0.8718
00002274914	NOVO-PIOGLITAZONE	TEV	\$	0.8718
00002307669	PHL-PIOGLITAZONE	PHH	\$	0.8718
00002303124	PMS-PIOGLITAZONE	PMS	\$	0.8718
00002301423	RATIO-PIOGLITAZONE	RPH	\$	0.8718
00002297906	SANDOZ PIOGLITAZONE	SDZ	\$	0.8718
00002242572	ACTOS	TAK	\$	2.3171
30 MG (BASE) ORAL TABLET				
00002303450	ACCEL PIOGLITAZONE	ACP	\$	1.2214
00002302950	APO-PIOGLITAZONE	APX	\$	1.2214
00002363240	AVA-PIOGLITAZONE	AVA	\$	1.2214
00002302888	CO PIOGLITAZONE	COB	\$	1.2214
00002326485	MINT-PIOGLITAZONE	MPI	\$	1.2214
00002298287	MYLAN-PIOGLITAZONE	MYP	\$	1.2214
00002274922	NOVO-PIOGLITAZONE	TEV	\$	1.2214
00002307677	PHL-PIOGLITAZONE	PHH	\$	1.2214
00002339587	PIOGLITAZONE HYDROCHLORIDE	AHI	\$	1.2214
00002303132	PMS-PIOGLITAZONE	PMS	\$	1.2214
00002301431	RATIO-PIOGLITAZONE	RPH	\$	1.2214
00002297914	SANDOZ PIOGLITAZONE	SDZ	\$	1.2214
00002242573	ACTOS	TAK	\$	3.2462
45 MG (BASE) ORAL TABLET				
00002303469	ACCEL PIOGLITAZONE	ACP	\$	1.8365
00002302977	APO-PIOGLITAZONE	APX	\$	1.8365
00002363259	AVA-PIOGLITAZONE	AVA	\$	1.8365
00002302896	CO PIOGLITAZONE	COB	\$	1.8365
00002326493	MINT-PIOGLITAZONE	MPI	\$	1.8365
00002298295	MYLAN-PIOGLITAZONE	MYP	\$	1.8365
00002274930	NOVO-PIOGLITAZONE	TEV	\$	1.8365
00002307723	PHL-PIOGLITAZONE	PHH	\$	1.8365
00002339595	PIOGLITAZONE HYDROCHLORIDE	AHI	\$	1.8365
00002303140	PMS-PIOGLITAZONE	PMS	\$	1.8365
00002301458	RATIO-PIOGLITAZONE	RPH	\$	1.8365
00002297922	SANDOZ PIOGLITAZONE	SDZ	\$	1.8365
00002242574	ACTOS	TAK	\$	4.8811

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

PIPERACILLIN SODIUM/ TAZOBACTAM SODIUM

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."

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	\$	9.6120
00002299623	PIPERACILLIN SODIUM/TAZOBACTAM SODIUM	SDZ	\$	9.6120
00002170817	TAZOCIN	WAY	\$	11.9220
3 G / VIAL (BASE) * 375 MG / VIAL (BASE) INJECTION				
00002308452	PIPERACILLIN AND TAZOBACTAM	APX	\$	14.4180
00002299631	PIPERACILLIN SODIUM/TAZOBACTAM SODIUM	SDZ	\$	14.4180
00002170795	TAZOCIN	WAY	\$	17.8830
4 G / VIAL (BASE) * 500 MG / VIAL (BASE) INJECTION				
00002308460	PIPERACILLIN AND TAZOBACTAM	APX	\$	19.2250
00002299658	PIPERACILLIN SODIUM/TAZOBACTAM SODIUM	SDZ	\$	19.2250
00002170809	TAZOCIN	WAY	\$	23.8450

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."

0.075 MG ORAL TABLET				
00002223767	NORPROLAC	FEI	\$	1.0900
0.15 MG ORAL TABLET				
00002223775	NORPROLAC	FEI	\$	1.6300

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

RALOXIFENE HCL

"For the treatment of osteoporosis in patients who have documented hip, vertebral or other fractures. Special authorization for this criteria may be granted for 6 months."

"For the treatment of osteoporosis in patients with documented evidence of intolerance or lack of response to etidronate (i.e. demonstrated as a > 2% loss in bone mineral density in one year). Special authorization for this criteria may be granted for 6 months."

"Coverage cannot be provided for two or more osteoporosis medications (alendronate, calcitonin, denosumab, etidronate, raloxifene, risedronate) 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."

All requests for raloxifene HCl must be completed using the Alendronate/Raloxifene/Risedronate/Synthetic Calcitonin Salmon for Osteoporosis Special Authorization Request Form (ABC 31086).

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

60 MG ORAL TABLET

00002279215	APO-RALOXIFENE	APX	\$	0.8457
00002312298	NOVO-RALOXIFENE	TEV	\$	0.8457
00002358921	PMS-RALOXIFENE	PMS	\$	0.8457
00002239028	EVISTA	LIL	\$	1.8805

RIFABUTIN

"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."

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

150 MG ORAL CAPSULE

00002063786	MYCOBUTIN	PFI	\$	3.9821
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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

00002242763	RILUTEK	SAV	\$	9.8173
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**ALBERTA HEALTH AND WELLNESS DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

RISEDRONATE SODIUM

"For the treatment of osteoporosis in patients who have documented hip, vertebral or other fractures. Special authorization may be granted for 6 months."

"For the treatment of osteoporosis in patients with documented evidence of intolerance or lack of response to etidronate (i.e. demonstrated as a > 2% loss in bone mineral density in one year). Special authorization for this criteria may be granted for 6 months."

"Coverage cannot be provided for two or more osteoporosis medications (alendronate, calcitonin, denosumab, etidronate, raloxifene, risedronate) 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."

"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."

All requests for risedronate sodium for Osteoporosis must be completed using the Alendronate/Raloxifene/Risedronate/Synthetic Calcitonin Salmon for Osteoporosis Special Authorization Request Form (ABC 31086).

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

5 MG ORAL TABLET

00002298376	NOVO-RISEDRONATE	TEV	\$	1.3897
00002242518	ACTONEL	WCC	\$	1.9125

30 MG ORAL TABLET

00002298384	NOVO-RISEDRONATE	TEV	\$	9.0033
00002239146	ACTONEL	WCC	\$	12.4090

35 MG ORAL TABLET

00002353687	APO-RISEDRONATE	APX	\$	3.9224
00002364816	AVA-RISEDRONATE	AVA	\$	3.9224
00002357984	MYLAN-RISEDRONATE	MYP	\$	3.9224
00002298392	NOVO-RISEDRONATE	TEV	\$	3.9224
00002302209	PMS-RISEDRONATE	PMS	\$	3.9224
00002319861	RATIO-RISEDRONATE	RPH	\$	3.9224
00002370255	RISEDRONATE	SNS	\$	3.9224
00002327295	SANDOZ RISEDRONATE	SDZ	\$	3.9224
00002246896	ACTONEL	WCC	\$	10.4250

ALBERTA HEALTH AND WELLNESS 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 meet at least two of three 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 (Note: one trial must include a first generation antipsychotic agent); OR
- Possesses clinical evidence of previous successful treatment with risperidone or paliperidone therapy.

Special Authorization may be granted for six months."

All requests (including renewal requests) for risperidone prolonged release injection must be completed using the Paliperidone/Risperidone Prolonged Release Injection Special Authorization Request Form (ABC 31258).

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

25 MG / VIAL INJECTION

00002255707	RISPERDAL CONSTA	JAI	\$ 161.0900
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37.5 MG / VIAL INJECTION

00002255723	RISPERDAL CONSTA	JAI	\$ 241.6200
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50 MG / VIAL INJECTION

00002255758	RISPERDAL CONSTA	JAI	\$ 322.1600
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ALBERTA HEALTH AND WELLNESS DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

RITUXIMAB

"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); AND
- One anti-tumor necrosis factor (anti-TNF) therapy (e.g., etanercept, infliximab or adalimumab) (minimum 12 week trial).

'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 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 experienced a subsequent loss of effect as defined by a worsening greater than or equal to 0.6 in the DAS28 score AND possess a DAS28 score of greater than or equal to 3.2.

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 31205).

10 MG / ML INJECTION

00002241927 RITUXAN HLR \$ 45.3100

**ALBERTA HEALTH AND WELLNESS 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 30776).

1.5 MG (BASE) ORAL CAPSULE

00002336715	APO-RIVASTIGMINE	APX	\$	0.9805
00002332809	MYLAN-RIVASTIGMINE	MYP	\$	0.9805
00002305984	NOVO-RIVASTIGMINE	TEV	\$	0.9805
00002306034	PMS-RIVASTIGMINE	PMS	\$	0.9805
00002311283	RATIO-RIVASTIGMINE	RPH	\$	0.9805
00002324563	SANDOZ RIVASTIGMINE	SDZ	\$	0.9805
00002242115	EXELON	NOV	\$	2.6059

3 MG (BASE) ORAL CAPSULE

00002336723	APO-RIVASTIGMINE	APX	\$	0.9805
00002332817	MYLAN-RIVASTIGMINE	MYP	\$	0.9805
00002305992	NOVO-RIVASTIGMINE	TEV	\$	0.9805
00002306042	PMS-RIVASTIGMINE	PMS	\$	0.9805
00002311291	RATIO-RIVASTIGMINE	RPH	\$	0.9805
00002324571	SANDOZ RIVASTIGMINE	SDZ	\$	0.9805
00002242116	EXELON	NOV	\$	2.6059

4.5 MG (BASE) ORAL CAPSULE

00002336731	APO-RIVASTIGMINE	APX	\$	0.9805
00002332825	MYLAN-RIVASTIGMINE	MYP	\$	0.9805
00002306018	NOVO-RIVASTIGMINE	TEV	\$	0.9805
00002306050	PMS-RIVASTIGMINE	PMS	\$	0.9805
00002311305	RATIO-RIVASTIGMINE	RPH	\$	0.9805
00002324598	SANDOZ RIVASTIGMINE	SDZ	\$	0.9805
00002242117	EXELON	NOV	\$	2.6059

6 MG (BASE) ORAL CAPSULE

00002336758	APO-RIVASTIGMINE	APX	\$	0.9805
00002332833	MYLAN-RIVASTIGMINE	MYP	\$	0.9805
00002306026	NOVO-RIVASTIGMINE	TEV	\$	0.9805
00002306069	PMS-RIVASTIGMINE	PMS	\$	0.9805
00002311313	RATIO-RIVASTIGMINE	RPH	\$	0.9805
00002324601	SANDOZ RIVASTIGMINE	SDZ	\$	0.9805
00002242118	EXELON	NOV	\$	2.6059

2 MG / ML (BASE) ORAL SOLUTION

00002245240	EXELON	NOV	\$	1.3700
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**ALBERTA HEALTH AND WELLNESS DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

RIZATRIPTAN BENZOATE

(Refer to 28:32.28 of the Alberta Health and Wellness 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.

10 MG (BASE)	ORAL TABLET			
00002240521	MAXALT	MFC	\$	15.2201
5 MG (BASE)	ORAL DISINTEGRATING TABLET			
00002374730	CO RIZATRIPTAN ODT	COB	\$	5.3270
00002379198	MYLAN-RIZATRIPTAN ODT	MYP	\$	5.3270
00002351870	SANDOZ RIZATRIPTAN ODT	SDZ	\$	5.3270
00002240518	MAXALT RPD	MFC	\$	15.2201
10 MG (BASE)	ORAL DISINTEGRATING TABLET			
00002374749	CO RIZATRIPTAN ODT	COB	\$	5.3270
00002379201	MYLAN-RIZATRIPTAN ODT	MYP	\$	5.3270
00002351889	SANDOZ RIZATRIPTAN ODT	SDZ	\$	5.3270
00002240519	MAXALT RPD	MFC	\$	15.2201

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.

2 MG (BASE)	ORAL TABLET			
00002241112	AVANDIA	GSK	\$	1.3755
4 MG (BASE)	ORAL TABLET			
00002241113	AVANDIA	GSK	\$	2.1584
8 MG (BASE)	ORAL TABLET			
00002241114	AVANDIA	GSK	\$	3.0865

ALBERTA HEALTH AND WELLNESS DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

ROSIGLITAZONE MALEATE/ 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

"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."

Special authorization may be granted for 24 months.

1 MG (BASE) * 500 MG ORAL TABLET				
00002247085	AVANDAMET	GSK	\$	0.6421
2 MG (BASE) * 500 MG ORAL TABLET				
00002247086	AVANDAMET	GSK	\$	1.1611
2 MG (BASE) * 1,000 MG ORAL TABLET				
00002248440	AVANDAMET	GSK	\$	1.2682
4 MG (BASE) * 500 MG ORAL TABLET				
00002247087	AVANDAMET	GSK	\$	1.5946
4 MG (BASE) * 1,000 MG ORAL TABLET				
00002248441	AVANDAMET	GSK	\$	1.7337

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.

5 MG (BASE) ORAL TABLET				
00002333554	ONGLYZA	BMS	\$	2.7560

ALBERTA HEALTH AND WELLNESS DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

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.

100 MG ORAL TABLET				
00002303922	JANUVIA	MFC	\$	2.8863

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.

50 MG * 500 MG ORAL TABLET				
00002333856	JANUMET	MFC	\$	1.5641
50 MG * 850 MG ORAL TABLET				
00002333864	JANUMET	MFC	\$	1.5641
50 MG * 1,000 MG ORAL TABLET				
00002333872	JANUMET	MFC	\$	1.5641

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

SOLIFENACIN SUCCINATE

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

FIRST-LINE DRUG PRODUCT(S): OXYBUTYNIN

"For patients who are intolerant to oxybutynin.

Special authorization may be granted for 24 months."

5 MG ORAL TABLET			
00002277263	VESICARE	ASP	\$ 1.5000
10 MG ORAL TABLET			
00002277271	VESICARE	ASP	\$ 1.5000

SOMATROPIN

"For replacement of endogenous growth hormone in adults with severe growth hormone deficiency. Information is required regarding the results of a diagnostic insulin tolerance test. Growth hormone values less than 3 mcg/litre during hypoglycemia 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 a diagnostic insulin tolerance test. Growth hormone values less than 3 mcg/litre during hypoglycemia 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 / VIAL INJECTION			
<input checked="" type="checkbox"/>	00002325063	OMNITROPE	SDZ \$ 103.8667
<input checked="" type="checkbox"/>	00002215136	SAIZEN	SRO \$ 144.9000
5 MG / VIAL INJECTION			
	00002237971	SAIZEN	SRO \$ 217.5200
5.83 MG / ML INJECTION			
	00002350122	SAIZEN	SRO \$ 261.0000
6.7 MG / ML INJECTION			
	00002325071	OMNITROPE	SDZ \$ 207.7333
8 MG / ML INJECTION			
<input checked="" type="checkbox"/>	00002350130	SAIZEN (1.5 ML)	SRO \$ 348.0000
<input checked="" type="checkbox"/>	00002350149	SAIZEN (2.5 ML)	SRO \$ 348.0000
8.8 MG / VIAL INJECTION			
	00002272083	SAIZEN	SRO \$ 348.0300

ALBERTA HEALTH AND WELLNESS DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

SULFUR/ SULFACETAMIDE SODIUM

"For the treatment seborrheic dermatitis and bacterial folliculitis.

Special authorization may be granted for 6 months."

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

5 % * 10 % TOPICAL LOTION			
00002220407	SULFACET-R	VCL	\$ 0.9628

SUMATRIPTAN HEMISULFATE

(Refer to 28:32.28 of the Alberta Health and Wellness 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	\$ 14.3859
20 MG / DOSE (BASE) NASAL UNIT DOSE SPRAY			
00002230420	IMITREX	GSK	\$ 14.8045

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

SUMATRIPTAN SUCCINATE

(Refer to 28:32.28 of the Alberta Health and Wellness 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	\$ 7.1350
00002366258	AVA-SUMATRIPTAN	AVA	\$ 7.1350
00002257890	CO SUMATRIPTAN	COB	\$ 7.1350
00002268914	MYLAN-SUMATRIPTAN	MYP	\$ 7.1350
00002286823	NOVO-SUMATRIPTAN DF	TEV	\$ 7.1350
00002256436	PMS-SUMATRIPTAN	PMS	\$ 7.1350
00002263025	SANDOZ SUMATRIPTAN	SDZ	\$ 7.1350
00002286521	SUMATRIPTAN	SNS	\$ 7.1350
00002212153	IMITREX DF	GSK	\$ 15.1567
100 MG (BASE) ORAL TABLET			
00002268396	APO-SUMATRIPTAN	APX	\$ 7.8600
00002366266	AVA-SUMATRIPTAN	AVA	\$ 7.8600
00002257904	CO SUMATRIPTAN	COB	\$ 7.8600
00002268922	MYLAN-SUMATRIPTAN	MYP	\$ 7.8600
00002239367	NOVO-SUMATRIPTAN	TEV	\$ 7.8600
00002286831	NOVO-SUMATRIPTAN DF	TEV	\$ 7.8600
00002256444	PMS-SUMATRIPTAN	PMS	\$ 7.8600
00002263033	SANDOZ SUMATRIPTAN	SDZ	\$ 7.8600
00002286548	SUMATRIPTAN	SNS	\$ 7.8600
00002212161	IMITREX DF	GSK	\$ 16.6968
6 MG / SYR (BASE) INJECTION SYRINGE			
00002361698	SUMATRIPTAN SUN (0.5 ML)	SPG	\$ 16.5889
00002212188	IMITREX (0.5 ML)	GSK	\$ 44.0900

ALBERTA HEALTH AND WELLNESS DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

SYNTHETIC CALCITONIN SALMON (SALCATONIN)

"For the treatment of osteoporosis in patients with documented evidence of intolerance or lack of response to etidronate (i.e. demonstrated as a >2% loss in bone mineral density in one year). Special authorization may be granted for 6 months."

"Coverage cannot be provided for two or more osteoporosis medications (alendronate, calcitonin, denosumab, etidronate, raloxifene, risedronate) 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."

All requests for synthetic calcitonin salmon must be completed using the Alendronate/Raloxifene/Risedronate/Synthetic Calcitonin Salmon for Osteoporosis Special Authorization Request Form (ABC 31086).

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

200 IU / DOSE NASAL METERED DOSE SPRAY				
00002247585	APO-CALCITONIN	APX	\$	1.4000
00002261766	SANDOZ CALCITONIN NS	SDZ	\$	1.4000
00002240775	MIACALCIN	NOV	\$	2.1888

TACROLIMUS

"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 criteria, information is also required regarding the area(s) affected. In order to comply with the second criteria, information is also required regarding the percentage body surface area affected.

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

0.1 % TOPICAL OINTMENT				
00002244148	PROTOPIC	ASP	\$	2.3005

ALBERTA HEALTH AND WELLNESS 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 criteria, information is also required regarding the area(s) affected. In order to comply with the fourth criteria, information is also required regarding the percentage body surface area affected.

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

0.03 % TOPICAL OINTMENT				
00002244149	PROTOPIC	ASP	\$	2.1498

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)	PAL	\$	1.9959
24.3 MG TRANSDERMAL PATCH				
00002245972	ANDRODERM (5 MG/DAY)	PAL	\$	3.9919

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				
00000782327	ANDRIOL	MFC	\$	0.9400

ALBERTA HEALTH AND WELLNESS DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

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

00002199270	NITOMAN	VCL	\$	6.9360
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TIZANIDINE HCL

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

FIRST-LINE DRUG PRODUCT(S): DIAZEPAM OR BACLOFEN

"For the treatment of spasticity in patients with documented evidence of intolerance or lack of response to diazepam or baclofen. Special authorization is granted for 24 months."

4 MG (BASE) ORAL TABLET

00002259893	APO-TIZANIDINE	APX	\$	0.3686
00002272059	MYLAN-TIZANIDINE	MYP	\$	0.3686
00002239170	ZANAFLEX	PAL	\$	0.7746

**ALBERTA HEALTH AND WELLNESS 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); AND
- At least one anti-tumor necrosis factor (anti-TNF) therapy (e.g., etanercept, infliximab or adalimumab) (minimum 12 week trial); AND
- Abatacept or rituximab (minimum 12 - 16 week 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 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 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 5 doses, 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].

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 dose of 4 mg/kg to 8 mg/kg (up to a maximum of 800 mg per dose) 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;
- 2) The RA Specialist must confirm in writing that the patient has maintained a response to

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

TOCILIZUMAB

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/Etanercept/Golimumab/Infliximab/Tocilizumab for Rheumatoid Arthritis Special Authorization Request Form (ABC 30902).

80 MG / VIAL INJECTION			
00002350092	ACTEMRA (4 ML)	HLR	\$ 179.2000
200 MG / VIAL INJECTION			
00002350106	ACTEMRA (10 ML)	HLR	\$ 448.0000
400 MG / VIAL INJECTION			
00002350114	ACTEMRA (20 ML)	HLR	\$ 896.0000

TOLTERODINE L-TARTRATE

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

FIRST-LINE DRUG PRODUCT(S): OXYBUTYNIN

"For patients who are intolerant to oxybutynin."

"Special authorization may be granted for 24 months."

2 MG ORAL EXTENDED-RELEASE CAPSULE			
00002244612	DETROL LA	PFI	\$ 1.9122
4 MG ORAL EXTENDED-RELEASE CAPSULE			
00002244613	DETROL LA	PFI	\$ 1.9122

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.

0.01 % TOPICAL CREAM			
00000657204	STIEVA-A	GSK	\$ 0.2996
0.025 % TOPICAL CREAM			
00000578576	STIEVA-A	GSK	\$ 0.2996
0.05 % TOPICAL CREAM			
00000518182	STIEVA-A	GSK	\$ 0.2996
0.1 % TOPICAL CREAM			
00000662348	STIEVA-A FORTE	GSK	\$ 0.2996
0.01 % TOPICAL GEL			
00001926462	VITAMIN A ACID	VCL	\$ 0.2964
0.025 % TOPICAL GEL			
00001926470	VITAMIN A ACID	VCL	\$ 0.2964
00000587966	STIEVA-A	GSK	\$ 0.2996

ALBERTA HEALTH AND WELLNESS DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

TRETINOIN

0.05 % TOPICAL GEL

00001926489	VITAMIN A ACID	VCL	\$	0.2964
00000641863	STIEVA-A	GSK	\$	0.2996

TROSPIUM CHLORIDE

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

FIRST-LINE DRUG PRODUCT(S): OXYBUTYNIN

"For patients who are intolerant to oxybutynin."

"Special authorization may be granted for 24 months."

20 MG ORAL TABLET

00002275066	TROSEC	SUN	\$	0.7635
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ALBERTA HEALTH AND WELLNESS DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

USTEKINUMAB

"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 three doses of 45 mg 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 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."

All requests (including renewal requests) for ustekinumab for Plaque Psoriasis must be completed using the Adalimumab/Etanercept/Infliximab/Ustekinumab for Plaque Psoriasis Special Authorization Request Form (ABC 31192).

45 MG INJECTION VIAL OR SYRINGE

00002320673 STELARA (0.5 ML VIAL OR SYRINGE) JAI \$ 4399.5900

For this product - pricing has been established on a per vial or syringe basis.

ALBERTA HEALTH AND WELLNESS DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

VALGANCICLOVIR HCL

"For the treatment of CMV retinitis in patients with acquired immunodeficiency syndrome (AIDS)."

"Special authorization may be granted for 12 months."

"For the prevention of CMV disease in solid organ transplant patients at risk (i.e. risk is defined as donor +ve/recipient -ve for CMV, or recipient +ve post-active treatment of CMV disease with IV ganciclovir, or recipient +ve in patients receiving antilymphocyte antibody [ALA]).

For the purpose of administering this criterion, islet transplant recipients are at similar risk of CMV disease to patients undergoing a solid organ transplant and qualify for drug coverage."

"Special authorization may be granted for 100 days."

"For the prevention of CMV disease in kidney transplant patients at risk (i.e. risk is defined as donor +ve/recipient -ve for CMV, or recipient +ve post-active treatment of CMV disease with IV ganciclovir, or recipient +ve in patients receiving antilymphocyte antibody [ALA])."

"Special authorization may be granted for 200 days."

450 MG (BASE)	ORAL TABLET			
00002245777	VALCYTE	HLR	\$	22.8582

VANCOMYCIN HCL

"For the treatment of:

1) Clostridium difficile enteritis if there is clinical deterioration or documented failure on metronidazole therapy. Documented failure is defined as no clinical improvement after 5 days of therapy or

2) Laboratory confirmed relapse of Clostridium difficile enteritis with symptoms after 2 courses of metronidazole therapy or

3) Clostridium difficile enteritis if there is documented or impending toxic megacolon or

4) Clostridium difficile enteritis if there is intolerance or side effects to metronidazole therapy."

125 MG (BASE)	ORAL CAPSULE			
00000800430	VANCOICIN	MLI	\$	7.5573
250 MG (BASE)	ORAL CAPSULE			
00000788716	VANCOICIN	MLI	\$	15.1141

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			
00002291177	CHAMPIX	PFI	\$	1.7206
1 MG (BASE)	ORAL TABLET			
00002291185	CHAMPIX	PFI	\$	1.7205

ALBERTA HEALTH AND WELLNESS DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

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			
00002298309	CHAMPIX (STARTER PACK)	PFI	\$ 1.7208

VORICONAZOLE

"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."

50 MG ORAL TABLET			
00002256460	VFEND	PFI	\$ 12.4818
200 MG ORAL TABLET			
00002256479	VFEND	PFI	\$ 49.9064
200 MG / VIAL INJECTION			
00002256487	VFEND	PFI	\$ 142.9416

ALBERTA HEALTH AND WELLNESS DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

ZAFIRLUKAST

(Refer to 48:10.24 of the Alberta Health and Wellness Drug Benefit List for coverage of patients 12 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 zafirlukast must be completed using the Montelukast/Zafirlukast Special Authorization Request Form (ABC 31313).

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

20 MG ORAL TABLET

00002236606	ACCOLATE	AZC	\$	0.7492
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ZOLEDRONIC ACID

"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 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

00002269198	ACLASTA	NOV	\$	6.7080
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ZOLEDRONIC ACID

"For the treatment of tumor-induced hypercalcemia in patients with documented evidence of intolerance or lack of response to clodronate or pamidronate. Special authorization may be granted for 6 months."

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

0.8 MG / ML INJECTION

00002248296	ZOMETA CONCENTRATE	NOV	\$	110.8160
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**ALBERTA HEALTH AND WELLNESS DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

ZOLMITRIPTAN

(Refer to 28:32.28 of the Alberta Health and Wellness 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

00002369036	MYLAN-ZOLMITRIPTAN	MYP	\$	5.2110
00002324229	PMS-ZOLMITRIPTAN	PMS	\$	5.2110
00002362988	SANDOZ ZOLMITRIPTAN	SDZ	\$	5.2110
00002313960	TEVA-ZOLMITRIPTAN	TEV	\$	5.2110
00002238660	ZOMIG	AZC	\$	13.8500

2.5 MG ORAL DISPERSIBLE TABLET

00002324768	PMS-ZOLMITRIPTAN ODT	PMS	\$	5.2110
00002362996	SANDOZ ZOLMITRIPTAN ODT	SDZ	\$	5.2110
00002342545	TEVA-ZOLMITRIPTAN OD	TEV	\$	5.2110
00002243045	ZOMIG RAPIMELT	AZC	\$	13.8500

5 MG / DOSE NASAL UNIT DOSE SPRAY

00002248993	ZOMIG	AZC	\$	13.8500
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