SECTION 3

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

Special Authorization Policy

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

1. The drug is covered by Alberta Health under specified criteria (listed in the following sections). Drug Products and indications other than those specified are not eligible for consideration by special authorization.

2. The drug is normally covered by another government program or agency for a specific approved clinical condition, but is needed for the treatment of a clinical condition that is not covered by that government program or agency.

3. The drug is required because other drug products listed in the Alberta Drug Benefit List are contraindicated or inappropriate because of the clinical condition of the patient.

4. The particular brand of drug is considered essential in the care of a patient, where the LCA price policy would otherwise apply. Coverage of a specific brand may be considered where a patient has experienced significant allergic reactions or documented untoward therapeutic effects with alternate brands in an interchangeable grouping. Coverage of a brand name product will not be considered in situations where the interchangeable grouping includes a pseudo-generic to the brand name drug.

5. A particular drug product or dosage form of a drug is essential in the care of a patient where the MAC price policy would otherwise apply. Exceptions may occur at the product level. Coverage may be considered only where a patient has experienced significant allergic reactions or documented untoward therapeutic effects with the drug product which establishes the MAC pricing.

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

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

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

1. For initial approval, a special authorization request must be submitted. If approval is granted, it will be effective for the Approval Period outlined in the drug product's Special Authorization criteria.

2. As long as the patient has submitted a claim for the drug product within the preceding Approval Period (example: within the preceding 6 months), approval will be automatically renewed for a further Approval Period (example: a further 6 months). There is no need for the prescriber to submit a new request as the automated real-time claims adjudication system will read the patient's claims history to determine if a claim has been made within the preceding Approval Period.

3. If the patient does not make a claim for the drug product during the Approval Period, the approval will lapse and a new special authorization request must be submitted.

STEP THERAPY APPROVAL PROCESS

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

1. If the patient has made a claim for the First-Line* drug product(s) within the preceding 12 months, the claim for the step therapy drug will be approved.

2. The automated real-time claims adjudication system will read the patient's claims history to determine if the required First-Line* drug product(s) have been claimed within the preceding 12 months.

3. Subsequent claims for drug product(s) permitted by step therapy will continue to be approved as long as the drug product has been claimed within the preceding 12 months.

4. The regular special authorization approval process will continue to be available for step therapy approvals for those patients whose First-Line* drug claims cannot be adjudicated through the automated real-time claims adjudication system.

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

DRUG PRODUCTS NOT ELIGIBLE FOR CONSIDERATION BY SPECIAL AUTHORIZATION

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

1. Drug products deleted from the List.

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

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.

EFFECTIVE APRIL 1, 2018

Section 3 • 2
Criteria for Coverage

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

Products Available Through Health Canada’s Special Access Program

PEMOLINE

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

<table>
<thead>
<tr>
<th>37.5 MG</th>
<th>ORAL TABLET</th>
</tr>
</thead>
<tbody>
<tr>
<td>DIN N/A*</td>
<td>CYLERT</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>75 MG</th>
<th>ORAL TABLET</th>
</tr>
</thead>
<tbody>
<tr>
<td>DIN N/A*</td>
<td>CYLERT</td>
</tr>
</tbody>
</table>

*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.
ABATACEPT
Rheumatoid Arthritis:

"Special authorization coverage may be provided for use in combination with methotrexate or other DMARDS, for the reduction in signs and symptoms of severely active Rheumatoid Arthritis (RA) in adult patients (18 years of age or older) who are refractory or intolerant to:
- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- Methotrexate with other disease modifying anti-rheumatic agent(s) (minimum 4 month trial), [e.g., methotrexate with hydroxychloroquine or methotrexate with sulfasalazine]; AND
- Leflunomide (minimum 10 week trial at 20 mg daily).

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

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

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

For continued coverage beyond 12 weeks, the patient must meet the following criteria:
1) The patient must be assessed by an RA Specialist after the initial 12 weeks to determine response.
2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
  - ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND
  - An improvement of 0.22 in HAQ score [reported to two (2) decimal places].
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be approved for a period of 12 months. Coverage for abacept will be provided for one intravenous dose of up to 1000 mg every 4 weeks, or one weekly 125 mg subcutaneous injection. Ongoing coverage
ABATACEPT may be considered only if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by an RA Specialist to determine response;
2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
   - confirmation of maintenance of ACR20, OR
   - maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.
3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.
   It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

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

125 MG / SYR INJECTION

| 00002402475   | ORENCIA       | BMS | $ 370.3630 |
ABATACEPT
Rheumatoid Arthritis:

"Special authorization coverage may be provided for use in combination with methotrexate or other DMARDS, for the reduction in signs and symptoms of severely active Rheumatoid Arthritis (RA) in adult patients (18 years of age or older) who are refractory or intolerant to:
- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- Methotrexate with other disease modifying anti-rheumatic agent(s) (minimum 4 month trial), [e.g., methotrexate with hydroxychloroquine or methotrexate with sulfasalazine]; AND
- Leflunomide (minimum 10 week trial at 20 mg daily).

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

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

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

For continued coverage beyond 12 weeks, the patient must meet the following criteria:
1) The patient must be assessed by an RA Specialist after the initial 12 weeks to determine response.
2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
   - ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND
   - An improvement of 0.22 in HAQ score [reported to two (2) decimal places].
   It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be approved for a period of 12 months. Coverage for abacept will be provided for one intravenous dose of up to 1000 mg every 4 weeks, or one weekly 125 mg subcutaneous injection. Ongoing coverage...
ABATACEPT may be considered only if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by an RA Specialist to determine response;
2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
   - confirmation of maintenance of ACR20, OR
   - maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.
3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above."

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

Polyarticular Juvenile Idiopathic Arthritis:

"Special authorization coverage may be provided for the reduction in signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis (pJIA) in patients 6 years of age and older who:
- Have 5 or more active joints (defined by either swelling or limitation of motion plus pain and/or tenderness), AND
- Are refractory to one or more disease modifying anti-rheumatic agents (DMARDs) conventionally used in children (minimum three month trial), AND
- Are refractory to or intolerant to etanercept and/or adalimumab (minimum 12 week trial).

'Refractory' is defined as lack of effect at the recommended doses and duration of treatments as listed above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in the product monographs.

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

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

For potential coverage for retreatment with abatacept following a subsequent disease flare, the patient must meet the following criteria:
1) The patient must be assessed by a Pediatric Rheumatology Specialist after the initial 16 weeks, but no longer than 20 weeks after, treatment with this biologic agent to
ABATACEPT

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

Following assessment and confirmation of initial treatment response, coverage for retreatment with abatacept may be approved for one dose of 10 mg/kg (maximum dose 1000 mg) at 0, 2*, 4, 8, 12 and 16 weeks (total of up to six doses; “the week 2 dose on retreatment is optional, to be administered at the discretion of the Pediatric Rheumatology Specialist). In order to be considered for coverage for retreatment, the patient must meet the following criteria:
1) The patient has been assessed by a Pediatric Rheumatology Specialist and the presence of disease flare confirmed. Disease flare is defined as worsening of at least 30% or greater in at least 3 of 6 ACR Pedi 30 variables for pJIA and 30% or greater improvement in no more than one variable.
2) The Pediatric Rheumatology Specialist must confirm in writing that the patient has had an initial treatment response (as assessed above) and that the patient has experienced a disease flare (as defined above)."

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

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

<table>
<thead>
<tr>
<th>250 MG / VIAL (BASE)</th>
<th>INJECTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002282097</td>
<td>ORENCIA</td>
</tr>
<tr>
<td>BMS</td>
<td>$ 496.7535</td>
</tr>
</tbody>
</table>
ACLIDINIUM BROMIDE/ FORMOTEROL FUMARATE DIHYDRATE
The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

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

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

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

"Special authorization may be granted for 24 months."

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

UP - First-line therapy ineffective

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

| 400 MCG / DOSE * 12 MCG / DOSE INHALATION METERED INHALATION POWDER |
|-------------------------|---------------------|-----------------|
| 00002439530             | DUAKLIR GENUAIR     | AZC             |
|                         |                     | $ 1.0000        |
ADALIMUMAB
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 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].

Following this assessment, continued coverage may be approved for 40 mg every other week for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by an RA Specialist to determine response;
2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
   - confirmation of maintenance of ACR20, or
   - maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.
3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal

The DBL is not a prescribing or a diagnostic tool. Prescribers should refer to drug monographs and utilize professional judgment.
UNIT OF ISSUE - REFER TO PRICE POLICY
Section 3 · 10
EFFECTIVE APRIL 1, 2018
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

ALBERTA DRUG BENEFIT LIST

ADALIMUMAB

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

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

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:
- 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:

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

PRODUCT IS NOT INTERCHANGEABLE

Section 3 · 11

EFFECTIVE APRIL 1, 2018
ADALIMUMAB

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

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

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

Ankylosing Spondylitis:

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

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

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

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

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

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

Following this assessment, continued coverage may be approved for one 40 mg dose every other week for a period of 12 months. Ongoing coverage may be considered if the patient is re-
ADALIMUMAB

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/Certolizumab/Etanercept/Golimumab/Infliximab for Ankylosing Spondylitis Special Authorization Request Form (ABC 60028).

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, tapering by 5 mg each week to 20 mg, then tapering by 2.5 mg each week to zero, or similar.

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

AND
b) Immunosuppressive therapy as follows:
   - Azathioprine: minimum of 2 mg/kg/day for a minimum of 3 months; OR
   - 6-mercaptopurine: minimum of 1 mg/kg/day for a minimum of 3 months; OR
   - Methotrexate: minimum or 15 mg/week for a minimum of 3 months.
   OR
   - Immunosuppressive therapy discontinued at less than 3 months due to serious adverse effects or reactions.

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

PRODUCT IS NOT INTERCHANGEABLE Section 3 · 13 EFFECTIVE APRIL 1, 2018
ADALIMUMAB

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 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.
ADALIMUMAB

Disease; AND
- For New Patients: The Specialist must confirm that the patient has maintained a greater than or equal to 3 point decrease from the New Patient's Baseline Score for Moderately to Severely Active Crohn's; OR
- For Existing Patients: The Specialist must confirm that the patient has maintained the Existing Patient's Baseline Score.

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

Plaque Psoriasis:

"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 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.

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

PRODUCT IS NOT INTERCHANGEABLE
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

ALBERTA DRUG BENEFIT LIST

ADALIMUMAB

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.

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

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

Polyarticular Juvenile Idiopathic Arthritis:

"Special authorization coverage may be provided for the reduction in signs and symptoms of severely active polyarticular juvenile idiopathic arthritis (pJIA) in patients 4 years of age and older who:
- Have 5 or more active joints (defined by either swelling or limitation of motion plus pain and/or tenderness), AND
- Are refractory to one or more disease modifying anti-rheumatic agents (DMARDS) conventionally used in children (minimum three month trial).

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

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

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

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

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

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

Following this assessment, continued coverage may be approved for 24 mg per square meter body surface area (maximum dose 40 mg) every other week, for a maximum of twelve months. After twelve months, in order to be considered for continued coverage, the patient must be re-assessed every twelve months by a Pediatric Rheumatology Specialist and must meet the following criteria:
1) The patient has been assessed by a Pediatric Rheumatology Specialist to determine response, and
2) The Pediatric Rheumatology Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by maintenance of the ACR Pedi 30,
3) Data from all of the six variables comprising the ACR Pedi 30 and the CHAQ scores must be reported in each request.

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

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

Ulcerative Colitis:

"Special authorization coverage may be provided for the reduction in signs and symptoms and induction and maintenance of clinical remission of Ulcerative Colitis in adult patients (18 years of age or older) with active disease (characterized by a partial Mayo score >4 prior to initiation of biologic therapy) and who are refractory or intolerant to:
- mesalamine: minimum of 4 grams/day for a minimum of 4 weeks; AND
- corticosteroids (failure to respond to prednisone 40 mg daily for 2 weeks, or; steroid dependent i.e. failure to taper off steroids without recurrence of disease or disease requiring a second dose of steroids within 12 months of previous dose).

'Refractory’ is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

Immunosuppressive therapy as follows may also be initiated if in the clinician's judgment a trial is warranted:
i) Azathioprine: minimum of 2 mg/kg/day for a minimum of 2 months; OR
ii) 6-mercaptopurine: minimum of 1 mg/kg/day for a minimum of 2 months

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

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

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

- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

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

Following this assessment, continued coverage may be approved for a dose of 40 mg every 2 weeks for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by a Specialist in Gastroenterology to determine response;
2) The Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
   - a decrease in the partial Mayo score of greater than or equal to 2 points from the score prior to initiation of adalimumab therapy.

All requests (including renewal requests) for adalimumab for Ulcerative Colitis must be completed using the Adalimumab/Golimumab/Infliximab/Vedolizumab for Ulcerative Colitis Special Authorization Request Form (ABC 60008).

**Hidradenitis Suppurativa**

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

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

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

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

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

1) The patient must be assessed by a Dermatology Specialist after 12 weeks of treatment to determine response.
2) The Dermatology Specialist must confirm, in writing, that the patient is a 'responder' that meets the following criteria:
   - Greater than or equal to 50% reduction in AN count from pre-treatment baseline AND
   - no increase in abscess count or draining fistula count relative to pre-treatment baseline.

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

Following this assessment, continued coverage may be considered for one 40 mg dose of adalimumab every week for an additional period of 12 months. Ongoing coverage may be
ADALIMUMAB

considered if the patient is re-assessed by a Dermatology Specialist every 12 months and is
confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above."

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

<table>
<thead>
<tr>
<th>40 MG / SYR INJECTION SYRINGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002258595 HUMIRA (40 MG/0.8 ML INJ SYR)</td>
</tr>
</tbody>
</table>

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

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

At least ONE of the following:
- interferon beta
- glatiramer acetate
- dimethyl fumarate
- teriflunomide.

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

Definition of 'refractory'
-Development of neutralizing antibodies to interferon beta.
-When the above MS DMTs are taken at the recommended doses for a full and adequate course of treatment, within a consecutive 12-month period while the patient was on the MS DMT, the patient has:

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

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

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

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

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

**Relapse severity: with moderate relapses modification or more time is required to carry out activities of daily living; with severe relapses there is inability to carry out some activities of daily living; with very severe relapses activities of daily living must be completed by others.

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

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

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

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

2) The patient must have active disease which is defined as at least two relapses* of MS during the previous two years or in the two years prior to starting an MS DMT. In most cases this will be satisfied by the 'refractory' to treatment criterion but if a patient failed an MS DMT more than one year earlier, ongoing active disease must be confirmed.
ALEMTUZUMAB
3) The patient must be ambulatory with or without aid (The registered MS Neurologist must provide a current updated Expanded Disability Status Scale (EDSS) score less than or equal to 5).

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

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

Following assessment of the request, alemtuzumab may be approved for coverage at a dose of 12 mg/day administered by intravenous (IV) infusion for 2 treatment courses:
- Initial Treatment Course: 12 mg/day for 5 consecutive days (60 mg total dose)
- Second Treatment Course: 12 mg/day for 3 consecutive days (36 mg total dose) administered 12 months after the initial treatment course.

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

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

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

<table>
<thead>
<tr>
<th>12 MG / VIAL</th>
<th>INJECTION</th>
<th>LEMTRADA</th>
<th>GZM</th>
<th>$ 12725.7000</th>
</tr>
</thead>
</table>
ALENDARONATE SODIUM

Osteoporosis:

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

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

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

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

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

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

Paget's Disease:

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

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

<table>
<thead>
<tr>
<th>Unit</th>
<th>Name</th>
<th>Manufacturer</th>
<th>Code</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>10 MG ORAL TABLET</td>
<td>ALENDARONATE SODIUM</td>
<td>AHI</td>
<td>00002381486</td>
<td>0.4986</td>
</tr>
<tr>
<td></td>
<td>APO-ALENDARONATE</td>
<td>APX</td>
<td>00002248728</td>
<td>0.4986</td>
</tr>
<tr>
<td></td>
<td>AURO-ALENDARONATE</td>
<td>AUR</td>
<td>00002388545</td>
<td>0.4986</td>
</tr>
<tr>
<td></td>
<td>SANDOZ ALENDARONATE</td>
<td>SDZ</td>
<td>00002288087</td>
<td>0.4986</td>
</tr>
<tr>
<td></td>
<td>VAN-ALENDARONATE</td>
<td>VAN</td>
<td>00002428725</td>
<td>0.4986</td>
</tr>
<tr>
<td>40 MG ORAL TABLET</td>
<td>ACT ALENDARONATE</td>
<td>APH</td>
<td>00002258102</td>
<td>3.0832</td>
</tr>
</tbody>
</table>

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

UNIT OF ISSUE - REFER TO PRICE POLICY

Section 3 - 22

EFFECTIVE APRIL 1, 2018
ALFUZOSIN HCL
The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

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

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

"Special authorization may be granted for 24 months"

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

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

10 MG ORAL SUSTAINED-RELEASE TABLET

<table>
<thead>
<tr>
<th>Product Code</th>
<th>Product Name</th>
<th>Intervention Code</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002447576</td>
<td>ALFUZOSIN</td>
<td>SIV</td>
<td>0.2601</td>
</tr>
<tr>
<td>00002315866</td>
<td>APO-ALFUZOSIN</td>
<td>APX</td>
<td>0.2601</td>
</tr>
<tr>
<td>00002443201</td>
<td>AURO-ALFUZOSIN</td>
<td>AUR</td>
<td>0.2601</td>
</tr>
<tr>
<td>00002304678</td>
<td>SANDOZ ALFUZOSIN</td>
<td>SDZ</td>
<td>0.2601</td>
</tr>
<tr>
<td>00002405792</td>
<td>XATRAL ALFUZOSIN</td>
<td></td>
<td>1.0404</td>
</tr>
</tbody>
</table>

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

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

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

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

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

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

6.25 MG (BASE) ORAL TABLET

<table>
<thead>
<tr>
<th>Product Code</th>
<th>Product Name</th>
<th>Intervention Code</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002405792</td>
<td>APO-ALMOTRIPTAN</td>
<td>APX</td>
<td>7.0433</td>
</tr>
<tr>
<td>00002398435</td>
<td>MYLAN-ALMOTRIPTAN</td>
<td>MYP</td>
<td>7.0433</td>
</tr>
</tbody>
</table>

12.5 MG (BASE) ORAL TABLET

<table>
<thead>
<tr>
<th>Product Code</th>
<th>Product Name</th>
<th>Intervention Code</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002405806</td>
<td>APO-ALMOTRIPTAN</td>
<td>APX</td>
<td>2.3478</td>
</tr>
<tr>
<td>00002398443</td>
<td>MYLAN-ALMOTRIPTAN</td>
<td>MYP</td>
<td>2.3478</td>
</tr>
<tr>
<td>00002405334</td>
<td>SANDOZ ALMOTRIPTAN</td>
<td>SDZ</td>
<td>2.3478</td>
</tr>
</tbody>
</table>
AMPICILLIN
(Refer to Section 1 - Restricted Benefits of the Alberta Drug Benefit List for coverage of the product when prescribed by a Specialist in Infectious Diseases or a designated prescriber.)

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

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

<table>
<thead>
<tr>
<th>250 MG ORAL CAPSULE</th>
<th>500 MG ORAL CAPSULE</th>
</tr>
</thead>
<tbody>
<tr>
<td>00000020877 NOVO-AMPICILLIN</td>
<td>TEV $ 0.4223</td>
</tr>
<tr>
<td>00000020885 NOVO-AMPICILLIN</td>
<td>TEV $ 0.8006</td>
</tr>
</tbody>
</table>

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

"Special authorization coverage may be provided for use in combination with methotrexate for the reduction in signs and symptoms of severely active Rheumatoid Arthritis (RA) in adult patients (18 years of age or older) in whom other biologics are contraindicated or in patients who have experienced serious adverse events while on other biologics and who are refractory or intolerant to:
- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- Methotrexate with other disease modifying anti-rheumatic agent(s) (minimum 4-month trial). [e.g., methotrexate with hydroxychloroquine or methotrexate with sulfasalazine]; AND
- Leflunomide (minimum 10 week trial at 20 mg daily).

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

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

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

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

For continued coverage beyond 8 weeks, the patient must meet the following criteria:
1) The patient must be assessed by an RA Specialist after 8 weeks but no longer than 12 weeks after treatment to determine response.
2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
   - ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND
   - An improvement of 0.22 in HAQ score [reported to two (2) decimal places].

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

Following this assessment, continued coverage may be approved for one 100 mg dose administered once daily for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by an RA Specialist to determine response;
2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
   - Confirmation of maintenance of ACR20, or
   - Maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.
3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.
ANAKINRA

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

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

| 100 MG / SYR INJECTION SYRINGE | 00002245913 | KINERET | BVM | $ 49.6999 |
APIXABAN
AT RISK PATIENTS WITH NON-VALVULAR ATRIAL FIBRILLATION

SPECIAL AUTHORIZATION (step therapy approval process)

FIRST-LINE DRUG PRODUCT(S): WARFARIN

Coverage Criteria

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

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

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

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

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

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

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

ALBERTA DRUG BENEFIT LIST

CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

APIXABAN

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

PROPHYLAXIS OF VENOUS THROMBOEMBOLISM

SPECIAL AUTHORIZATION

Coverage Criteria:

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

OTHER CRITERIA:

The dosage shall be 2.5mg twice daily.

DURATION OF COVERAGE:

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

Notes:

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

VENOUS THROMBOEMBOLIC EVENTS

SPECIAL AUTHORIZATION

COVERAGE:

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

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

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

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

All requests for apixaban must be completed using the
APIXABAN

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

2.5 MG  ORAL  TABLET

00002377233  ELIQUIS  BMS  $  1.6336
APIXABAN
AT RISK PATIENTS WITH NON-VALVULAR ATRIAL FIBRILLATION

SPECIAL AUTHORIZATION (step therapy approval process)

FIRST-LINE DRUG PRODUCT(S): WARFARIN

Coverage Criteria

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

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

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

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

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

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

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.
APIXABAN
UP - First-line therapy ineffective
UQ - First-line therapy not tolerated

VENOUS THROMBOEMBOLIC EVENTS

SPECIAL AUTHORIZATION

COVERAGE:

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

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

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

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

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

<table>
<thead>
<tr>
<th>5 MG ORAL TABLET</th>
<th>ELIQUIS</th>
<th>BMS</th>
<th>$</th>
<th>1.6336</th>
</tr>
</thead>
</table>

ARIPIPRAZOLE

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

AND who meet at least one of the following criteria:

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

Special Authorization may be granted for six months."

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

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

<table>
<thead>
<tr>
<th>300 MG / VIAL INJECTION</th>
<th>ABILIFY MAINTENA</th>
<th>OTS</th>
<th>$</th>
<th>456.1800</th>
</tr>
</thead>
<tbody>
<tr>
<td>400 MG / VIAL INJECTION</td>
<td>ABILIFY MAINTENA</td>
<td>OTS</td>
<td>$</td>
<td>456.1800</td>
</tr>
</tbody>
</table>
ASENAPINE MALEATE

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

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

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

These products are eligible for auto-renewal.

<table>
<thead>
<tr>
<th>5 MG (BASE)</th>
<th>ORAL</th>
<th>SUBLINGUAL TABLET</th>
<th>LBC</th>
<th>$</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002374803</td>
<td>SAPHRIS</td>
<td>LBC</td>
<td>$</td>
<td>1.4500</td>
</tr>
<tr>
<td>10 MG (BASE)</td>
<td>ORAL</td>
<td>SUBLINGUAL TABLET</td>
<td>LBC</td>
<td>$</td>
</tr>
<tr>
<td>00002374811</td>
<td>SAPHRIS</td>
<td>LBC</td>
<td>$</td>
<td>1.4500</td>
</tr>
</tbody>
</table>
1. ELIGIBILITY CRITERIA FOR ASFOTASE ALFA COVERAGE

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

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

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

There is no guarantee that any application, whether for initial or continued coverage, will be approved. Depending on the circumstances of each case, the Minister or the Minister’s delegate may:
- approve an Application;
- approve an Application with conditions;
- deny an Application;
- discontinue an approved Application; OR
- defer an Application pending the provision of further supporting information.

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

2. REGISTRATION REQUIREMENTS

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

If the patient is not a citizen or permanent resident of Canada, the patient must be continuously registered in the Alberta Health Care Insurance Plan for a minimum of five (5) years prior to an application for coverage unless:
- the patient is less than five years of age at the date of the application, then the patient’s parent/guardian/legal representative must be registered continuously in the Alberta Health Care Insurance Plan for a minimum of five years; OR
- the patient has moved to Alberta from another province or territory in Canada (the "province of origin"), and immediately prior to moving to Alberta, was covered for asfotase alfa in the province of origin by a provincial or territorial government sponsored drug plan, (or the province of origin provided equivalent coverage for asfotase alfa as does Alberta) and the patient has been registered in the Alberta Health Care Insurance Plan (the patient must provide supporting documentation from the province of origin to prove prior coverage).

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

purpose of obtaining coverage of asfotase alfa.

3. CLINICAL CRITERIA

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

Initiation Criteria:

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

   AND

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

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

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

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

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

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

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

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

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

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

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

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

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

4. PROCESS FOR ASFOTASE ALFA COVERAGE

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

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

a. Expert Review

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

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

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

5. APPROVAL OF COVERAGE

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

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

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

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

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

6. WITHDRAWAL

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

Applications, withdrawal requests, and any other information to be provided must be sent to Clinical Drug Services, Alberta Blue Cross.
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

ALBERTA DRUG BENEFIT LIST

ASFOTASE ALFA

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

AZITHROMYCIN

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

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

Special authorization may be granted for 6 months."

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

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

600 MG ORAL TABLET
00002256088 ACT AZITHROMYCIN APH $ 6.0000
00002261642 PMS-AZITHROMYCIN PMS $ 6.0000

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."

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

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

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

<table>
<thead>
<tr>
<th>3 MG ORAL CONTROLLED-RELEASE CAPSULE</th>
<th>ENTOCORT</th>
<th>TPG</th>
<th>$</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002229293</td>
<td></td>
<td></td>
<td>1.7071</td>
</tr>
</tbody>
</table>

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

ASTHMA

FIRST-LINE DRUG PRODUCT(S): INHALED CORTICOSTEROID (ICS)
"For the treatment of asthma in patients uncontrolled on inhaled steroid therapy."

CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD)

FIRST-LINE DRUG PRODUCT(S): LONG-ACTING BRONCHODILATOR (I.E., LONG-ACTING BETA-2 AGONIST [LABA] OR LONG-ACTING MUSCARINIC ANTAGONIST [LAMA])
"For the long-term maintenance treatment of airflow obstruction in patients with moderate to severe (i.e., FEV1 < 80% predicted) chronic obstructive pulmonary disease (COPD), who have an inadequate response to a long-acting bronchodilator (long-acting beta-2 agonist [LABA] or long-acting muscarinic antagonist [LAMA])."

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

"Special authorization may be granted for 24 months."

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

UP - First-line therapy ineffective

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

<table>
<thead>
<tr>
<th>100 MCG / DOSE * 6 MCG / DOSE INHALATION METERED INHALATION POWDER</th>
<th>SYMBICORT 100 TURBUHALER</th>
<th>AZC</th>
<th>$</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002245385</td>
<td></td>
<td></td>
<td>0.5620</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>200 MCG / DOSE * 6 MCG / DOSE INHALATION METERED INHALATION POWDER</th>
<th>SYMBICORT 200 TURBUHALER</th>
<th>AZC</th>
<th>$</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002245386</td>
<td></td>
<td></td>
<td>0.7305</td>
</tr>
</tbody>
</table>
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.

<table>
<thead>
<tr>
<th>Strength</th>
<th>Formulation</th>
<th>Name</th>
<th>Intervention Code</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 MG / ML (BASE)</td>
<td>NASAL SOLUTION</td>
<td>SUPREFACT INTRANASAL</td>
<td>SAV</td>
<td>$ 8.4100</td>
</tr>
<tr>
<td>1 MG / ML (BASE)</td>
<td>INJECTION</td>
<td>SUPREFACT</td>
<td>SAV</td>
<td>$ 11.9827</td>
</tr>
<tr>
<td>6.3 MG (BASE)</td>
<td>INJECTION IMPLANT</td>
<td>SUPREFACT DEPOT</td>
<td>SAV</td>
<td>$ 813.9600</td>
</tr>
</tbody>
</table>

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

FIRST-LINE DRUG PRODUCT(S): BROMOCRIPITINE

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

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

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

<table>
<thead>
<tr>
<th>Strength</th>
<th>Formulation</th>
<th>Name</th>
<th>Intervention Code</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.5 MG</td>
<td>ORAL TABLET</td>
<td>APO-CABERGOLINE</td>
<td>APX</td>
<td>$ 12.3941</td>
</tr>
<tr>
<td>0.5 MG</td>
<td>ORAL TABLET</td>
<td>DOSTINEX</td>
<td>PAL</td>
<td>$ 14.8870</td>
</tr>
</tbody>
</table>
CANAGLIFLOZIN
The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

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

As add-on therapy for the treatment of Type 2 diabetes in patients with intolerance to and/or inadequate glycemic control on:
- a sufficient trial (i.e. a minimum of 6 months) of metformin, AND
- a sulfonylurea, AND
- for whom insulin is not an option.

Or, for whom these products are contraindicated.

Special authorization may be granted for 24 months.

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

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

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

<table>
<thead>
<tr>
<th>Strength</th>
<th>Trade Name</th>
<th>Intervention Code</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>100 MG ORAL TABLET</td>
<td>INVOKANA JAI</td>
<td>$2.7627</td>
<td></td>
</tr>
<tr>
<td>300 MG ORAL TABLET</td>
<td>INVOKANA JAI</td>
<td>$2.7627</td>
<td></td>
</tr>
</tbody>
</table>

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

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

For treatment of invasive candidiasis resistant or intolerant to fluconazole.

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

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

<table>
<thead>
<tr>
<th>Strength</th>
<th>Trade Name</th>
<th>Intervention Code</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>50 MG / VIAL INJECTION</td>
<td>CASPOFUNGIN MDA</td>
<td>$188.7000</td>
<td></td>
</tr>
<tr>
<td>70 MG / VIAL INJECTION</td>
<td>CASPOFUNGIN MDA</td>
<td>$188.7000</td>
<td></td>
</tr>
</tbody>
</table>

The DBL is not a prescribing or a diagnostic tool. Prescribers should refer to drug monographs and utilize professional judgment.
CEFADROXIL
(Refer to Section 1 - Restricted Benefits of the Alberta Drug Benefit List for coverage of the product when prescribed by a Specialist in Infectious Diseases or a designated prescriber.)

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

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

<table>
<thead>
<tr>
<th>500 MG ORAL CAPSULE</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>00002240774</td>
<td>APO-CEFADROXIL</td>
<td>APX</td>
<td>$0.8421</td>
</tr>
<tr>
<td>00002235134</td>
<td>TEVA-CEFADROXIL</td>
<td>TEV</td>
<td>$0.8421</td>
</tr>
</tbody>
</table>

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

"For the treatment of Mycobacterium abscessus infection."**

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

<table>
<thead>
<tr>
<th>1 G / VIAL (BASE) INJECTION</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>00002291711</td>
<td>CEFOXITIN</td>
<td>APX</td>
<td>$10.6000</td>
</tr>
<tr>
<td>00002128187</td>
<td>CEFOXITIN SODIUM</td>
<td>TEV</td>
<td>$10.6000</td>
</tr>
<tr>
<td>2 G / VIAL (BASE) INJECTION</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>00002291738</td>
<td>CEFOXITIN</td>
<td>APX</td>
<td>$21.2500</td>
</tr>
<tr>
<td>00002128195</td>
<td>CEFOXITIN SODIUM</td>
<td>TEV</td>
<td>$21.2500</td>
</tr>
</tbody>
</table>
CELECOXIB

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

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

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

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

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

| 100 MG ORAL CAPSULE | ACP | 0.1279
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>00002435632 ACCEL-CELECOXIB</td>
<td>ACP</td>
<td>$ 0.1279</td>
</tr>
<tr>
<td>00002420155 ACT CELECOXIB</td>
<td>ACP</td>
<td>$ 0.1279</td>
</tr>
<tr>
<td>00002418932 APO-CELECOXIB</td>
<td>ACP</td>
<td>$ 0.1279</td>
</tr>
<tr>
<td>00002445670 AURO-CELECOXIB</td>
<td>AUR</td>
<td>$ 0.1279</td>
</tr>
<tr>
<td>00002426382 BIO-CELECOXIB</td>
<td>BMD</td>
<td>$ 0.1279</td>
</tr>
<tr>
<td>00002429675 CELECOXIB</td>
<td>SIV</td>
<td>$ 0.1279</td>
</tr>
<tr>
<td>00002436299 CELECOXIB</td>
<td>SNS</td>
<td>$ 0.1279</td>
</tr>
<tr>
<td>000024291975 GD-CELECOXIB</td>
<td>GMD</td>
<td>$ 0.1279</td>
</tr>
<tr>
<td>00002424533 JAMP-CELECOXIB</td>
<td>JPC</td>
<td>$ 0.1279</td>
</tr>
<tr>
<td>00002420058 MAR-CELECOXIB</td>
<td>MAR</td>
<td>$ 0.1279</td>
</tr>
<tr>
<td>00002412497 MINT-CELECOXIB</td>
<td>MPI</td>
<td>$ 0.1279</td>
</tr>
<tr>
<td>00002423278 MYLAN-CELECOXIB</td>
<td>MYP</td>
<td>$ 0.1279</td>
</tr>
<tr>
<td>00002435640 MYLAN-CELECOXIB</td>
<td>PMS</td>
<td>$ 0.1279</td>
</tr>
<tr>
<td>00002426390 CELECOXIB</td>
<td>SIV</td>
<td>$ 0.1279</td>
</tr>
<tr>
<td>000024291975 GD-CELECOXIB</td>
<td>SNS</td>
<td>$ 0.1279</td>
</tr>
<tr>
<td>00002424541 CELECOXIB</td>
<td>PFI</td>
<td>$ 0.6992</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>200 MG ORAL CAPSULE</th>
<th>ACP</th>
<th>0.2558</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002435640 ACCEL-CELECOXIB</td>
<td>ACP</td>
<td>$ 0.2558</td>
</tr>
<tr>
<td>00002420163 ACT CELECOXIB</td>
<td>ACP</td>
<td>$ 0.2558</td>
</tr>
<tr>
<td>00002418940 APO-CELECOXIB</td>
<td>APX</td>
<td>$ 0.2558</td>
</tr>
<tr>
<td>00002445689 AURO-CELECOXIB</td>
<td>AUR</td>
<td>$ 0.2558</td>
</tr>
<tr>
<td>00002426390 BIO-CELECOXIB</td>
<td>BMD</td>
<td>$ 0.2558</td>
</tr>
<tr>
<td>00002429683 CELECOXIB</td>
<td>SIV</td>
<td>$ 0.2558</td>
</tr>
<tr>
<td>00002436302 CELECOXIB</td>
<td>SNS</td>
<td>$ 0.2558</td>
</tr>
<tr>
<td>000024291983 GD-CELECOXIB</td>
<td>GMD</td>
<td>$ 0.2558</td>
</tr>
<tr>
<td>00002424541 JAMP-CELECOXIB</td>
<td>JPC</td>
<td>$ 0.2558</td>
</tr>
<tr>
<td>00002420066 MAR-CELECOXIB</td>
<td>MAR</td>
<td>$ 0.2558</td>
</tr>
<tr>
<td>00002412500 MINT-CELECOXIB</td>
<td>MPI</td>
<td>$ 0.2558</td>
</tr>
<tr>
<td>000024355450 MYLAN-CELECOXIB</td>
<td>MYP</td>
<td>$ 0.2558</td>
</tr>
<tr>
<td>000024212381 RAN-CELECOXIB</td>
<td>RAN</td>
<td>$ 0.2558</td>
</tr>
<tr>
<td>00002442647 SDZ CELECOXIB</td>
<td>SDZ</td>
<td>$ 0.2558</td>
</tr>
<tr>
<td>00002239942 CELEBREX</td>
<td>PFI</td>
<td>$ 1.3988</td>
</tr>
</tbody>
</table>

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

Rheumatoid Arthritis

"Special authorization coverage may be provided for use in combination with methotrexate for the reduction in signs and symptoms of severely active Rheumatoid Arthritis (RA) in adult patients (18 years of age or older) who are refractory or intolerant to:
- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- Methotrexate with other disease modifying anti-rheumatic agent(s) (minimum 4 month trial) [e.g., methotrexate with hydroxychloroquine or methotrexate with sulfasalazine]; AND
- Leflunomide (minimum 10 week trial at 20 mg daily)

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

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

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

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

For continued coverage beyond 12 weeks, the patient must meet the following criteria:
1) The patient must be assessed by an RA Specialist after the initial five doses to determine response.
2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
   - ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND
   - An improvement of 0.22 in HAQ score [reported to two (2) decimal places].
   It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be approved for 400 mg per 4 weeks, for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by an RA Specialist to determine response;
2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
   - confirmation of maintenance of ACR20, or
   - maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1)
CERTOLIZUMAB PEGOL

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

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

Ankylosing Spondylitis

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

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

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

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

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

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

For continued coverage beyond 12 weeks, the patient must meet the following criteria:
1) The patient must be assessed by an RA Specialist after the initial 5 doses to determine response.
2) The RA Specialist must confirm, in writing, that the patient is a 'responder' that meets the following criteria:
- Reduction of the BASDAI score by at least 50% of the pre-treatment value or by 2 or more units, AND
- Reduction of the Spinal Pain VAS by 2 cm or more.

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

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

Psoriatic Arthritis

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

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

- An adequate trial of another disease modifying anti-rheumatic agent(s) (minimum 4 month trial). Special authorization coverage of this agent may be provided for use as monotherapy in adult patients for whom methotrexate is contraindicated and/or for those patients who have experienced serious adverse effects.

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

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

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

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

- Patients will be limited to receiving a one-month supply of certolizumab per prescription at their pharmacy.

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

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

- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

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

1) The patient must be assessed by an RA Specialist after the initial 5 doses to determine response.

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

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

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

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

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

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

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

- Confirmation of maintenance of ACR20, or
CERTOLIZUMAB PEGOL
- Maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.
3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests. It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above."

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

<table>
<thead>
<tr>
<th>200 MG / SYR</th>
<th>INJECTION SYRINGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>☑ 00002331675</td>
<td>CIMZIA</td>
</tr>
<tr>
<td>☑ 00002465574</td>
<td>CIMZIA AUTO-INJECTOR</td>
</tr>
</tbody>
</table>

$664.5100

CLINDAMYCIN PHOSPHATE/ BENZOYL PEROXIDE
1 % * 3 % TOPICAL GEL

00002382822 CLINDOXYL ADV GSK $0.7995

"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.

<table>
<thead>
<tr>
<th>1 % (BASE) * 5 % TOPICAL GEL</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002440180 TARO-CLINDAMYCIN/BENZOYL PEROXIDE TAR $0.6857</td>
</tr>
<tr>
<td>00002243158 CLINDOXYL GSK $0.9331</td>
</tr>
</tbody>
</table>

"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.

<table>
<thead>
<tr>
<th>1 % (BASE) * 5 % TOPICAL GEL</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002464519 TARO-BENZOYL PEROXIDE/CLINDAMYCIN TAR KIT $0.7422</td>
</tr>
<tr>
<td>00002248472 BENZACLIN VCL $0.9954</td>
</tr>
</tbody>
</table>
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 | $ 0.6368 |
| 25 MG ORAL CAPSULE | 00002247073 | SANDOZ CYCLOSPORINE | SDZ | $ 1.3050 |
| 50 MG ORAL CAPSULE | 00002247074 | SANDOZ CYCLOSPORINE | SDZ | $ 2.5450 |
| 100 MG ORAL CAPSULE | 00002242821 | SANDOZ CYCLOSPORINE | SDZ | $ 5.0900 |
| 100 MG / ML ORAL SOLUTION | 00002244324 | APO-CYCLOSPORINE | APX | $ 3.7708 |
| 100 MG / ML INJECTION | 00000704431 | ANDROCUR | PMS | $ 1.4000 |
| 100 MG / ML INJECTION | 00002245898 | CYPROTERONE | AAP | $ 1.4000 |
| 100 MG / ML INJECTION | 00002390760 | MED-CYPROTERONE | GMP | $ 1.4000 |
| 100 MG / ML INJECTION | 00000704423 | ANDROCUR DEPOT | PMS | $ 31.2474 |

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 | 00000702441 | ANDROCUR | PMS | $ 1.4000 |
| 50 MG ORAL TABLET | 00002245898 | CYPROTERONE | AAP | $ 1.4000 |
| 50 MG ORAL TABLET | 00002390760 | MED-CYPROTERONE | GMP | $ 1.4000 |

The DBL is not a prescribing or a diagnostic tool. Prescribers should refer to drug monographs and utilize professional judgment.
DABIGATRAN ETILXILATE
The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

FIRST-LINE DRUG PRODUCT(S): WARFARIN

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

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

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

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

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

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

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

Special Authorization may be granted for 24 months.

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

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

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

<table>
<thead>
<tr>
<th>110 MG ORAL CAPSULE</th>
<th>150 MG ORAL CAPSULE</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002312441 PRADAXA</td>
<td>BOE $ 1.6720</td>
</tr>
<tr>
<td>00002358808 PRADAXA</td>
<td>BOE $ 1.6720</td>
</tr>
</tbody>
</table>
DACLATASVIR DIHYDROCHLORIDE

For use as combination therapy with sofosbuvir for treatment-naive or treatment-experienced (1) adult patients with chronic hepatitis C (CHC) infection who meet all of the following criteria:
I) Prescribed by a hepatologist, gastroenterologist, infectious disease specialist, or a designated prescriber;
AND
II) Laboratory confirmed hepatitis C infection with genotype 3;
AND
III) Laboratory confirmed quantitative HCV RNA value within the last 6 months;
AND
IV) Fibrosis (2) stage of F0 or greater (Metavir scale or equivalent).

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

Exclusion criteria:
- Patients currently being treated with another HCV antiviral agent
- Retreatment for failure or re-infection in patients who have received an adequate prior course of an HCV direct-acting antiviral drug regimen may be considered on an exceptional case-by-case basis

Notes:
1. Treatment-experienced is defined as those who failed prior therapy with an interferon-based regimen, including regimens containing an HCV protease inhibitor.
2. Fibrosis score test is optional. Acceptable methods include liver biopsy, transient elastography (FibroScan), fibrotest and serum biomarker panels (such as AST-to-Platelet Ratio Index or Fibrosis-4 score) either alone or in combination.
3. Health care professionals are advised to refer to the product monograph and prescribing guidelines for appropriate use of the selected drugs, including use in special populations.

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

<table>
<thead>
<tr>
<th>30 MG (BASE)</th>
<th>ORAL TABLET</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002444747</td>
<td>DAKLINZA</td>
</tr>
<tr>
<td>60 MG (BASE)</td>
<td>ORAL TABLET</td>
</tr>
<tr>
<td>00002444755</td>
<td>DAKLINZA</td>
</tr>
</tbody>
</table>
DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE
The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

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

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

Special authorization may be granted for 24 months.

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

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

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

<table>
<thead>
<tr>
<th>5 MG (BASE)</th>
<th>ORAL TABLET</th>
<th>10 MG (BASE)</th>
<th>ORAL TABLET</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002435462</td>
<td>FORXIGA</td>
<td>00002435470</td>
<td>FORXIGA</td>
</tr>
<tr>
<td></td>
<td>AZC</td>
<td></td>
<td>AZC</td>
</tr>
<tr>
<td></td>
<td>$ 2.6750</td>
<td></td>
<td>$ 2.6750</td>
</tr>
</tbody>
</table>
DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE/ METFORMIN HCL
The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

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

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

Special authorization may be granted for 24 months."

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

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

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

<table>
<thead>
<tr>
<th>5 MG * 850 MG ORAL TABLET</th>
<th>XIGDUO</th>
<th>AZC</th>
<th>$ 1.2250</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002449935</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>5 MG * 1,000 MG ORAL TABLET</th>
<th>XIGDUO</th>
<th>AZC</th>
<th>$ 1.2250</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002449943</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

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

Special Authorization may be granted for 12 months.

<table>
<thead>
<tr>
<th>500 MG / VIAL INJECTION</th>
<th>CUBICIN</th>
<th>CUB</th>
<th>$ 184.0000</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002299909</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
DARBEPOETIN

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

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

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

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

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

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

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

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

<table>
<thead>
<tr>
<th>Dose</th>
<th>Product</th>
<th>Unit Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>100 MCG / SYR</td>
<td>ARANESP (0.5 ML SYRINGE)</td>
<td>AMG $268.000</td>
</tr>
<tr>
<td>10 MCG / SYR</td>
<td>ARANESP (0.4 ML SYRINGE)</td>
<td>AMG $26.8000</td>
</tr>
<tr>
<td>20 MCG / SYR</td>
<td>ARANESP (0.5 ML SYRINGE)</td>
<td>AMG $53.6000</td>
</tr>
<tr>
<td>30 MCG / SYR</td>
<td>ARANESP (0.3 ML SYRINGE)</td>
<td>AMG $80.4000</td>
</tr>
<tr>
<td>40 MCG / SYR</td>
<td>ARANESP (0.4 ML SYRINGE)</td>
<td>AMG $107.2000</td>
</tr>
<tr>
<td>50 MCG / SYR</td>
<td>ARANESP (0.5 ML SYRINGE)</td>
<td>AMG $134.0000</td>
</tr>
<tr>
<td>60 MCG / SYR</td>
<td>ARANESP (0.3 ML SYRINGE)</td>
<td>AMG $160.8000</td>
</tr>
<tr>
<td>80 MCG / SYR</td>
<td>ARANESP (0.4 ML SYRINGE)</td>
<td>AMG $214.4000</td>
</tr>
<tr>
<td>130 MCG / SYR</td>
<td>ARANESP (0.65 ML SYRINGE)</td>
<td>AMG $348.4000</td>
</tr>
<tr>
<td>150 MCG / SYR</td>
<td>ARANESP (0.3 ML SYRINGE)</td>
<td>AMG $439.7550</td>
</tr>
<tr>
<td>200 MCG / SYR</td>
<td>ARANESP (0.4 ML SYRINGE)</td>
<td>AMG $597.7300</td>
</tr>
<tr>
<td>300 MCG / SYR</td>
<td>ARANESP (0.6 ML SYRINGE)</td>
<td>AMG $914.6900</td>
</tr>
<tr>
<td>500 MCG / SYR</td>
<td>ARANESP (1.0 ML SYR)</td>
<td>AMG $1524.4800</td>
</tr>
</tbody>
</table>

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

UNIT OF ISSUE - REFER TO PRICE POLICY

Section 3 - 52

EFFECTIVE APRIL 1, 2018
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."

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

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

<table>
<thead>
<tr>
<th>7.5 MG (BASE)</th>
<th>ORAL EXTENDED-RELEASE TABLET</th>
<th>15 MG (BASE)</th>
<th>ORAL EXTENDED-RELEASE TABLET</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002273217</td>
<td>ENABLEX</td>
<td>MLL</td>
<td>$ 1.5450</td>
</tr>
<tr>
<td>00002273225</td>
<td>ENABLEX</td>
<td>MLL</td>
<td>$ 1.5450</td>
</tr>
</tbody>
</table>
DEFERASIROX
The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

FIRST-LINE DRUG PRODUCT(S): DEFEROXAMINE

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

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

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

Special authorization may be granted for 24 months."

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

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

90 MG ORAL TABLET
00002452219  JADENU  NOV  $ 10.3890
DEFERASIROX
The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

FIRST-LINE DRUG PRODUCT(S): DEFEROXAMINE

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

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

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

Special authorization may be granted for 24 months."

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

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

180 MG ORAL TABLET
00002452227 JADENU NOV $ 20.7790
DEFERASIROX
The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

FIRST-LINE DRUG PRODUCT(S): DEFEROXAMINE

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

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

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

Special authorization may be granted for 24 months."

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

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

360 MG ORAL TABLET
00002452235  JADENU  NOV  $  41.5600
DEFERASIROX
The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

FIRST-LINE DRUG PRODUCT(S): DEFEROXAMINE

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

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

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

Special authorization may be granted for 24 months."

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

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

125 MG ORAL DISPERSIBLE TABLET FOR SUSPENSION

<table>
<thead>
<tr>
<th>Product Code</th>
<th>Product Name</th>
<th>Number of Days Available</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002461544</td>
<td>APO-DEFERASIROX</td>
<td>24</td>
<td>$2.6204</td>
</tr>
<tr>
<td>00002464454</td>
<td>SANDOZ DEFERASIROX</td>
<td>24</td>
<td>$2.6204</td>
</tr>
<tr>
<td>00002463520</td>
<td>TARO-DEFERASIROX</td>
<td>24</td>
<td>$2.6204</td>
</tr>
<tr>
<td>00002407957</td>
<td>TEVA-DEFERASIROX</td>
<td>24</td>
<td>$2.6204</td>
</tr>
<tr>
<td>00002287420</td>
<td>EXJADE</td>
<td>24</td>
<td>$10.4814</td>
</tr>
</tbody>
</table>
DEFERASIROX
The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

FIRST-LINE DRUG PRODUCT(S): DEFEROXAMINE

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

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

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

Special authorization may be granted for 24 months."

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

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

250 MG ORAL DISPERSIBLE TABLET FOR SUSPENSION

<table>
<thead>
<tr>
<th>Code</th>
<th>Product Name</th>
<th>Code</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002461552</td>
<td>APO-DEFERASIROX</td>
<td>APX</td>
<td>$5.2410</td>
</tr>
<tr>
<td>00002464462</td>
<td>SANDOZ DEFERASIROX</td>
<td>SDZ</td>
<td>$5.2410</td>
</tr>
<tr>
<td>00002463539</td>
<td>TARO-DEFERASIROX</td>
<td>TAR</td>
<td>$5.2410</td>
</tr>
<tr>
<td>00002407965</td>
<td>TEVA-DEFERASIROX</td>
<td>TEV</td>
<td>$5.2410</td>
</tr>
<tr>
<td>00002287439</td>
<td>EXJADE</td>
<td>NOV</td>
<td>$20.9639</td>
</tr>
</tbody>
</table>
DEFERASIROX
The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

FIRST-LINE DRUG PRODUCT(S): DEFEROXAMINE

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

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

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

Special authorization may be granted for 24 months."

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

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

<table>
<thead>
<tr>
<th>500 MG</th>
<th>ORAL</th>
<th>DISPERSIBLE TABLET FOR SUSPENSION</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>00002461560</td>
<td>APO-DEFERASIROX</td>
<td>APX</td>
<td>$ 10.4824</td>
</tr>
<tr>
<td>00002464470</td>
<td>SANDOZ DEFERASIROX</td>
<td>SDZ</td>
<td>$ 10.4824</td>
</tr>
<tr>
<td>00002463547</td>
<td>TARO-DEFERASIROX</td>
<td>TAR</td>
<td>$ 10.4824</td>
</tr>
<tr>
<td>00002407973</td>
<td>TEVA-DEFERASIROX</td>
<td>TEV</td>
<td>$ 10.4824</td>
</tr>
<tr>
<td>00002287447</td>
<td>EXJADE</td>
<td>NOV</td>
<td>$ 41.9296</td>
</tr>
</tbody>
</table>
DEFERIPRONE

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

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

Special authorization may be granted for 6 months."

This product is eligible for auto-renewal.

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

<table>
<thead>
<tr>
<th>1,000 MG ORAL TABLET</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>00002436558</td>
<td>FERRIPROX</td>
<td>APP</td>
<td>$ 31.8780</td>
<td>00002436523</td>
<td>FERRIPROX</td>
<td>APP</td>
</tr>
</tbody>
</table>

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

UNIT OF ISSUE - REFER TO PRICE POLICY  
Section 3 - 60  
EFFECTIVE APRIL 1, 2018
DENOSUMAB

Postmenopausal Osteoporosis:

"For the treatment of postmenopausal osteoporosis in women who have a high 10-year risk (i.e., greater than 20%) of experiencing a major osteoporotic fracture, as demonstrated by 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

AND

at least one of the following:
1) For whom oral bisphosphonates are contraindicated due to drug-induced hypersensitivity (i.e., immunologically mediated),
OR
2) For whom oral bisphosphonates are contraindicated due to an abnormality of the esophagus which delays esophageal emptying,
OR
3) For whom bisphosphonates are contraindicated due to severe renal impairment (i.e. creatinine clearance < 35 mL/min),
OR
4) Who have demonstrated severe gastrointestinal intolerance to a course of therapy with either alendronate or risedronate. Severe gastrointestinal intolerance is defined as manifested by weight loss or vomiting directly attributable to the oral bisphosphonates,
OR
5) Who had an unsatisfactory response (defined as a fragility fracture despite adhering to oral alendronate or risedronate treatment fully for 1 year and evidence of a decline in BMD below pre-treatment baseline level).

Special authorization may be granted for 12 months.

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

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

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

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

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

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

Osteoporosis in men:

"For the treatment of osteoporosis in men who have:
A high 10-year risk (i.e., greater than 20%) of experiencing a major osteoporotic fracture,
OR
A moderate 10-year fracture risk (10-20%) and have experienced a prior fragility fracture;

AND

at least one of the following:
1) For whom oral bisphosphonates are contraindicated due to drug-induced hypersensitivity (i.e., immunologically mediated),
DENOSUMAB

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

OR

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

OR

4) Who have demonstrated severe gastrointestinal intolerance to a course of therapy with either alendronate or risedronate. Severe gastrointestinal intolerance is defined as manifested by weight loss or vomiting directly attributable to the oral bisphosphonates,

OR

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

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

Special authorization may be granted for 12 months.

Patients will be limited to receiving one dose of denosumab per prescription at their pharmacy.
- Coverage cannot be provided for two or more osteoporosis medications (alendronate, denosumab, 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 60 mg/syr injection syringe.

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

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

<table>
<thead>
<tr>
<th>60 MG / SYR INJECTION SYRINGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002343541 PROLIA AMG</td>
</tr>
</tbody>
</table>

DIENOGEST

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

"Special authorization may be granted for 6 months."

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

<table>
<thead>
<tr>
<th>2 MG ORAL TABLET</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002374900 VISANNE BAI</td>
</tr>
</tbody>
</table>
DIMETHYL FUMARATE

Relapsing Remitting Multiple Sclerosis (RRMS):

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

Coverage

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

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

Initial Coverage

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

2) The adult patient must have active disease which is defined as at least two relapses* of MS during the previous two years or in the two years prior to starting an MS disease modifying therapy (DMT).

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

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

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

Continued Coverage

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

1) The adult patient must be assessed by a registered MS Neurologist;

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

3) The registered MS Neurologist must provide a current updated EDSS score. The adult patient must not have an EDSS score of 7.0 or above sustained for one year or more.

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

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

Restarting After an Interruption in Therapy Greater Than 12 Months

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

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

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

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

120 MG  ORAL  DELAYED-RELEASE CAPSULE

00002404508  TECFIDERA  BIO  $ 16.8632
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 HCI must be completed using the Donepezil/Galantamine/Rivastigmine Special Authorization Request Form (ABC 60034).

---

**5 MG ORAL TABLET**

<table>
<thead>
<tr>
<th>Code</th>
<th>Brand Name</th>
<th>Strength</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002362260</td>
<td>APO-DONEPEZIL</td>
<td>5 MG</td>
<td>$0.4586</td>
</tr>
<tr>
<td>00002400561</td>
<td>AURO-DONEPEZIL</td>
<td>10 MG</td>
<td>$0.4586</td>
</tr>
<tr>
<td>00002412853</td>
<td>BIO-DONEPEZIL</td>
<td></td>
<td>$0.4586</td>
</tr>
<tr>
<td>00002420597</td>
<td>DONEPEZIL</td>
<td></td>
<td>$0.4586</td>
</tr>
<tr>
<td>00002402645</td>
<td>DONEPEZIL HYDROCHLORIDE</td>
<td>5 MG</td>
<td>$0.4586</td>
</tr>
<tr>
<td>00002404419</td>
<td>JAMP-DONEPEZIL</td>
<td></td>
<td>$0.4586</td>
</tr>
<tr>
<td>00002416948</td>
<td>JAMP-DONEPEZIL</td>
<td></td>
<td>$0.4586</td>
</tr>
<tr>
<td>00002402092</td>
<td>MAR-DONEPEZIL</td>
<td></td>
<td>$0.4586</td>
</tr>
<tr>
<td>00002359472</td>
<td>MYLAN-DONEPEZIL</td>
<td></td>
<td>$0.4586</td>
</tr>
<tr>
<td>00002439557</td>
<td>NAT-DONEPEZIL</td>
<td></td>
<td>$0.4586</td>
</tr>
<tr>
<td>00002322331</td>
<td>PMS-DONEPEZIL</td>
<td></td>
<td>$0.4586</td>
</tr>
<tr>
<td>00002381508</td>
<td>RAN-DONEPEZIL</td>
<td></td>
<td>$0.4586</td>
</tr>
<tr>
<td>00002328666</td>
<td>SANDOZ DONEPEZIL</td>
<td></td>
<td>$0.4586</td>
</tr>
<tr>
<td>00002428482</td>
<td>SEPTA DONEPEZIL</td>
<td></td>
<td>$0.4586</td>
</tr>
<tr>
<td>00002340607</td>
<td>TEVA-DONEPEZIL</td>
<td></td>
<td>$0.4586</td>
</tr>
<tr>
<td>00002426943</td>
<td>VAN-DONEPEZIL</td>
<td></td>
<td>$0.4586</td>
</tr>
<tr>
<td>00002232043</td>
<td>ARICEPT</td>
<td></td>
<td>5.0779</td>
</tr>
</tbody>
</table>

**10 MG ORAL TABLET**

<table>
<thead>
<tr>
<th>Code</th>
<th>Brand Name</th>
<th>Strength</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002362279</td>
<td>APO-DONEPEZIL</td>
<td>5 MG</td>
<td>$0.4586</td>
</tr>
<tr>
<td>00002400588</td>
<td>AURO-DONEPEZIL</td>
<td>10 MG</td>
<td>$0.4586</td>
</tr>
<tr>
<td>00002412861</td>
<td>BIO-DONEPEZIL</td>
<td></td>
<td>$0.4586</td>
</tr>
<tr>
<td>00002420600</td>
<td>DONEPEZIL</td>
<td></td>
<td>$0.4586</td>
</tr>
<tr>
<td>00002402653</td>
<td>DONEPEZIL HYDROCHLORIDE</td>
<td>5 MG</td>
<td>$0.4586</td>
</tr>
<tr>
<td>00002404427</td>
<td>JAMP-DONEPEZIL</td>
<td></td>
<td>$0.4586</td>
</tr>
<tr>
<td>00002416956</td>
<td>JAMP-DONEPEZIL</td>
<td></td>
<td>$0.4586</td>
</tr>
<tr>
<td>00002402106</td>
<td>MAR-DONEPEZIL</td>
<td></td>
<td>$0.4586</td>
</tr>
<tr>
<td>00002359480</td>
<td>MYLAN-DONEPEZIL</td>
<td></td>
<td>$0.4586</td>
</tr>
<tr>
<td>00002439565</td>
<td>NAT-DONEPEZIL</td>
<td></td>
<td>$0.4586</td>
</tr>
<tr>
<td>00002322358</td>
<td>PMS-DONEPEZIL</td>
<td></td>
<td>$0.4586</td>
</tr>
<tr>
<td>00002381516</td>
<td>RAN-DONEPEZIL</td>
<td></td>
<td>$0.4586</td>
</tr>
<tr>
<td>00002328682</td>
<td>SANDOZ DONEPEZIL</td>
<td></td>
<td>$0.4586</td>
</tr>
<tr>
<td>00002428490</td>
<td>SEPTA DONEPEZIL</td>
<td></td>
<td>$0.4586</td>
</tr>
<tr>
<td>00002340615</td>
<td>TEVA-DONEPEZIL</td>
<td></td>
<td>$0.4586</td>
</tr>
<tr>
<td>00002426951</td>
<td>VAN-DONEPEZIL</td>
<td></td>
<td>$0.4586</td>
</tr>
<tr>
<td>00002232044</td>
<td>ARICEPT</td>
<td></td>
<td>5.0779</td>
</tr>
</tbody>
</table>
ECULIZUMAB

1. ELIGIBILITY CRITERIA FOR ECULIZUMAB COVERAGE

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

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

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

There is no guarantee that any application, whether for initial or continued coverage, will be approved. Depending on the circumstances of each case, the Minister or the Minister's delegate may:
- approve an Application;
- approve an Application with conditions;
- deny an Application;
- discontinue an approved Application; OR
- defer an Application pending the provision of further supporting information.

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

2. REGISTRATION REQUIREMENTS

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

If the patient is not a citizen or permanent resident of Canada, the patient must be continuously registered in the Alberta Health Care Insurance Plan for a minimum of five (5) years prior to an application for coverage unless:
- the patient is less than five years of age at the date of the application, then the patients parent/guardian/legal representative must be registered continuously in the Alberta Health Care Insurance Plan for a minimum of five (5) years; OR
- the patient has moved to Alberta from another province or territory in Canada (the "province of origin"), and immediately prior to moving to Alberta, was covered for eculizumab in the province of origin by a provincial or territorial government sponsored drug plan, (or the province of origin provided equivalent coverage for eculizumab as does Alberta) and the patient has been registered in the Alberta Health Care Insurance Plan (the patient must provide supporting documentation from the province of origin to prove prior coverage).

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

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

3. CLINICAL CRITERIA

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

a. Clinical Criteria - Initial Coverage

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

1) The diagnosis of PNH must have been established by flow cytometry and/or a FLAER test. The proportion of circulating cells of each type which are GPI-deficient and hence of the PNH clone is quantitated by flow cytometry. Patients must have a:
   - PNH granulocyte or monocyte clone size equal to or greater than 10%, AND
   - Raised LDH (value at least 1.5 times the upper limit of normal for the reporting laboratory).

2) Patients with a granulocyte or monocyte clone size equal to or greater than 10% also require AT LEAST ONE of the following:
   - Thrombosis: Evidence that the patient has had a thrombotic or embolic event which required the institution of therapeutic anticoagulant therapy;
   - Transfusions: Evidence that the patient has been transfused with at least four (4) units of red blood cells in the last twelve (12) months;
   - Anemia: Evidence that the patient has chronic or recurrent anemia where causes other than hemolysis have been excluded and demonstrated by more than one measure of less than or equal to 70g/L or by more than one measure of less than or equal to 100 g/L with concurrent symptoms of anemia;
   - Pulmonary insufficiency: Evidence that the patient has debilitating shortness of breath and/or chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded;
   - Renal insufficiency: Evidence that the patient has a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60mL/min/1.73m^2, where causes other than PNH have been excluded; OR
   - Smooth muscle spasm: Evidence that the patient has recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded.

AND

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

b. Clinical Criteria - Continued Coverage

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

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

AND
ECULIZUMAB

2) Continued eligibility will be subject to the assessment of evidence, in accordance with the following monitoring requirements, which demonstrates:
- Clinical improvement in the patient, OR
- Stabilization of the patient's condition;

Monitoring requirements;

The patient's Specialist in Hematology must provide the following monitoring information every six (6) months:
- Lactate dehydrogenase (LDH);
- Full blood count and reticulocytes;
- Transfusion history for previous six months;
- Iron studies;
- Urea, electrolytes and eGFR;
- Recent clinical history; AND
- Any other information requested by the Minister, the Minister's delegate, or an Expert Advisor.

The patient's Specialist in Hematology must provide the following monitoring information every twelve (12) months:
- Confirmation that the patient has been immunized or reimmunized (meningococcal, pneumococcal 23-valent, pneumococcal 13-valent and Hib) according to current clinical guidelines for vaccine use;
- Progress reports on the clinical symptoms that formed the basis of initial eligibility;
- Quality of life, through clinical narrative;
- Granulocyte or monocyte clone size (by flow cytometry): AND
- Any other information requested by the Minister, the Minister's delegate, or an Expert Advisor.

c. Contraindications to Coverage

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

d. Discontinuation of Coverage

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

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

4. PROCESS FOR ECULIZUMAB COVERAGE

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

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

a. Expert Review

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

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

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

5. APPROVAL OF COVERAGE

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

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

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

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

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

6. WITHDRAWAL

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

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

300 MG / VIAL INJECTION
00002322285 SOLIRIS APG $ 6742.0000

ELBASVIR/ GRAZOPREVIR
For treatment-naive or treatment-experienced (1) adult patients with chronic hepatitis C (CHC) infection who meet all of the following criteria:
I) Prescribed by a hepatologist, gastroenterologist, infectious disease specialist, or a designated prescriber;
AND
II) Laboratory confirmed hepatitis C genotype 1 or genotype 4;
AND
III) Laboratory confirmed quantitative HCV RNA value within the last 6 months;
AND
IV) Fibrosis (2) stage of F0 or greater (Metavir scale or equivalent).

Duration of therapy reimbursed:
- Treatment-naive, without cirrhosis or with compensated cirrhosis (3): 12 weeks*
- Treatment-experienced relapers, without cirrhosis or with compensated cirrhosis (3): 12 weeks
- Treatment-experienced genotype 1b who have had on-treatment virologic failures (4), without cirrhosis or with compensated cirrhosis (3): 12 weeks
- Treatment-experienced genotype 1a or genotype 4 who have had on-treatment virologic failures (4), without cirrhosis or with compensated cirrhosis (3): 16 weeks in combination with ribavirin

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

Exclusion criteria:
- Patients currently being treated with another HCV antiviral agent
- Retreatment for failure or re-infection in patients who have received an adequate prior course of an HCV direct-acting antiviral drug regimen may be considered on an exceptional case-by-case basis
- Combination therapy with sofosbuvir will not be considered for any genotypes

Notes:
1. Treatment experienced for patients with genotype 1 is defined as patients who have been previously treated with a pegylated interferon + ribavirin regimen or a protease inhibitor + pegylated interferon + ribavirin regimen and have not experienced adequate response.
   Treatment experienced for patients with genotype 4 is defined as patients who have been previously treated with a pegylated interferon + ribavirin regimen and have not experienced adequate response.
2. Fibrosis score test is optional. Acceptable methods include liver biopsy, transient elastography (FibroScan), fibrotest and serum biomarker panels (such as AST-to-Platelet Ratio Index or Fibrosis-4 score) either alone or in combination.
3. Compensated cirrhosis is defined as cirrhosis with Child-Turcotte-Pugh A (i.e. score 5 to 6).
4. On-treatment virologic failures are patients who have not experienced adequate response to prior treatment, including a null response, partial response or virologic breakthrough or rebound.
5. Health care professionals are advised to refer to the product monograph and prescribing guidelines for appropriate use of the selected drug, including use in special populations.

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

50 MG * 100 MG ORAL TABLET
00002451131 ZEPATIER MFC $ 666.9400
EMPAGLIFLOZIN

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

First-Line Drug Product(s): Metformin
Second-Line Drug Product(s): Sulfonylureas
And where insulin is not an option

As add-on therapy for the treatment of Type 2 diabetes in patients with intolerance to and/or inadequate glycemic control on:
- a sufficient trial (i.e. a minimum of 6 months) of metformin, AND
- a sulfonylurea, AND
- for whom insulin is not an option.

Or, for whom these products are contraindicated.

Special authorization may be granted for 24 months.

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

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

All requests for empagliflozin must be completed using the DPP-4/SGLT2 Inhibitors Special Authorization Request Form (ABC 60012).

<table>
<thead>
<tr>
<th>10 MG</th>
<th>ORAL TABLET</th>
<th>JARDIANCE</th>
<th>BOE</th>
<th>$ 2.6726</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002443937</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>00002443945</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

EPLERENONE

"For persons suffering from New York Heart Association (NYHA) class II chronic heart failure with left ventricular systolic dysfunction with ejection fraction less than or equal to 35 per cent, as a complement to standard therapy."

Special authorization will be granted for 12 months.

This product is eligible for auto-renewal.

All requests (including renewal requests) for eplerenone must be completed using the Eplerenone/Sacubitril+Valstaritan Special Authorization Request Form (ABC 60050).

<table>
<thead>
<tr>
<th>25 MG</th>
<th>ORAL TABLET</th>
<th>INSPRA</th>
<th>PFI</th>
<th>$ 2.7164</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002323052</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>00002323060</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>50 MG</th>
<th>ORAL TABLET</th>
<th>INSPRA</th>
<th>PFI</th>
<th>$ 2.7164</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
EPOETIN ALFA

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

According to current clinical practice, hemoglobin levels should be maintained between 95 g/L to 110 g/L and the dose should be held or reduced when hemoglobin is greater than or equal to 115 g/L. Doses should not exceed 60,000 units per month."

"For the treatment of anemia in AZT-treated/HIV infected patients. Special authorization will be granted for twelve months."

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

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

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

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

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

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

| 1,000 UNIT / SYR  | INJECTION SYRINGE | EPREX (0.5 ML SYRINGE) | JAI | $14.2500 |
| 2,000 UNIT / SYR  | INJECTION SYRINGE | EPREX (0.5 ML SYRINGE) | JAI | $28.5000 |
| 3,000 UNIT / SYR  | INJECTION SYRINGE | EPREX (0.3 ML SYRINGE) | JAI | $42.7500 |
| 4,000 UNIT / SYR  | INJECTION SYRINGE | EPREX (0.4 ML SYRINGE) | JAI | $57.0000 |
| 5,000 UNIT / SYR  | INJECTION SYRINGE | EPREX (0.5 ML SYRINGE) | JAI | $71.2500 |
| 6,000 UNIT / SYR  | INJECTION SYRINGE | EPREX (0.6 ML SYRINGE) | JAI | $85.5000 |
| 8,000 UNIT / SYR  | INJECTION SYRINGE | EPREX (0.8 ML SYRINGE) | JAI | $114.0000 |
| 10,000 UNIT / SYR | INJECTION SYRINGE | EPREX (1 ML SYRINGE)  | JAI | $142.5000 |
| 20,000 UNIT / SYR | INJECTION SYRINGE | EPREX (0.5 ML SYRINGE) | JAI | $303.1500 |

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

UNIT OF ISSUE - REFER TO PRICE POLICY

EFFECTIVE APRIL 1, 2018

Section 3 · 72
EPOETIN ALFA

"For the treatment of chemotherapy-induced anemia in patients with non-myeloid malignancies with low hemoglobin (<100 g/L) in whom blood transfusions are not possible due to transfusion reactions, cross-matching difficulties or iron overload. If hemoglobin is rising by more than 20 g/L per month, the dose should be reduced by about 25%. Patients may be granted a maximum allowable dose of 40,000 IU per week. Special authorization will be granted for twelve months."

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

Renewal requests may be considered if the patient's hemoglobin is <110 g/L while on therapy.

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

<table>
<thead>
<tr>
<th>30,000 UNIT / SYR</th>
<th>INJECTION</th>
<th>SYRINGE</th>
<th></th>
<th></th>
<th>$</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002288680</td>
<td>EPREX</td>
<td>JAI</td>
<td>360.8300</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>40,000 UNIT / SYR</th>
<th>INJECTION</th>
<th>SYRINGE</th>
<th></th>
<th></th>
<th>$</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002240722</td>
<td>EPREX</td>
<td>JAI</td>
<td>453.9400</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

ERTAPENEM

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

"For therapy of complicated polymicrobial skin and skin structure infections."

"For the therapy of community-acquired intra-abdominal infections."

"For culture & susceptibility directed therapy against infections with Enterobacteriaceae producing AmpC or extended-spectrum beta-lactamases (ESBLs) where there is resistance to first line agents."

"For use in other Health Canada approved indications, in consultation with a specialist in Infectious Diseases."

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

In order to comply with all of the above criteria, information is required regarding the type of infection and organisms involved. Also, where the criteria restrict coverage of the requested drug to non-first line therapy, information is required regarding previous first-line antibiotic therapy that has been utilized, the patient's response to therapy, and the first line agents the organism is resistant to or why other first-line therapies cannot be used in this patient. Also, where applicable, the specialist in Infectious Diseases that recommended this drug is required.

<table>
<thead>
<tr>
<th>1 G / VIAL</th>
<th>INJECTION</th>
<th></th>
<th></th>
<th>$</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002247437</td>
<td>INVANZ</td>
<td>MFC</td>
<td>53.9106</td>
<td></td>
</tr>
</tbody>
</table>
ESLICARBbazepine ACETATE

"For adjunctive therapy in patients with refractory partial-onset seizures who meet all of the following criteria:
- Are currently receiving two or more antiepileptic medications, AND
- Have failed or demonstrated intolerance to three other antiepileptic medications, AND
- Therapy must be initiated by a Neurologist.

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

Special authorization may be granted for six months.

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

Each of these products is eligible for auto-renewal.

<table>
<thead>
<tr>
<th>Dosage</th>
<th>Formulation</th>
<th>Strength</th>
<th>Unit of Issue</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>200 MG</td>
<td>Oral Tablet</td>
<td></td>
<td></td>
<td>$9.70</td>
</tr>
<tr>
<td>400 MG</td>
<td>Oral Tablet</td>
<td></td>
<td></td>
<td>$9.70</td>
</tr>
<tr>
<td>600 MG</td>
<td>Oral Tablet</td>
<td></td>
<td></td>
<td>$9.70</td>
</tr>
<tr>
<td>800 MG</td>
<td>Oral Tablet</td>
<td></td>
<td></td>
<td>$9.70</td>
</tr>
</tbody>
</table>

The DBL is not a prescribing or a diagnostic tool. Prescribers should refer to drug monographs and utilize professional judgment.
ETANERCEPT
25 MG / VIAL INJECTION

00002242903  ENBREL  AMG  $  200.7100

***Effective March 1, 2018, all new Special Authorization requests for the treatment of Rheumatoid Arthritis or Ankylosing Spondylitis for etanercept-naive patients will be assessed for coverage with Brenzys or Erelzi. Enbrel will not be approved for new etanercept starts for patients with the indications stated above; however, coverage for Enbrel will continue for patients who are currently well maintained on Enbrel and are considered a 'responder' as defined in criteria.

In addition, all new Special Authorization requests for the treatment of Polyarticular Juvenile Idiopathic Arthritis for etanercept-naive patients weighing 63 kg (138 pounds) or more will be assessed for coverage with Erelzi. Enbrel will be approved for new etanercept starts for pediatric patients with Polyarticular Juvenile Idiopathic Arthritis weighing less than 63 kg, and coverage for Enbrel will continue for patients who are currently well maintained on Enbrel and are considered a 'responder' as defined in criteria.

Additionally, patients will not be permitted to switch between etanercept products, if the patient has been previously trialed on any etanercept product and deemed unresponsive to therapy.***

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

the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be approved for 50 mg per week, for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by an RA Specialist to determine response;
2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
   - Confirmation of maintenance of ACR20, or
   - Maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.
3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.

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

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

Polyarticular Juvenile Idiopathic Arthritis:

"Special authorization coverage may be provided for the reduction in signs and symptoms of severely active polyarticular juvenile idiopathic arthritis (pJIA) in patients 4 years of age and older who:
- Have 5 or more active joints (defined by either swelling or limitation of motion plus pain and/or tenderness), AND
- Are refractory to one or more disease modifying anti-rheumatic agents (DMARDS) conventionally used in children (minimum three month trial).

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

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

- Coverage may be approved for 0.8 mg/kg/dose (maximum dose 50 mg) weekly for 12 weeks.
- Patients will be limited to receiving a one-month supply of etanercept per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another (with the exception of abatacept) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients will not be permitted to switch from abatacept to other biologic agents except under exceptional circumstances.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

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

reported in each request

Following this assessment, continued coverage may be approved for 0.8 mg/kg/dose (maximum dose 50 mg) weekly, for a maximum of twelve months. After twelve months, in order to be considered for continued coverage, the patient must be re-assessed every twelve months by a Pediatric Rheumatology Specialist and must meet the following criteria:
1) The patient has been assessed by a Pediatric Rheumatology Specialist to determine response, and
2) The Pediatric RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by maintenance of the ACR Pedi 30,
3) Data from all of the six variables comprising the ACR Pedi 30 and the CHAQ scores must be reported in each request.

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

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

Psoriatic Arthritis:

"Special authorization coverage may be provided for use in combination with methotrexate for reducing signs and symptoms and inhibiting the progression of structural damage of active arthritis in adult patients (18 years of age or older) with moderate to severe polyarticular psoriatic arthritis (PsA) or pauciarticular PsA with involvement of knee or hip joint who are refractory or intolerant to:
- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- An adequate trial of another disease modifying anti-rheumatic agent(s) (minimum 4 month trial).

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

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

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

- Initial coverage may be approved for 50 mg per week for 8 weeks.
- Patients will be limited to receiving a one-month supply of etanercept per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond 8 weeks, the patient must meet the following criteria:
1) The patient must be assessed by an RA Specialist after 8 weeks, but no longer than 12 weeks after treatment to determine response.
2) The RA Specialist must confirm in writing that the patient is a ‘responder’ that meets the following criteria:
   - ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND
   - An improvement of 0.22 in HAQ score [reported to two (2) decimal places].

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

Following this assessment, continued coverage may be approved for 50 mg per week, for a period of 12 months. Ongoing coverage may be considered if the following criteria are met at the end of each 12-month period:

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

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

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

Ankylosing Spondylitis:

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

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

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

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

- Initial coverage may be approved for 50 mg per week for 12 weeks.
- Patients will be limited to receiving a one-month supply of etanercept per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

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

Following this assessment, continued coverage may be approved for 50 mg per week for a period of 12 months. Ongoing coverage may be considered if the patient is re-assessed by an RA Specialist every 12 months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above.

All requests (including renewal requests) for etanercept for Ankylosing Spondylitis must be

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

completed using the Adalimumab/Certolizumab/Etanercept/Golimumab/Infliximab for Ankylosing Spondylitis Special Authorization Request Form (ABC 60028).

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 which it is being prescribed.

For continued coverage beyond 12 weeks, the patient must meet all of the following criteria:
1) The patient must be assessed by a Dermatology Specialist after the initial 12 weeks of therapy to determine response.
2) The Dermatology Specialist must confirm, in writing, that the patient is a 'responder' that meets the following criteria:
- Greater than or equal to 75% reduction in PASI score, OR
- Greater than or equal to 50% reduction in PASI score AND improvement of greater than or equal to 5 points in the DLQI

Following this assessment, continued coverage may be considered for 50 mg per week for a period of 12 months. Ongoing coverage may be considered if the patient is re-assessed by a Dermatology Specialist every 12 months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above."

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

All requests (including renewal requests) for etanercept for Plaque Psoriasis must be completed using the Adalimumab/Etanercept/Infliximab/Secukinumab/Ustekinumab for Plaque Psoriasis Special Authorization Request Form (ABC 60030).
ETANERCEPT
25 MG / SYR INJECTION SYRINGE
00002462877 ERELZI $ 127.5000 SDZ

***Effective March 1, 2018, all new Special Authorization requests for the treatment of Rheumatoid Arthritis or Ankylosing Spondylitis for etanercept-naive patients will be assessed for coverage with Brenzys or Erelzi. Enbrel will not be approved for new etanercept starts for patients with the indications stated above; however, coverage for Enbrel will continue for patients who are currently well maintained on Enbrel and are considered a ‘responder’ as defined in criteria.

In addition, all new Special Authorization requests for the treatment of Polyarticular Juvenile Idiopathic Arthritis for etanercept-naive patients weighing 63 kg (138 pounds) or more will be assessed for coverage with Erelzi. Enbrel will be approved for new etanercept starts for pediatric patients with Polyarticular Juvenile Idiopathic Arthritis weighing less than 63 kg, and coverage for Enbrel will continue for patients who are currently well maintained on Enbrel and are considered a ‘responder’ as defined in criteria.

Additionally, patients will not be permitted to switch between etanercept products, if the patient has been previously trialed on any etanercept product and deemed unresponsive to therapy.***

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 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
ETANERCEPT

the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be approved for 50 mg per week, for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:

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

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

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

Polyarticular Juvenile Idiopathic Arthritis:

“Special authorization coverage may be provided for the reduction in signs and symptoms of severely active polyarticular juvenile idiopathic arthritis (pJIA) in patients 4 years of age and older who:
- Have 5 or more active joints (defined by either swelling or limitation of motion plus pain and/or tenderness), AND
- Are refractory to one or more disease modifying anti-rheumatic agents (DMARDS) conventionally used in children (minimum three month trial).

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

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

- Coverage may be approved for 0.8 mg/kg/dose (maximum dose 50 mg) weekly for 12 weeks.
- Patients will be limited to receiving a one-month supply of etanercept per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another (with the exception of abatacept) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients will not be permitted to switch from abatacept to other biologic agents except under exceptional circumstances.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

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

reported in each request

Following this assessment, continued coverage may be approved for 0.8 mg/kg/dose (maximum dose 50 mg) weekly, for a maximum of twelve months. After twelve months, in order to be considered for continued coverage, the patient must be re-assessed every twelve months by a Pediatric Rheumatology Specialist and must meet the following criteria:
1) The patient has been assessed by a Pediatric Rheumatology Specialist to determine response, and
2) The Pediatric RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by maintenance of the ACR Pedi 30,
3) Data from all of the six variables comprising the ACR Pedi 30 and the CHAQ scores must be reported in each request.

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

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

Ankylosing Spondylitis:

"Special authorization coverage may be provided for the reduction in the signs and symptoms of severely active Ankylosing Spondylitis, as defined by the Modified New York criteria for Ankylosing Spondylitis, in adult patients (18 years of age or older) who have active disease as demonstrated by:
- a BASDAI greater than or equal to 4 units, demonstrated on 2 occasions at least 8 weeks apart AND
- a Spinal Pain VAS of greater than or equal to 4 cm (on a 0-10 cm scale), demonstrated on 2 occasions at least 8 weeks apart AND
- who are refractory or intolerant to treatment with 2 or more NSAIDS each taken for a minimum of 4 weeks at maximum tolerated or recommended doses.

‘Refractory’ is defined as lack of effect at the recommended doses and for duration of treatments specified above. ‘Intolerant’ is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

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

- Initial coverage may be approved for 50 mg per week for 12 weeks.
- Patients will be limited to receiving a one-month supply of etanercept per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

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

Following this assessment, continued coverage may be approved for 50 mg per week for a period of 12 months. Ongoing coverage may be considered if the patient is re-assessed by an RA Specialist every 12 months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above."
ETANERCEPT

All requests (including renewal requests) for etanercept for Ankylosing Spondylitis must be completed using the Adalimumab/Certolizumab/Etanercept/Golimumab/Infliximab for Ankylosing Spondylitis Special Authorization Request Form (ABC 60028).
ETANERCEPT
50 MG / SYR INJECTION SYRINGE
00002455323 BRENZYS SSB $ 255.0000

***Effective March 1, 2018, all new Special Authorization requests for the treatment of Rheumatoid Arthritis or Ankylosing Spondylitis for etanercept-naive patients will be assessed for coverage with Brenzys or Erelzi. Enbrel will not be approved for new etanercept starts for patients with the indications stated above; however, coverage for Enbrel will continue for patients who are currently well maintained on Enbrel and are considered a 'responder' as defined in criteria.

Additionally, patients will not be permitted to switch between etanercept products, if the patient has been previously trialed on any etanercept product and deemed unresponsive to therapy.***

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

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

- Initial coverage may be approved for 50 mg per week for 8 weeks.
- Patients will be limited to receiving a one-month supply of etanercept per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another (with the exception of anakinra) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients will not be permitted to switch from anakinra to other biologic agents except under exceptional circumstances.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond 8 weeks, the patient must meet the following criteria:
1) The patient must be assessed by an RA Specialist after 8 weeks, but no longer than 12 weeks after treatment to determine response.
2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
- ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND
- An improvement of 0.22 in HAQ score [reported to two (2) decimal places].

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

Following this assessment, continued coverage may be approved for 50 mg per week, for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by an RA Specialist to determine response;
2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy.
ETANERCEPT

as indicated by:
- Confirmation of maintenance of ACR20, or
- Maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.
3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.

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

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

Ankylosing Spondylitis

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

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

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

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

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

- Initial coverage may be approved for 50 mg per week for 12 weeks.
- Patients will be limited to receiving a one-month supply of etanercept per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

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

Following this assessment, continued coverage may be approved for 50 mg per week for a period of 12 months. Ongoing coverage may be considered if the patient is re-assessed by an RA Specialist every 12 months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above."

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

| 00002455331 | BRENZYS | SSB | $ 255.000 |
| 00002462850 | ERELZI | SDZ | $ 255.000 |

***Effective March 1, 2018, all new Special Authorization requests for the treatment of Rheumatoid Arthritis or Ankylosing Spondylitis for etanercept-naive patients will be assessed for coverage with Brenzys or Erelzi. Enbrel will not be approved for new etanercept starts for patients with the indications stated above; however, coverage for Enbrel will continue for patients who are currently well maintained on Enbrel and are considered a 'responder' as defined in criteria.

In addition, all new Special Authorization requests for the treatment of Polyarticular Juvenile Idiopathic Arthritis for etanercept-naive patients weighing 63 kg (138 pounds) or more will be assessed for coverage with Erelzi. Enbrel will be approved for new etanercept starts for pediatric patients with Polyarticular Juvenile Idiopathic Arthritis weighing less than 63 kg, and coverage for Enbrel will continue for patients who are currently well maintained on Enbrel and are considered a 'responder' as defined in criteria.

Additionally, patients will not be permitted to switch between etanercept products, if the patient has been previously trialed on any etanercept product and deemed unresponsive to therapy.***

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 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].
**ETANERCEPT**

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

Following this assessment, continued coverage may be approved for 50 mg per week, for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by an RA Specialist to determine response;
2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
   - Confirmation of maintenance of ACR20, or
   - Maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.
3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.

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

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

**Polyarticular Juvenile Idiopathic Arthritis:**

“Special authorization coverage may be provided for the reduction in signs and symptoms of severely active polyarticular juvenile idiopathic arthritis (pJIA) in patients 4 years of age and older who:
- Have 5 or more active joints (defined by either swelling or limitation of motion plus pain and/or tenderness), AND
- Are refractory to one or more disease modifying anti-rheumatic agents (DMARDS) conventionally used in children (minimum three month trial).

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

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

- Coverage may be approved for 0.8 mg/kg/dose (maximum dose 50 mg) weekly for 12 weeks.
- Patients will be limited to receiving a one-month supply of etanercept per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another (with the exception of abatacept) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients will not be permitted to switch from abatacept to other biologic agents except under exceptional circumstances.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

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

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

Following this assessment, continued coverage may be approved for 0.8 mg/kg/dose (maximum dose 50 mg) weekly, for a maximum of twelve months. After twelve months, in order to be considered for continued coverage, the patient must be re-assessed every twelve months by a Pediatric Rheumatology Specialist and must meet the following criteria:
1) The patient has been assessed by a Pediatric Rheumatology Specialist to determine response, and
2) The Pediatric RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by maintenance of the ACR Pedi 30,
3) Data from all of the six variables comprising the ACR Pedi 30 and the CHAQ scores must be reported in each request.

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

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

Ankylosing Spondylitis:

"Special authorization coverage may be provided for the reduction in the signs and symptoms of severely active Ankylosing Spondylitis, as defined by the Modified New York criteria for Ankylosing Spondylitis, in adult patients (18 years of age or older) who have active disease as demonstrated by:
- a BASDAI greater than or equal to 4 units, demonstrated on 2 occasions at least 8 weeks apart
AND
- a Spinal Pain VAS of greater than or equal to 4 cm (on a 0-10 cm scale), demonstrated on 2 occasions at least 8 weeks apart
AND
- who are refractory or intolerant to treatment with 2 or more NSAIDS each taken for a minimum of 4 weeks at maximum tolerated or recommended doses.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").
- Initial coverage may be approved for 50 mg per week for 12 weeks.
- Patients will be limited to receiving a one-month supply of etanercept per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

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

Following this assessment, continued coverage may be approved for 50 mg per week for a period of 12 months. Ongoing coverage may be considered if the patient is re-assessed by an RA Specialist every 12 months and is confirmed to be continuing to respond to therapy by meeting...
ETANERCEPT

criteria as outlined in (2) above."

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

00002462869 ERELZI SDZ $ 255.0000

***Effective March 1, 2018, all new Special Authorization requests for the treatment of Rheumatoid Arthritis or Ankylosing Spondylitis for etanercept-naive patients will be assessed for coverage with Brenzys or Erelzi. Enbrel will not be approved for new etanercept starts for patients with the indications stated above; however, coverage for Enbrel will continue for patients who are currently well maintained on Enbrel and are considered a 'responder' as defined in criteria.

In addition, all new Special Authorization requests for the treatment of Polyarticular Juvenile Idiopathic Arthritis for etanercept-naive patients weighing 63 kg (138 pounds) or more will be assessed for coverage with Erelzi. Enbrel will be approved for new etanercept starts for pediatric patients with Polyarticular Juvenile Idiopathic Arthritis weighing less than 63 kg, and coverage for Enbrel will continue for patients who are currently well maintained on Enbrel and are considered a 'responder' as defined in criteria.

Additionally, patients will not be permitted to switch between etanercept products, if the patient has been previously trialed on any etanercept product and deemed unresponsive to therapy.***

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 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.

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

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

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

Following this assessment, continued coverage may be approved for 50 mg per week, for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by an RA Specialist to determine response;
2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
   - Confirmation of maintenance of ACR20, or
   - Maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.
3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.

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

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

Polyarticular Juvenile Idiopathic Arthritis:

"Special authorization coverage may be provided for the reduction in signs and symptoms of severely active polyarticular juvenile idiopathic arthritis (pJIA) in patients 4 years of age and older who:
- Have 5 or more active joints (defined by either swelling or limitation of motion plus pain and/or tenderness), AND
- Are refractory to one or more disease modifying anti-rheumatic agents (DMARDs) conventionally used in children (minimum three month trial).

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

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

- Coverage may be approved for 0.8 mg/kg/dose (maximum dose 50 mg) weekly for 12 weeks.
- Patients will be limited to receiving a one-month supply of etanercept per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another (with the exception of abatacept) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients will not be permitted to switch from abatacept to other biologic agents except under exceptional circumstances.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage of this agent beyond 12 weeks, the patient must meet the following criteria:
1) The patient must be assessed by a Pediatric Rheumatology Specialist after 12 weeks, but no longer than 16 weeks after, treatment with this biologic agent to determine response.
2) The Pediatric Rheumatology Specialist must confirm in writing that the patient is a responder that meets the following criteria (ACR Pedi 30):
- 30% improvement from baseline in at least three of the following six response variables, with worsening of 30% or more in no more than one of the six variables. The variables include:
  i. global assessment of the severity of the disease by the Pediatric Rheumatology Specialist,
  ii. global assessment of overall well-being by the patient or parent,
ETANERCEPT

iii. number of active joints (joints with swelling not due to deformity or joints with limitation of motion with pain tenderness or both),
iv. number of joints with limitation of motion,
v. functional ability based on CHAQ scores,
vi. ESR or CRP

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

Following this assessment, continued coverage may be approved for 0.8 mg/kg/dose (maximum dose 50 mg) weekly, for a maximum of twelve months. After twelve months, in order to be considered for continued coverage, the patient must be re-assessed every twelve months by a Pediatric Rheumatology Specialist and must meet the following criteria:
1) The patient has been assessed by a Pediatric Rheumatology Specialist to determine response, and
2) The Pediatric RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by maintenance of the ACR Pedi 30.
3) Data from all of the six variables comprising the ACR Pedi 30 and the CHAQ scores must be reported in each request.

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

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

Ankylosing Spondylitis:

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

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

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

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

- Initial coverage may be approved for 50 mg per week for 12 weeks.
- Patients will be limited to receiving a one-month supply of etanercept per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

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

- Reduction of the Spinal Pain VAS by 2 cm or more.

Following this assessment, continued coverage may be approved for 50 mg per week for a period of 12 months. Ongoing coverage may be considered if the patient is re-assessed by an RA Specialist every 12 months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above.*

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

00002274728 ENBREL AMG $ 401.5400

***Effective March 1, 2018, all new Special Authorization requests for the treatment of Rheumatoid Arthritis or Ankylosing Spondylitis for etanercept-naive patients will be assessed for coverage with Brenzys or Erelzi. Enbrel will not be approved for new etanercept starts for patients with the indications stated above; however, coverage for Enbrel will continue for patients who are currently well maintained on Enbrel and are considered a 'responder' as defined in criteria.

In addition, all new Special Authorization requests for the treatment of Polyarticular Juvenile Idiopathic Arthritis for etanercept-naive patients weighing 63 kg (138 pounds) or more will be assessed for coverage with Erelzi. Enbrel will be approved for new etanercept starts for pediatric patients with Polyarticular Juvenile Idiopathic Arthritis weighing less than 63 kg, and coverage for Enbrel will continue for patients who are currently well maintained on Enbrel and are considered a 'responder' as defined in criteria.

Additionally, patients will not be permitted to switch between etanercept products, if the patient has been previously trialed on any etanercept product and deemed unresponsive to therapy.***

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 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

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

it is being prescribed.

For continued coverage beyond 8 weeks, the patient must meet the following criteria:
1) The patient must be assessed by an RA Specialist after 8 weeks, but no longer than 12 weeks after treatment to determine response.
2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
   - ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND
   - An improvement of 0.22 in HAQ score [reported to two (2) decimal places].
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be approved for 50 mg per week, for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by an RA Specialist to determine response;
2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
   - Confirmation of maintenance of ACR20, or
   - Maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.
3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

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

Polyarticular Juvenile Idiopathic Arthritis:

"Special authorization coverage may be provided for the reduction in signs and symptoms of severely active polyarticular juvenile idiopathic arthritis (pJIA) in patients 4 years of age and older who:
- Have 5 or more active joints (defined by either swelling or limitation of motion plus pain and/or tenderness), AND
- Are refractory to one or more disease modifying anti-rheumatic agents (DMARDs) conventionally used in children (minimum three month trial).

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

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

- Coverage may be approved for 0.8 mg/kg/dose (maximum dose 50 mg) weekly for 12 weeks.
- Patients will be limited to receiving a one-month supply of etanercept per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another (with the exception of abatacept) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients will not be permitted to switch from abatacept to other biologic agents except under exceptional circumstances.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage of this agent beyond 12 weeks, the patient must meet the following criteria:
1) The patient must be assessed by a Pediatric Rheumatology Specialist after 12 weeks, but no longer than 16 weeks after treatment with this biologic agent to determine response.
2) The Pediatric Rheumatology Specialist must confirm in writing that the patient is a responder...
ETANERCEPT

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

Following this assessment, continued coverage may be approved for 0.8 mg/kg/dose (maximum dose 50 mg) weekly, for a maximum of twelve months. After twelve months, in order to be considered for continued coverage, the patient must be re-assessed every twelve months by a Pediatric Rheumatology Specialist and must meet the following criteria:

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

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

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

Psoriatic Arthritis:

"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.
ETANERCEPT

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

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

Following this assessment, continued coverage may be approved for 50 mg per week, for a period of 12 months. Ongoing coverage may be considered if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by an RA Specialist to determine response;
2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
   - Confirmation of maintenance of ACR20, or
   - Maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.
3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.

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

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

Ankylosing Spondylitis:

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

- a BASDAI greater than or equal to 4 units, demonstrated on 2 occasions at least 8 weeks apart
- 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
- who are refractory or intolerant to treatment with 2 or more NSAIDS each taken for a minimum of 4 weeks at maximum tolerated or recommended doses.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

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

- Initial coverage may be approved for 50 mg per week for 12 weeks.
- Patients will be limited to receiving a one-month supply of etanercept per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond 12 weeks, the patient must meet the following criteria:
1) The patient must be assessed at week 12 by an RA Specialist after the initial twelve weeks of therapy to determine response.
2) The RA Specialist must confirm, in writing, that the patient is a ‘responder’ that meets the
ETANERCEPT

following criteria:
- Reduction of the BASDAI score by at least 50% of the pre-treatment value or by 2 or more units, AND
- Reduction of the Spinal Pain VAS by 2 cm or more.

Following this assessment, continued coverage may be approved for 50 mg per week for a period of 12 months. Ongoing coverage may be considered if the patient is re-assessed by an RA Specialist every 12 months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above.

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

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 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."
ETANERCEPT

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

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

EZETIMIBE

"For the treatment of hypercholesterolemia in patients who are intolerant to statins or in whom a statin is contraindicated and who are at high cardiovascular risk*; or

For the treatment of hypercholesterolemia when used in combination with a statin in patients failing to achieve target LDL with a statin at maximum tolerable dose or maximum recommended dose as per respective product monograph and who are at high cardiovascular risk*:

* High cardiovascular risk is defined as possessing one of the following:
  1) Pre-existing cardiovascular disease and/or cerebrovascular disease, or
  2) Diabetes, or
  3) Familial hypercholesterolemia, or
  4) Greater than or equal to 20% risk as defined by the Framingham Risk Assessment Tool, or
  5) Three or more of the following risk factors:
     - Family history of premature cardiovascular disease
     - Smoking
     - Hypertension
     - Obesity
     - Glucose intolerance
     - Renal disease.

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

All requests for ezetimibe must be completed using the Ezetimibe Special Authorization Request Form (ABC 60036).

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

<table>
<thead>
<tr>
<th>10 MG</th>
<th>ORAL TABLET</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002425610</td>
<td>ACH-EZETIMIBE</td>
</tr>
<tr>
<td>00002427826</td>
<td>APO-EZETIMIBE</td>
</tr>
<tr>
<td>00002429659</td>
<td>EZETIMIBE</td>
</tr>
<tr>
<td>00002431300</td>
<td>EZETIMIBE</td>
</tr>
<tr>
<td>00002423235</td>
<td>JAMP-EZETIMIBE</td>
</tr>
<tr>
<td>00002422662</td>
<td>MAR-EZETIMIBE</td>
</tr>
<tr>
<td>00002423243</td>
<td>MINT-EZETIMIBE</td>
</tr>
<tr>
<td>00002416409</td>
<td>PMS-EZETIMIBE</td>
</tr>
<tr>
<td>00002419548</td>
<td>RAN-EZETIMIBE</td>
</tr>
<tr>
<td>00002416778</td>
<td>SANDOZ EZETIMIBE</td>
</tr>
<tr>
<td>00002354101</td>
<td>TEVA-EZETIMIBE</td>
</tr>
<tr>
<td>00002247521</td>
<td>EZETROL</td>
</tr>
</tbody>
</table>

The DBL is not a prescribing or a diagnostic tool. Prescribers should refer to drug monographs and utilize professional judgment.
FEBUXOSTAT
"For patients with symptomatic gout who have documented hypersensitivity OR severe intolerance to allopurinol, AND intolerance or lack of response to sulfinpyrazone.

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 60037).

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

<table>
<thead>
<tr>
<th>80 MG ORAL TABLET</th>
<th>TAK</th>
<th>$ 1.5900</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002357380</td>
<td>ULORIC</td>
<td></td>
</tr>
</tbody>
</table>

FENTANYL
"For the treatment of persistent, severe chronic pain in those patients who require continuous around-the-clock analgesia for an extended period of time in those patients who cannot swallow. Special authorization may be granted for 6 months."

"For the treatment of persistent, severe chronic pain in those patients who require continuous around-the-clock analgesia for an extended period of time in those patients who require opioid therapy at a total daily dose of at least 60 mg/day oral morphine equivalents. Patients must have tried and not been able to tolerate at least two discrete courses of therapy with two of the following agents: morphine, hydromorphone and oxycodone, if not contraindicated. Special authorization may be granted for 6 months."

Information is required regarding previous medications utilized and the patient's response to therapy. Also, information regarding the number of discrete (separate) courses of these medications is required. A discrete course is defined as a separate treatment course, which may involve more than 1 agent, used at one time to manage the patient's condition.

All requests for fentanyl must be completed using the Fentanyl Special Authorization Request Form (ABC 60005).

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

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

<table>
<thead>
<tr>
<th>12 MCG/HR TRANSDERMAL PATCH</th>
<th>MYP</th>
<th>$ 2.2280</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002396696</td>
<td>MYLAN-FENTANYL MATRIX</td>
<td></td>
</tr>
<tr>
<td>00002341379</td>
<td>PMS-FENTANYL MTX</td>
<td></td>
</tr>
<tr>
<td>00002330105</td>
<td>RAN-FENTANYL MATRIX</td>
<td></td>
</tr>
<tr>
<td>00002327112</td>
<td>SANDOZ FENTANYL PATCH</td>
<td></td>
</tr>
<tr>
<td>00002311925</td>
<td>TEVA-FENTANYL</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>25 MCG/HR TRANSDERMAL PATCH</th>
<th>APX</th>
<th>$ 3.6560</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002314630</td>
<td>APO-FENTANYL 25</td>
<td></td>
</tr>
<tr>
<td>00002396718</td>
<td>MYLAN-FENTANYL MATRIX</td>
<td></td>
</tr>
<tr>
<td>00002341387</td>
<td>PMS-FENTANYL MTX</td>
<td></td>
</tr>
<tr>
<td>00002330113</td>
<td>RAN-FENTANYL MATRIX</td>
<td></td>
</tr>
<tr>
<td>00002327120</td>
<td>SANDOZ FENTANYL PATCH</td>
<td></td>
</tr>
<tr>
<td>00002282941</td>
<td>TEVA-FENTANYL</td>
<td></td>
</tr>
</tbody>
</table>
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

ALBERTA DRUG BENEFIT LIST

PRODUCT IS NOT INTERCHANGEABLE

FENTANYL

<table>
<thead>
<tr>
<th>50 MCG/HR TRANSDERMAL PATCH</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002314649 APO-FENTANYL 50</td>
</tr>
<tr>
<td>00002396726 MYLAN-FENTANYL MATRIX</td>
</tr>
<tr>
<td>00002341395 PMS-FENTANYL MTX</td>
</tr>
<tr>
<td>00002330121 RAN-FENTANYL MATRIX</td>
</tr>
<tr>
<td>00002327147 SANDOZ FENTANYL PATCH</td>
</tr>
<tr>
<td>00002282968 TEVA-FENTANYL</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>75 MCG/HR TRANSDERMAL PATCH</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002314657 APO-FENTANYL 75</td>
</tr>
<tr>
<td>00002396734 MYLAN-FENTANYL MATRIX</td>
</tr>
<tr>
<td>00002341409 PMS-FENTANYL MTX</td>
</tr>
<tr>
<td>00002330148 RAN-FENTANYL MATRIX</td>
</tr>
<tr>
<td>00002327155 SANDOZ FENTANYL PATCH</td>
</tr>
<tr>
<td>00002282976 TEVA-FENTANYL</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>100 MCG/HR TRANSDERMAL PATCH</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002314665 APO-FENTANYL 100</td>
</tr>
<tr>
<td>00002396742 MYLAN-FENTANYL MATRIX</td>
</tr>
<tr>
<td>00002341417 PMS-FENTANYL MTX</td>
</tr>
<tr>
<td>00002330156 RAN-FENTANYL MATRIX</td>
</tr>
<tr>
<td>00002327163 SANDOZ FENTANYL PATCH</td>
</tr>
<tr>
<td>00002282984 TEVA-FENTANYL</td>
</tr>
</tbody>
</table>

FENTANYL CITRATE

"For the treatment of persistent, severe chronic pain in those patients who cannot swallow, or who are intolerant of morphine and/or hydromorphone, if not contraindicated. Special authorization may be granted for 6 months."

All requests for fentanyl must be completed using the Fentanyl Special Authorization Request Form (ABC 60005).

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

This product is eligible for auto-renewal.

<table>
<thead>
<tr>
<th>0.05 MG / ML (BASE) INJECTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002240434 FENTANYL CITRATE</td>
</tr>
</tbody>
</table>

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

PRODUCT IS NOT INTERCHANGEABLE

Section 3 · 99

EFFECTIVE APRIL 1, 2018
FESOTERODINE FUMARATE
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."

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

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

<table>
<thead>
<tr>
<th>Unit</th>
<th>Description</th>
<th>Code</th>
<th>PFI</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>4 MG</td>
<td>ORAL EXTENDED-RELEASE TABLET</td>
<td>00002380021 TOVIAZ</td>
<td>PFI</td>
<td>$1.5000</td>
</tr>
<tr>
<td>8 MG</td>
<td>ORAL EXTENDED-RELEASE TABLET</td>
<td>00002380048 TOVIAZ</td>
<td>PFI</td>
<td>$1.5000</td>
</tr>
</tbody>
</table>

FIDAXOMICIN
For the treatment of:
1) C. difficile infection (CDI) where the patient has failed, or is intolerant of oral vancomycin*; or
2) Patients with third or greater recurrence of CDI (i.e. 4th or greater episode of CDI)

*For CDI treatment protocol, please refer to vancomycin Special Authorization Criteria.

Note:
- Fidaxomicin should not be used as an add-on to existing therapy (metronidazole or vancomycin).
- Not studied in multiple recurrences or those with life-threatening or fulminant CDI, toxic megacolon, or inflammatory bowel disease.

Special authorization coverage for fidaxomicin will be provided for one treatment course (10 days) plus one additional treatment course for an early relapse occurring within 8 weeks of the start of the most recent fidaxomicin course.

New episode of CDI after 8 weeks will require treatment with metronidazole and oral vancomycin* before fidaxomicin coverage may be considered.

All requests (including renewal requests) for fidaxomicin must be completed using the Oral Vancomycin/Fidaxomicin Special Authorization Request Form (ABC 60014).

<table>
<thead>
<tr>
<th>Unit</th>
<th>Description</th>
<th>Code</th>
<th>Type</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>200 MG</td>
<td>ORAL TABLET</td>
<td>00002387174 DIFICID</td>
<td>MFC</td>
<td>$94.6000</td>
</tr>
</tbody>
</table>
**FILGRASTIM**

***Effective April 1, 2017, all Special Authorization requests for filgrastim will be assessed for coverage with Grastofil. Neupogen will not be approved for new filgrastim starts or repeat treatments (e.g. new course of chemotherapy); however, coverage for Neupogen will continue for pediatric patients and patients with congenital, cyclic or idiopathic neutropenia who are currently maintained on Neupogen.***

"In patients with non-myeloid malignancies, receiving myelosuppresive anti-neoplastic drugs with curative intent, to decrease the incidence of infection, as manifested by febrile neutropenia."

"Following induction and consolidation treatment for acute myeloid leukemia, for the reduction in the duration of neutropenia, fever, antibiotic use and hospitalization."

"In patients with a diagnosis of congenital, cyclic or idiopathic neutropenia, to increase neutrophil counts and to reduce the incidence and duration of infection."

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

All requests for filgrastim must be completed using the Filgrastim/Pegfilgrastim/Plerixafor Special Authorization Request Form (ABC 60013).

<table>
<thead>
<tr>
<th>0.3 MG / ML INJECTION</th>
<th>NEUPOGEN</th>
<th>AMG</th>
<th>$173.1890</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.3 MG / SYR INJECTION SYRINGE</td>
<td>GRASTOFIL</td>
<td>APX</td>
<td>$144.3135</td>
</tr>
<tr>
<td>0.48 MG / SYR INJECTION SYRINGE</td>
<td>GRASTOFIL</td>
<td>APX</td>
<td>$230.9017</td>
</tr>
</tbody>
</table>

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

Relapsing Remitting Multiple Sclerosis (RRMS):

Special authorization coverage may be provided for the treatment of relapsing remitting multiple sclerosis (RRMS) to reduce the frequency of clinical relapses and to delay the progression of physical disability in adult patients (18 years of age or older) who are refractory or intolerant to at least ONE of the following:
- interferon beta
- glatiramer acetate
- dimethyl fumarate
- teriflunomide.

Definition of 'intolerant'

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

Definition of 'refractory'

- Development of neutralizing antibodies to interferon beta.

-When the above MS DMTs (interferon beta, glatiramer acetate, dimethyl fumarate, teriflunomide) are taken at the recommended doses for a full and adequate course of treatment, within a consecutive 12-month period while the patient was on the MS DMT, the patient has:

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

2) Experienced at least two relapses* of MS confirmed by the presence of neurologic deficits on examination.
   i. The first qualifying clinical relapse must have begun at least one month after treatment initiation.
   ii. Both qualifying relapses must be classified with a relapse severity of moderate, severe or very severe**.

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

**Relapse Severity: with moderate relapses modification or more time is required to carry out activities of daily living; with severe relapses there is inability to carry out some activities of daily living; with very severe relapses activities of daily living must be completed by others.

Coverage

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

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

Initial Coverage

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

2) The patient must have active disease which is defined as at least two relapses* of MS during...
FINGOLIMOD HYDROCHLORIDE

the previous two years or in the two years prior to starting an MS DMT. In most cases this will be satisfied by the refractory to treatment criterion but if a patient failed interferon beta, glatiramer acetate, dimethyl fumarate, or teriflunomide more than one year earlier, ongoing active disease must be confirmed.

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

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

Coverage of fingolimod will not be approved if the patient was deemed to be refractory to fingolimod in the past, i.e., has not met the ‘responder’ criteria below in ‘Continued Coverage’.

Following assessment of the request, coverage may be approved for up to 12 months. Patients will be limited to receiving a one-month supply of fingolimod per prescription at their pharmacy for the first 12 months of coverage.

Continued Coverage

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

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

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

4) The registered MS Neurologist must confirm in writing that the patient is a ‘responder’ who has experienced no more than one inflammatory event in the last year (defined as either a clinical relapse or gadolinium-enhancing lesion). In instances where a patient has had four or more clinical relapses in the year prior to starting treatment, there must be at least a 50% reduction in relapse rate over the entire treatment period.

Following assessment of the request, continued coverage may be approved for maintenance therapy for up to 12 months. Patients may receive up to 100 days’ supply of fingolimod per prescription at their pharmacy.

Restarting After an Interruption in Therapy Greater Than 12 Months

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

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

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

0.5 MG ORAL CAPSULE

00002365480    GILENYA

NOV    $    86.9525
FINGOLIMOD HYDROCHLORIDE

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

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

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

<table>
<thead>
<tr>
<th>10 MG / ML ORAL SUSPENSION</th>
<th>PFI</th>
<th>$</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002024152 DIFLUCAN</td>
<td></td>
<td>1.1577</td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>250 MG ORAL TABLET</th>
<th>APX</th>
<th>$</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002238560 APO-FLUTAMIDE</td>
<td></td>
<td>1.8255</td>
</tr>
</tbody>
</table>
FLUTICASONE FUROATE/ VILANTEROL TRIFENATATE

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

ASTHMA

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

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

CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD)

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

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

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

"Special authorization may be granted for 24 months."

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

UP - First-line therapy ineffective

All requests for fluticasone furoate + vilanterol trifenate must be completed using the Long-Acting Fixed-Dose Combination Products for Asthma/COPD Special Authorization Request Form (ABC 60025).

100 MCG / DOSE * 25 MCG / DOSE (BASE) INHALATION METERED INHALATION POWDER

00002408872 BREO ELLIPTA GSK $ 2.7973

The DBL is not a prescribing or a diagnostic tool. Prescribers should refer to drug monographs and utilize professional judgment.
SECTION 3

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

ASTHMA

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

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

"Special authorization may be granted for 24 months."

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

UP - First-line therapy ineffective

All requests for fluticasone furoate + vilanterol trifenatate must be completed using the Long-Acting Fixed-Dose Combination Products for Asthma/COPD Special Authorization Request Form (ABC 60025).

GALANTAMINE HYDROBROMIDE

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

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

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

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

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

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

8 MG (BASE) ORAL EXTENDED-RELEASE CAPSULE

<p>| | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>00002425157</td>
<td>AURO-GALANTAMINE ER</td>
<td>AUR</td>
<td>$ 1.2463</td>
</tr>
<tr>
<td>00002443015</td>
<td>GALANTAMINE ER</td>
<td>SNS</td>
<td>$ 1.2463</td>
</tr>
<tr>
<td>00002339439</td>
<td>MYLAN-GALANTAMINE ER</td>
<td>MYP</td>
<td>$ 1.2463</td>
</tr>
<tr>
<td>00002398370</td>
<td>PMS-GALANTAMINE ER</td>
<td>PMS</td>
<td>$ 1.2463</td>
</tr>
</tbody>
</table>

16 MG (BASE) ORAL EXTENDED-RELEASE CAPSULE

<p>| | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>00002425165</td>
<td>AURO-GALANTAMINE ER</td>
<td>AUR</td>
<td>$ 1.2463</td>
</tr>
<tr>
<td>00002443023</td>
<td>GALANTAMINE ER</td>
<td>SNS</td>
<td>$ 1.2463</td>
</tr>
<tr>
<td>00002339447</td>
<td>MYLAN-GALANTAMINE ER</td>
<td>MYP</td>
<td>$ 1.2463</td>
</tr>
<tr>
<td>00002398389</td>
<td>PMS-GALANTAMINE ER</td>
<td>PMS</td>
<td>$ 1.2463</td>
</tr>
</tbody>
</table>
### GALANTAMINE HYDROBROMIDE

<table>
<thead>
<tr>
<th>Product Code</th>
<th>Product Name</th>
<th>Brand</th>
<th>Unit Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002425173</td>
<td>AURO-GALANTAMINE ER</td>
<td>AUR</td>
<td>$1.2463</td>
</tr>
<tr>
<td>00002443031</td>
<td>GALANTAMINE ER</td>
<td>SNS</td>
<td>$1.2463</td>
</tr>
<tr>
<td>00002339455</td>
<td>MYLAN-GALANTAMINE ER</td>
<td>MYP</td>
<td>$1.2463</td>
</tr>
<tr>
<td>00002398397</td>
<td>PMS-GALANTAMINE ER</td>
<td>PMS</td>
<td>$1.2463</td>
</tr>
</tbody>
</table>

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

PRODUCT IS NOT INTERCHANGEABLE

EFFECTIVE APRIL 1, 2018
GLATIRAMER ACETATE
Relapsing Remitting Multiple Sclerosis (RRMS):

"Special authorization coverage may be provided for the reduction of the frequency and severity of clinical relapses and reduction of the number and volume of active brain lesions, identified on MRI scans, in ambulatory patients with relapsing remitting multiple sclerosis.

Coverage

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

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

Initial Coverage

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

2) The patient must have active disease which is defined as at least two relapses* of MS during the previous two years or in the two years prior to starting an MS disease modifying therapy (DMT).

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

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

Coverage may be approved for up to 12 months. Patients will be limited to receiving a one-month supply of glatiramer acetate per prescription at their pharmacy for the first 12 months of coverage.

Continued Coverage

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

1) The patient must be assessed by a registered MS Neurologist;

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

3) The registered MS Neurologist must provide a current updated EDSS score. The patient must not have an EDSS score of 7.0 or above sustained for one year or more.

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

Continued coverage may be approved for up to 12 months. Patients may receive up to 100 days' supply of glatiramer acetate per prescription at their pharmacy.

Restarting After an Interruption in Therapy Greater Than 12 Months

In order to be eligible for coverage, after an interruption in therapy greater than 12 months, the...
GLATIRAMER ACETATE

patient must meet the following criteria:

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

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

<table>
<thead>
<tr>
<th>20 MG / SYR INJECTION SYRINGE</th>
<th>COPAXONE</th>
<th>TMP</th>
<th>$ 47.1550</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002245619</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
GOLIMUMAB

Ankylosing Spondylitis:

“Special authorization coverage may be provided for the reduction in the signs and symptoms of severely active Ankylosing Spondylitis, as defined by the Modified New York criteria for Ankylosing Spondylitis, in adult patients (18 years of age or older) who have active disease as demonstrated by:
- a BASDAI greater than or equal to 4 units, demonstrated on 2 occasions at least 8 weeks apart AND
- a Spinal Pain VAS of greater than or equal to 4 cm (on a 0-10 cm scale), demonstrated on 2 occasions at least 8 weeks apart AND
- who are refractory or intolerant to treatment with 2 or more NSAIDS each taken for a minimum of 4 weeks at maximum tolerated or recommended doses.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

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

- Initial coverage may be approved for 50 mg once per month for four doses.
- Patients will be limited to receiving one dose (50 mg) of golimumab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

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

Following this assessment, continued coverage may be approved for 50 mg once per month for a further 12 month period. Should continued coverage criteria be met, coverage will only be granted for 12 doses per 12 month period. Ongoing coverage may be considered if the patient is re-assessed by an RA Specialist every 12 months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above."

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

Psoriatic Arthritis:

“Special authorization coverage may be provided for use in combination with methotrexate for reducing signs and symptoms of active arthritis in adult patients (18 years of age or older) with moderate to severe polyarticular psoriatic arthritis (PsA) or pauciarticular PsA with involvement of knee or hip joint who are refractory or intolerant to:
GOLIMUMAB
- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- An adequate trial of another disease modifying anti-rheumatic agent(s) (minimum 4 month trial).

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

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

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

- Initial coverage may be approved for 50 mg per month for four doses.
- Patients will be limited to receiving one dose (50 mg) of golimumab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

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

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

Following this assessment, continued coverage may be approved for 50 mg per month, for a further 12 month period. Should coverage criteria be met, coverage will only be granted for 12 doses per 12-month period. Ongoing coverage may be considered if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by an RA Specialist to determine response;
2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
- Confirmation of maintenance of ACR20, or
- Maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.
3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.

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

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

Rheumatoid Arthritis:

"Special authorization coverage may be provided for use in combination with methotrexate for the reduction in signs and symptoms of severely active Rheumatoid Arthritis (RA) in adult patients (18 years of age or older) who are refractory or intolerant to:
- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- Methotrexate with other disease modifying anti-rheumatic agent(s) (minimum 4-month trial). [e.g., methotrexate with hydroxychloroquine or methotrexate with sulfasalazine]; AND
- Leflunomide (minimum 10 week trial at 20 mg daily).

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

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

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

- Initial coverage may be approved for 50 mg per month for a total of four doses.
- Patients will be limited to receiving one dose (50 mg) of golimumab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another (with the exception of anakinra) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at 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:
GOLIMUMAB

1) The patient has been assessed by an RA Specialist to determine response;
2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
   - Confirmation of maintenance of ACR20, or
   - Maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.
3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.
   It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above."

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

Ulcerative Colitis

Special authorization coverage may be provided for the reduction in signs and symptoms and induction and maintenance of clinical remission of Ulcerative Colitis in adult patients (18 years of age or older) with active disease (characterized by a partial Mayo score >4 prior to initiation of biologic therapy) and who are refractory or intolerant to:
- mesalamine: minimum of 4 grams/day for a minimum of 4 weeks; AND
- corticosteroids (failure to respond to prednisone 40 mg daily for 2 weeks, or; steroid dependent i.e. failure to taper off steroids without recurrence of disease or disease requiring a second dose of steroids within 12 months of previous dose).

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

Immunosuppressive therapy as follows may also be initiated if in the clinician's judgment a trial is warranted:
  i) Azathioprine: minimum of 2 mg/kg/day for a minimum of 2 months; OR
  ii) 6-mercaptopurine: minimum of 1 mg/kg/day for a minimum of 2 months

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

Initial coverage may be approved for 200 mg of golimumab administered by subcutaneous injection at Week 0, followed by 100 mg at Week 2. As an interim measure, an additional dose of 50 mg of golimumab will be provided at weeks 6 and 10 to allow time to determine whether the patient meets coverage criteria for maintenance dosing, see below.
- Patients will be limited to receiving a one-month supply of golimumab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.
GOLIMUMAB
For continued coverage beyond three doses, the patient must meet the following criteria:
1) The patient must be assessed by a Specialist between week 12 and week 14 to
determine response.
2) The Specialist must confirm in writing that the patient is a ‘responder’ that meets the
following criteria:
- a decrease in the partial Mayo score of greater than or equal to 2 points

Following this assessment, continued coverage may be approved for a dose of 50 mg
every 4 weeks for a period of 12 months. Ongoing coverage may be considered only if
the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by a Specialist to determine response;
2) The Specialist must confirm in writing that the patient has maintained a response to
therapy as indicated by:
- a decrease in the partial Mayo score of greater than or equal to 2 points from the score
prior to initiation of golimumab therapy

Note: For patients who showed a response to induction therapy then experienced
secondary loss of response while on maintenance dosing with 50 mg, the maintenance
dose may be adjusted from 50 mg to 100 mg by making an additional special
authorization request to Alberta Blue Cross for the increased dose.

All requests (including renewal requests) for golimumab for Ulcerative Colitis must be
completed using the Adalimumab/Golimumab/Infliximab/Vedolizumab for Ulcerative
Colitis Special Authorization Request Form (ABC 60008).

50 MG / SYR INJECTION SYRINGE

<table>
<thead>
<tr>
<th>Item Code</th>
<th>Product Code</th>
<th>Product Name</th>
<th>Unit</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002324776</td>
<td>SIMPONI</td>
<td>JAI</td>
<td>$</td>
<td>1516.0000</td>
</tr>
<tr>
<td>00002324784</td>
<td>SIMPONI</td>
<td>JAI</td>
<td>$</td>
<td>1516.0000</td>
</tr>
</tbody>
</table>

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

Special authorization coverage may be provided for the reduction in signs and symptoms and induction and maintenance of clinical remission of Ulcerative Colitis in adult patients (18 years of age or older) with active disease (characterized by a partial Mayo score >4 prior to initiation of biologic therapy) and who are refractory or intolerant to:
- mesalamine: minimum of 4 grams/day for a minimum of 4 weeks; AND
- corticosteroids (failure to respond to prednisone 40 mg daily for 2 weeks, or; steroid dependent i.e. failure to taper off steroids without recurrence of disease or disease requiring a second dose of steroids within 12 months of previous dose).

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

Immunosuppressive therapy as follows may also be initiated if in the clinician's judgment a trial is warranted:
- i) Azathioprine: minimum of 2 mg/kg/day for a minimum of 2 months; OR
- ii) 6-mercaptopurine: minimum of 1 mg/kg/day for a minimum of 2 months

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

Initial coverage may be approved for 200 mg of golimumab administered by subcutaneous injection at Week 0, followed by 100 mg at Week 2. As an interim measure, an additional dose of 50 mg of golimumab will be provided at weeks 6 and 10 to allow time to determine whether the patient meets coverage criteria for maintenance dosing, see below.

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

For continued coverage beyond three doses, the patient must meet the following criteria:
1) The patient must be assessed by a Specialist between week 12 and week 14 to determine response.
2) The Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
- a decrease in the partial Mayo score of greater than or equal to 2 points

Following this assessment, continued coverage may be approved for a dose of 50 mg every 4 weeks for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by a Specialist to determine response;
2) The Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
- a decrease in the partial Mayo score of greater than or equal to 2 points from the score prior to initiation of golimumab therapy

Note: For patients who showed a response to induction therapy then experienced
**GOLIMUMAB**

Secondary loss of response while on maintenance dosing with 50 mg, the maintenance dose may be adjusted from 50 mg to 100 mg by making an additional special authorization request to Alberta Blue Cross for the increased dose.

All requests (including renewal requests) for golimumab for Ulcerative Colitis must be completed using the Adalimumab/Golimumab/Infliximab/Vedolizumab for Ulcerative Colitis Special Authorization Request Form (ABC 60008).

<table>
<thead>
<tr>
<th>100 MG / SYR</th>
<th>INJECTION</th>
<th>SYRINGE</th>
<th>JAI</th>
<th>$</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002413175</td>
<td>SIMPONI</td>
<td>JAI</td>
<td>$1516.0000</td>
<td></td>
</tr>
<tr>
<td>00002413183</td>
<td>SIMPONI</td>
<td>JAI</td>
<td>$1516.0000</td>
<td></td>
</tr>
</tbody>
</table>

**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.

<table>
<thead>
<tr>
<th>3.6 MG / SYR (BASE)</th>
<th>INJECTION</th>
<th>SYRINGE</th>
<th>TSA</th>
<th>$</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002049325</td>
<td>ZOLADEX</td>
<td>TSA</td>
<td>$422.6778</td>
<td></td>
</tr>
<tr>
<td>10.8 MG / SYR (BASE)</td>
<td>INJECTION</td>
<td>SYRINGE</td>
<td>TSA</td>
<td>$1204.7322</td>
</tr>
</tbody>
</table>

**ICATIBANT ACETATE**

"For the treatment of acute attacks of confirmed Type 1 or Type 2 hereditary angioedema (HAE) in patients with C1-esterase inhibitor deficiency. Icatibant is to be used for:
- acute non-laryngeal attack(s) of at least moderate severity, or
- acute laryngeal attack(s) of any severity

This medication must be prescribed by, or in consultation with, a physician experienced in the treatment of HAE.

Special authorization may be granted for 12 months.

Patients will be limited to a maximum of two doses of icatibant per prescription at their pharmacy."

This product is eligible for auto-renewal.

<table>
<thead>
<tr>
<th>30 MG / SYR (BASE)</th>
<th>INJECTION</th>
<th>SOT</th>
<th>$</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002425696</td>
<td>FIRAZYR</td>
<td>SOT</td>
<td>$2700.0000</td>
</tr>
</tbody>
</table>
IMIPENEM/ CILASTATIN SODIUM
(Refer to Section 1 - Restricted Benefits of the Alberta Drug Benefit List for coverage of the product when prescribed by a Specialist in Infectious Diseases or Hematology, or a designated prescriber.)

"For the treatment of:

1) Second-line therapy of intra-abdominal sepsis where there is failure of first-line therapy (e.g. ampicillin + gentamicin + metronidazole), as defined by clinical deterioration after 72 h of antibiotic therapy or lack of improvement after completion of antibiotic therapy or

2) Second-line therapy of severe polymicrobial skin and skin structure infections (e.g. limb threatening diabetic foot) or

3) Empiric therapy of mixed synergistic necrotizing gangrene (Fournier's gangrene) or

4) Therapy of severe ventilator-associated pneumonia where Pseudomonas and Staphylococcus aureus coverage is needed or

5) Second-line therapy of infections due to gram-negative organisms producing inducible beta-lactamases or extended spectrum beta-lactamases where there is resistance to first-line agents or

6) For use in other Health Canada approved indications in consultation with a specialist in Infectious Diseases."

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

In order to comply with all of the above criteria, information is required regarding the type of infection and organisms involved. Also, where the criteria restrict coverage of the requested drug to non-first line therapy, information is required regarding previous first-line antibiotic therapy that has been utilized, the patient's response to therapy, and the first line agents the organism is resistant to or why other first-line therapies cannot be used in this patient. Also, where applicable, the specialist in Infectious Diseases that recommended this drug is required.

IMIQUIMOD
"For the treatment of Actinic Keratosis located on the head and neck in patients who have failed treatment with cryotherapy (where appropriate) and 5-fluorouracil (5-FU).

Special authorization may be granted for 6 months."

All requests for imiquimod must be completed using the Imiquimod Special Authorization Request Form (ABC 60038).

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

The DBL is not a prescribing or a diagnostic tool. Prescribers should refer to drug monographs and utilize professional judgment.
INDACATEROL MALEATE/ GLYCOPYRRONIUM BROMIDE
The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD)

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

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

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

"Special authorization may be granted for 24 months."

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

UP - First-line therapy ineffective

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

<table>
<thead>
<tr>
<th>110 MCG (BASE) * 50 MCG (BASE) INHALATION CAPSULE</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002418282 ULTIBRO BREEZHALER NOV $ 2.6800</td>
</tr>
</tbody>
</table>
INFANT FORMULA
ORAL POWDER

00000999543 PURAMINO A+ MJO $ 0.1275

"For the dietary management of infants with:
- cow milk protein allergy OR
- soy protein allergy OR
- multiple food protein intolerance OR
- conditions where an amino acid-based diet is indicated:
- short bowel syndrome
- gastroesophageal reflux disease (GERD)
- eosinophilic esophagitis (EoE)
- malabsorption.

AND

Who have failed or are intolerant to an appropriate trial (1 to 2 week trial is recommended) of an extensively hydrolyzed infant formula.

This product must be prescribed by or in consultation with a general pediatrician, neonatologist, pediatric gastroenterologist or pediatric allergist.

Special authorization may be granted for a maximum of 24 months."

(Refer to Criteria for Special Authorization of Select Drug Products in the Alberta Human Services Drug Benefit Supplement for eligibility in Alberta Human Services clients.)

00000999568 NEOCATE WITH DHA & ARA NUN $ 0.1341

"For the dietary management of infants with:
- cow milk protein allergy OR
- soy protein allergy OR
- multiple food protein intolerance OR
- conditions where an amino acid-based diet is indicated:
- short bowel syndrome
- gastroesophageal reflux disease (GERD)
- eosinophilic esophagitis (EoE)
- malabsorption.

AND

Who have failed or are intolerant to an appropriate trial (1 to 2 week trial is recommended) of an extensively hydrolyzed infant formula.

This product must be prescribed by or in consultation with a general pediatrician, neonatologist, pediatric gastroenterologist or pediatric allergist.

Special authorization may be granted for a maximum of 24 months."

(Refer to Criteria for Special Authorization of Select Drug Products in the Alberta Human Services Drug Benefit Supplement for eligibility in Alberta Human Services clients.)
INFLIXIMAB

***Effective April 1, 2016, all new Special Authorization requests for the treatment of Ankylosing Spondylitis, Plaque Psoriasis, Psoriatic Arthritis or Rheumatoid Arthritis for infliximab naive patients will be assessed for coverage with Inflectra. Effective December 1, 2016, all new Special Authorization requests for the treatment of Moderately to Severely Active Crohn's Disease and Fistulizing Crohn's Disease or Ulcerative Colitis for infliximab naive patients will be assessed for coverage with Inflectra. Remicade will not be approved for new infliximab starts for patients with the indications stated above; however, coverage for Remicade will continue for patients who are currently well maintained on Remicade and are considered a 'responder' as defined in criteria. Additionally, patients will not be permitted to switch from Inflectra to Remicade or vice versa, if previously trialed and deemed unresponsive to therapy.***

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 ("RA Specialist").

- Initial coverage may be approved for three doses as follows: An initial dose of 3 mg/kg, followed by additional 3 mg/kg doses at 2 and 6 weeks after the first infusion.
- Patients will be limited to receiving one dose of infliximab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another (with the exception of anakinra) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients will not be permitted to switch from anakinra to other biologic agents except under exceptional circumstances.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond three doses, the patient must meet the following criteria:
1) The patient must be assessed by an RA Specialist after the initial three doses to determine response.
2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
   - ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND

The DBL is not a prescribing or a diagnostic tool. Prescribers should refer to drug monographs and utilize professional judgment.
INFLIXIMAB
- An improvement of 0.22 in HAQ score [reported to two (2) decimal places].
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be approved for one 3 mg/kg dose every 8 weeks for a period of 12 months [Note: For patients who have an incomplete response, consideration may be given to adjusting the dose up to 10 mg/kg and/or treating as often as every 4 weeks]. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by an RA Specialist to determine response;
2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
   - confirmation of maintenance of ACR20, OR
   - maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.
3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

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

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

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

(New Patient's Baseline Score), AND be Refractory.

Refractory is defined as one or more of the following:
1) Serious adverse effects or reactions to the treatments specified below; OR
2) Contraindications (as defined in product monographs) to the treatments specified below; OR
3) Previous documented lack of effect at doses and for duration of all treatments specified below:
   a) mesalamine: minimum of 3 grams/day for a minimum of 6 weeks; AND refractory to, or dependent on, glucocorticoids:
      following at least one tapering dosing schedule of 40 mg/day, tapering by 5 mg each week to 20 mg, then tapering by 2.5 mg each week to zero, or similar;
   [Note: Patients who have used the above treatments in combination will not be required to be challenged with individual treatments as monotherapy]

   AND
   b) Immunosuppressive therapy as follows:
      - Azathioprine: minimum of 2 mg/kg/day for a minimum of 3 months; OR
      - 6-mercaptopurine: minimum of 1 mg/kg/day for a minimum of 3 months; OR
      - Methotrexate: minimum or 15 mg/week for a minimum of 3 months.
      OR
      - Immunosuppressive therapy discontinued at less than 3 months due to serious adverse effects or reactions.

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:
INFLIXIMAB

- Coverage for Induction Dosing may only be approved for New Patients (those who have never been treated with infliximab by any health care provider).
- 'Induction Dosing' means a maximum of one 5 mg/kg dose of infliximab per New Patient at each 0, 2 and 6 weeks (for a maximum total of three doses).
- New Patients are eligible to receive Induction Dosing only once, after which time the Maintenance Dosing for New Patients and Continued Coverage for Maintenance Dosing criteria will apply.

Maintenance Dosing:

'Maintenance Dosing' means one 5 mg/kg dose of infliximab per patient provided no more often than every 8 weeks for a period of 12 months to:
- New Patients following the completion of Induction Dosing; OR
- Existing Patients, who are patients that are being treated, or have previously been treated, with infliximab.

Maintenance Dosing for New Patients after Completion of Induction Dosing:

- The New Patient must be assessed by a Specialist between weeks 10 and 14 after the initiation of Induction Dosing to determine response by obtaining a Modified Harvey Bradshaw Index score for patients with Moderately to Severely Active Crohn's Disease and/or closure of individual fistulas as evidenced by no or minimal fistula drainage despite gentle finger compression of fistulas that were draining at baseline for Fistulizing Crohn's; AND
- The Specialist must confirm the Modified Harvey Bradshaw Index score shows a decrease from the New Patient's Baseline Score of greater than or equal to 3 points for patients with Moderately to Severely Active Crohn's and/or confirm closure of individual fistulas as evidenced by no or minimal fistula drainage despite gentle finger compression of fistulas that were draining at baseline for Fistulizing Crohn's.

Maintenance Dosing for Existing Patients:

- The patient must be assessed by a Specialist at least 4 to 8 weeks after the day the last dose of 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
INFLIXIMAB

greater than or equal to 3 point decrease from the New Patient's Baseline Score for Moderately to Severely Active Crohn's and/or closure of individual fistulas as evidenced by no or minimal fistula drainage despite gentle finger compression of fistulas that were draining at baseline for Fistulizing Crohn's; OR
- For Existing Patients: The Specialist must confirm that the patient has maintained the Existing Patient's Baseline Score and/or closure of individual fistulas as evidenced by no or minimal fistula drainage despite gentle finger compression of fistulas that were draining at baseline for Fistulizing Crohn's.

(For new and existing patients with Moderately to Severely Active Crohn's Disease with an incomplete response or for new and existing patients with Fistulizing Crohn's who respond then lose their response, the maintenance dose may be adjusted to 10 mg/kg by making an additional special authorization request to Alberta Blue Cross for the increased dose.)""

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

Ankylosing Spondylitis:

"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:
INFLIXIMAB

- Reduction of the BASDAI score by at least 50% of the pre-treatment value or by 2 or more units, AND
- Reduction of the Spinal Pain VAS by 2 cm or more.

Following this assessment, continued coverage may be approved for one 5 mg/kg dose of infliximab every 6 to 8 weeks for a period of 12 months. Ongoing coverage may be considered if the patient is re-assessed by an RA Specialist every 12 months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above.

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

Psoriatic Arthritis:

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

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

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

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

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

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

- Initial coverage may be approved for three doses as follows: An initial dose of 5 mg/kg, followed by additional 5 mg/kg doses at 2 and 6 weeks after the first infusion.
- Patients will be limited to receiving one dose of infliximab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond three doses, the patient must meet the following criteria:
1) The patient must be assessed by an RA Specialist after the initial three doses to determine response.
2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
   - ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1)
INFLIXIMAB

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

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.

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

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.
INFLIXIMAB
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond three doses, the patient must meet all of the following criteria:
1) The patient must be assessed by a Dermatology Specialist after the initial three doses to determine response.
2) The Dermatology Specialist must confirm, in writing, that the patient is a 'responder' that meets the following criteria:
   - Greater than or equal to 75% reduction in PASI score, or
   - Greater than or equal to 50% reduction in PASI score AND improvement of greater than or equal to 5 points in the DLQI.

Following this assessment, continued coverage may be considered for one 5 mg/kg dose of infliximab every 8 weeks for a period of 12 months. Ongoing coverage may be considered if the patient is re-assessed by a Dermatology Specialist every 12 months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above."

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

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

Ulcerative Colitis:
"Special authorization coverage may be provided for the reduction in signs and symptoms and induction and maintenance of clinical remission of Ulcerative Colitis in adult patients (18 years of age or older) with active disease (characterized by a partial Mayo score >4 prior to initiation of biologic therapy) and who are refractory or intolerant to:
- mesalamine: minimum of 4 grams/day for a minimum of 4 weeks AND
- corticosteroids (failure to respond to prednisone 40 mg daily for 2 weeks, or; steroid dependent i.e. failure to taper off steroids without recurrence of disease or disease requiring a second dose of steroids within 12 months of previous dose).

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

Immunosuppressive therapy as follows may also be initiated if in the clinician's judgment a trial is warranted:
   i) Azathioprine: minimum of 2 mg/kg/day for a minimum of 2 months; OR
   ii) 6-mercaptopurine: minimum of 1 mg/kg/day for a minimum of 2 months

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

Initial coverage may be approved for three doses of 5 mg/kg of infliximab at 0, 2 and 6 weeks.
- Patients will be limited to receiving a one dose of infliximab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an
INFLIXIMAB

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

For continued coverage beyond three doses, the patient must meet the following criteria:
1) The patient must be assessed by a Specialist between weeks 10 and 14 after the initiation of therapy to determine response.
2) The Specialist must confirm in writing that the patient is a ‘responder’ that meets the following criteria:
   - a decrease in the partial Mayo score of greater than or equal to 2 points

Following this assessment, continued coverage may be approved for dose of 5 mg/kg every 8 weeks for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by a Specialist in Gastroenterology to determine response;
2) The Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
   - a decrease in the partial Mayo score of greater than or equal to 2 points from the score prior to initiation of infliximab therapy

Note: For patients who showed a response to induction therapy then experienced secondary loss of response while on maintenance dosing with 5 mg/kg, the maintenance dose may be adjusted from 5 mg/kg to 10 mg/kg by making an additional special authorization request to Alberta Blue Cross for the increased dose."

All requests (including renewal requests) for infliximab for Ulcerative Colitis must be completed using the Adalimumab/Golimumab/Infliximab/Vedolizumab for Ulcerative Colitis Special Authorization Request Form (ABC 60008).

100 MG / VIAL INJECTION

00002244016 REMICADE JAI $ 962.6800
INFLIXIMAB

***Effective April 1, 2016, all new Special Authorization requests for the treatment of Ankylosing Spondylitis, Plaque Psoriasis, Psoriatic Arthritis or Rheumatoid Arthritis for infliximab naive patients will be assessed for coverage with Inflectra. Effective December 1, 2016, all new Special Authorization requests for the treatment of Moderately to Severely Active Crohn's Disease and Fistulizing Crohn's Disease or Ulcerative Colitis for infliximab naive patients will be assessed for coverage with Inflectra. Remicade will not be approved for new infliximab starts for patients with the indications stated above; however, coverage for Remicade will continue for patients who are currently well maintained on Remicade and are considered a 'responder' as defined in criteria. Additionally, patients will not be permitted to switch from Inflectra to Remicade or vice versa, if previously trialed and deemed unresponsive to therapy.***

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

For continued coverage beyond three doses, the patient must meet all of the following criteria:
1) The patient must be assessed by a Dermatology Specialist after the initial three doses to determine response.
2) The Dermatology Specialist must confirm, in writing, that the patient is a 'responder' that meets the following criteria:
   - Greater than or equal to 75% reduction in PASI score, or
   - Greater than or equal to 50% reduction in PASI score AND improvement of greater
INFLIXIMAB

than or equal to 5 points in the DLQI.

Following this assessment, continued coverage may be considered for one 5 mg/kg dose of infliximab every 8 weeks for a period of 12 months. Ongoing coverage may be considered if the patient is re-assessed by a Dermatology Specialist every 12 months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above."

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

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

Psoriatic Arthritis:

"Special authorization coverage may be provided for use in combination with methotrexate for reducing signs and symptoms and inhibiting the progression of structural damage of active arthritis in adult patients (18 years of age or older) with moderate to severe polyarticular psoriatic arthritis (PsA) or pauciarticular PsA with involvement of knee or hip joint who are refractory or intolerant to:
- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- An adequate trial of another disease modifying anti-rheumatic agent(s) (minimum 4 month trial).

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

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

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

- Initial coverage may be approved for three doses as follows: An initial dose of 5 mg/kg, followed by additional 5 mg/kg doses at 2 and 6 weeks after the first infusion.
- Patients will be limited to receiving one dose of infliximab per prescription at their pharmacy.
- Patients will be permitted to switch from another biologic agent to infliximab following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to infliximab if previously trialed and deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond three doses, the patient must meet the following criteria:
1) The patient must be assessed by an RA Specialist after the initial three doses to determine response.
2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets
INFLIXIMAB

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

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

Following this assessment, continued coverage may be approved for one 5 mg/kg dose every 8 weeks, for a period of 12 months. Ongoing coverage may be considered if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by an RA Specialist to determine response;
2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
- Confirmation of maintenance of ACR20, or
- Maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.
3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.

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

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

Rheumatoid Arthritis:

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

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

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

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

- Initial coverage may be approved for three doses as follows: An initial dose of 3 mg/kg, followed by additional 3 mg/kg doses at 2 and 6 weeks after the first infusion.
- Patients will be limited to receiving one dose of infliximab per prescription at their pharmacy.
- Patients will be permitted to switch from another biologic agent (with the exception of anakinra) to infliximab following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to infliximab if previously trialed and deemed unresponsive to therapy.

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

- Patients will not be permitted to switch from anakinra to other biologic agents except under exceptional circumstances.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond the initial three doses, the patient must meet the following criteria:
1) The patient must be assessed by an RA Specialist after the initial three doses to determine response.
2) The RA Specialist must confirm in writing that the patient is a ‘responder’ that meets the following criteria:
   - ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND
   - An improvement of 0.22 in HAQ score [reported to two (2) decimal places].
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Continued coverage may be approved for one 3 mg/kg dose every 8 weeks for a period of 12 months [Note: For patients who have an incomplete response, consideration may be given to adjusting the dose up to 10 mg/kg and/or treating as often as every 4 weeks]. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by an RA Specialist to determine response;
2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
   - confirmation of maintenance of ACR20, OR
   - maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.
3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above."

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

Ankylosing Spondylitis:

"Special authorization coverage may be provided for the reduction in the signs and symptoms 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").
INFLIXIMAB

- Initial coverage may be approved for three doses as follows: An initial dose of 5 mg/kg, followed by additional 5 mg/kg doses at 2 and 6 weeks after the first infusion.
- Patients will be limited to receiving one dose of infliximab per prescription at their pharmacy.
- Patients will be permitted to switch from another biologic agent to infliximab following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to infliximab if previously trialed and deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond three doses, the patient must meet the following criteria:
1) The patient must be assessed by an RA Specialist after the initial three doses to determine response.
2) The RA Specialist must confirm, in writing, that the patient is a ‘responder’ that meets the following criteria:
   - 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/Cetrotizumab/Etanercept/Golimumab/Infliximab for Ankylosing Spondylitis Special Authorization Request Form (ABC 60028).

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

Prior to initiation of infliximab therapy for New Patients:

'New Patients' are patients who have never been treated with infliximab by any health
INFLIXIMAB

Moderately to Severely Active Crohn's Disease:

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

Refractory is defined as one or more of the following:
1) Serious adverse effects or reactions to the treatments specified below; OR
2) Contraindications (as defined in product monographs) to the treatments specified below; OR
3) Previous documented lack of effect at doses and for duration of all treatments specified below:
   a) mesalamine: minimum of 3 grams/day for a minimum of 6 weeks; AND refractory to, or dependent on, glucocorticoids: following at least one tapering dosing schedule of 40 mg/day, tapering by 5 mg each week to 20 mg, then tapering by 2.5 mg each week to zero, or similar;

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

AND

b) Immunosuppressive therapy as follows:
   - Azathioprine: minimum of 2 mg/kg/day for a minimum of 3 months; OR
   - 6-mercaptopurine: minimum of 1 mg/kg/day for a minimum of 3 months; OR
   - Methotrexate: minimum or 15 mg/week for a minimum of 3 months. OR
   - Immunosuppressive therapy discontinued at less than 3 months due to serious adverse effects or reactions.

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

Induction Dosing for New Patients:

- Coverage for Induction Dosing may only be approved for New Patients (those who have never been treated with infliximab by any health care provider).
- 'Induction Dosing' means a maximum of one 5 mg/kg dose of infliximab per New Patient at each 0, 2 and 6 weeks (for a maximum total of three doses).
- New Patients are eligible to receive Induction Dosing only once, after which time the Maintenance Dosing for New Patients and Continued Coverage for Maintenance Dosing criteria will apply.

Maintenance Dosing:

'Maintenance Dosing' means one 5 mg/kg dose of infliximab per patient provided no more often than every 8 weeks for a period of 12 months to:
- New Patients following the completion of Induction Dosing; OR
- Existing Patients, who are patients that are being treated, or have previously been treated, with infliximab.

Maintenance Dosing for New Patients after Completion of Induction Dosing:

- The New Patient must be assessed by a Specialist between weeks 10 and 14 after the initiation of Induction Dosing to determine response by obtaining a Modified Harvey Bradshaw Index score for patients with Moderately to Severely Active Crohn's Disease and/or closure of individual fistulas as evidenced by no or minimal fistula drainage despite gentle finger compression of fistulas that were draining at baseline for Fistulizing Crohn's; AND
- The Specialist must confirm the Modified Harvey Bradshaw Index score shows a decrease from the New Patient's Baseline Score of greater than or equal to 3 points for patients with Moderately to Severely Active Crohn's and/or confirm closure of individual fistulas as evidenced by no or minimal fistula drainage despite gentle finger compression of fistulas that were draining at baseline for Fistulizing Crohn's.

Maintenance Dosing for Existing Patients:

- The patient must be assessed by a Specialist at least 4 to 8 weeks after the day the last dose of 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
INFLIXIMAB
prior to the administration of the next dose to obtain a Modified Harvey Bradshaw Index Score for Moderately to Severely Active Crohn's and/or closure of individual fistulas as evidenced by no or minimal fistula drainage despite gentle finger compression of fistulas that were draining at baseline for Fistulizing Crohn's; AND
- For New Patients: The Specialist must confirm that the patient has maintained a greater than or equal to 3 point decrease from the New Patient's Baseline Score for Moderately to Severely Active Crohn's and/or closure of individual fistulas as evidenced by no or minimal fistula drainage despite gentle finger compression of fistulas that were draining at baseline for Fistulizing Crohn's; OR
- For Existing Patients: The Specialist must confirm that the patient has maintained the Existing Patient's Baseline Score and/or closure of individual fistulas as evidenced by no or minimal fistula drainage despite gentle finger compression of fistulas that were draining at baseline for Fistulizing Crohn's.

(For new and existing patients with Moderately to Severely Active Crohn's Disease with an incomplete response or for new and existing patients with Fistulizing Crohn's who respond then lose their response, the maintenance dose may be adjusted to 10 mg/kg by making an additional special authorization request to Alberta Blue Cross for the increased dose.)"

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

Ulcerative Colitis:

Special authorization coverage may be provided for the reduction in signs and symptoms and induction and maintenance of clinical remission of Ulcerative Colitis in adult patients (18 years of age or older) with active disease (characterized by a partial Mayo score >4 prior to initiation of biologic therapy) and who are refractory or intolerant to:
- mesalamine: minimum of 4 grams/day for a minimum of 4 weeks
AND
- corticosteroids (failure to respond to prednisone 40 mg daily for 2 weeks, or; steroid dependent i.e. failure to taper off steroids without recurrence of disease or disease requiring a second dose of steroids within 12 months of previous dose).

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

Immunosuppressive therapy as follows may also be initiated if in the clinician's judgment a trial is warranted:
1) Azathioprine: minimum of 2 mg/kg/day for a minimum of 2 months; OR
2) 6-mercaptopurine: minimum of 1 mg/kg/day for a minimum of 2 months

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

Initial coverage may be approved for three doses of 5 mg/kg of infliximab at 0, 2 and 6 weeks.

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

For continued coverage beyond three doses, the patient must meet the following criteria:
1) The patient must be assessed by a Specialist between weeks 10 and 14 after the initiation of therapy to determine response.
2) The Specialist must confirm in writing that the patient is a ‘responder’ that meets the following criteria:
   - a decrease in the partial Mayo score of greater than or equal to 2 points

Following this assessment, continued coverage may be approved for dose of 5 mg/kg every 8 weeks for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by a Specialist in Gastroenterology to determine response;
2) The Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
   - a decrease in the partial Mayo score of greater than or equal to 2 points from the score prior to initiation of infliximab therapy

Note: For patients who showed a response to induction therapy then experienced secondary loss of response while on maintenance dosing with 5 mg/kg, the maintenance dose may be adjusted from 5 mg/kg to 10 mg/kg by making an additional special authorization request to Alberta Blue Cross for the increased dose.

All requests (including renewal requests) for infliximab for Ulcerative Colitis must be completed using the Adalimumab/Golimumab/Infliximab/Vedolizumab for Ulcerative Colitis Special Authorization Request Form (ABC 60008).

100 MG / VIAL  INJECTION
00002419475  INFLECTRA  CHH  $  525.0000

The DBL is not a prescribing or a diagnostic tool. Prescribers should refer to drug monographs and utilize professional judgment.
INTERFERON BETA-1A
Relapsing Remitting Multiple Sclerosis (RRMS):

"Special authorization coverage may be provided for the reduction of the frequency and severity of clinical relapses and reduction of the number and volume of active brain lesions, identified on MRI scans, in ambulatory patients with relapsing remitting multiple sclerosis.

Coverage

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

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

Initial Coverage

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

2) The patient must have active disease which is defined as at least two relapses* of MS during the previous two years or in the two years prior to starting an MS disease modifying therapy (DMT).

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

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

Coverage may be approved for up to 12 months. Patients will be limited to receiving a one-month supply of interferon beta-1a per prescription at their pharmacy for the first 12 months of coverage.

Continued Coverage

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

1) The patient must be assessed by a registered MS Neurologist;

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

3) The registered MS Neurologist must provide a current updated EDSS score. The patient must not have an EDSS score of 7.0 or above sustained for one year or more.

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

Continued coverage may be approved for up to 12 months. Patients may receive up to 100 days' supply of interferon beta-1a per prescription at their pharmacy.

Restarting After an Interruption in Therapy Greater Than 12 Months

In order to be eligible for coverage, after an interruption in therapy greater than 12 months, the

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

UNIT OF ISSUE - REFER TO PRICE POLICY

Section 3 • 138

EFFECTIVE APRIL 1, 2018
**INTERFERON BETA-1A**

patient must meet the following criteria:

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

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

<table>
<thead>
<tr>
<th>Product Description</th>
<th>Strength</th>
<th>Form</th>
<th>Code</th>
<th>Hospital Acquisition Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>REBIF (1.5 ML CARTRIDGE)</td>
<td>44 MCG / ML INJECTION CARTRIDGE</td>
<td>SRO</td>
<td>00002318253</td>
<td>$ 255.5463</td>
</tr>
<tr>
<td>REBIF (1.5 ML CARTRIDGE)</td>
<td>88 MCG / ML INJECTION CARTRIDGE</td>
<td>SRO</td>
<td>00002318261</td>
<td>$ 311.0999</td>
</tr>
<tr>
<td>AVONEX PS/PEN (30 MCG/0.5 ML)</td>
<td>6 MIU / SYR INJECTION SYRINGE</td>
<td>BIO</td>
<td>00002269201</td>
<td>$ 408.2101</td>
</tr>
<tr>
<td>REBIF (0.5 ML SYRINGE)</td>
<td>22 MCG / SYR INJECTION SYRINGE</td>
<td>SRO</td>
<td>00002237319</td>
<td>$ 127.7731</td>
</tr>
<tr>
<td>REBIF (0.5 ML SYRINGE)</td>
<td>44 MCG / SYR INJECTION SYRINGE</td>
<td>SRO</td>
<td>00002237320</td>
<td>$ 155.5498</td>
</tr>
</tbody>
</table>
INTERFERON BETA-1B
Relapsing Remitting Multiple Sclerosis (RRMS):

"Special authorization coverage may be provided for the reduction of the frequency and severity of clinical relapses and reduction of the number and volume of active brain lesions, identified on MRI scans, in ambulatory patients with relapsing remitting multiple sclerosis.

Coverage

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

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

Initial Coverage

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

2) The patient must have active disease which is defined as at least two relapses* of MS during the previous two years or in the two years prior to starting an MS disease modifying therapy (DMT).

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

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

Coverage may be approved for up to 12 months. Patients will be limited to receiving a one-month supply of interferon beta-1b per prescription at their pharmacy for the first 12 months of coverage.

Continued Coverage

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

1) The patient must be assessed by a registered MS Neurologist;

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

3) The registered MS Neurologist must provide a current updated EDSS score. The patient must not have an EDSS score of 7.0 or above sustained for one year or more.

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

Continued coverage may be approved for up to 12 months. Patients may receive up to 100 days' supply of interferon beta-1b per prescription at their pharmacy.

Restarting After an Interruption in Therapy Greater Than 12 Months

In order to be eligible for coverage, after an interruption in therapy greater than 12 months, the
INTERFERON BETA-1B

patient must meet the following criteria:

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

All requests (including renewal requests) for interferon beta-1b must be completed using the Dimethyl Fumarate/Glatiramer Acetate/Interferon Beta-1a/Interferon Beta-1b/Teriflunomide Special Authorization Request Form (ABC 60001).

Secondary Progressive Multiple Sclerosis with Relapses (SPMS with relapses):

"Special authorization coverage may be provided for the slowing of progression in disability and the reduction of the frequency of clinical relapses in patients with secondary progressive multiple sclerosis with relapses.

Coverage

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

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

Initial Coverage

1) The registered MS Neurologist must confirm a diagnosis of SPMS with relapses;

2) The patient must have active disease which is defined as two relapses* of MS during the previous two years or in the two years prior to starting an MS disease modifying therapy (DMT).

*A relapse is defined as the appearance of new symptoms or worsening of old symptoms (documented by a physician), lasting at least 72 hours in the absence of fever, not associated with withdrawal from steroids, and preceded by stability for at least one month. Onset of clinical relapses must be separated by a period of at least one month. At least one definite gadolinium-enhancing T1 MRI lesion (not questionable faint enhancement) obtained at least 90 days after initiation of the DMT and at least 90 days before or after a relapse may substitute for one clinical relapse.

3) The patient must be ambulatory to 100m without an aid (The registered MS Neurologist must provide an updated Expanded Disability Status Scale (EDSS) score of less than or equal to 5.5).

Coverage may be approved for up to 12 months. Patients will be limited to receiving a one-month supply of interferon beta-1b per prescription at their pharmacy for the first 12 months of coverage.

Continued Coverage

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

1) The patient must be assessed by a registered MS Neurologist;

2) The registered MS Neurologist must confirm a diagnosis of SPMS with relapses;

3) The registered MS Neurologist must provide a current updated EDSS score. The patient must not have an EDSS score of 7.0 or above sustained for one year or more.

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

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

PRODUCT IS NOT INTERCHANGEABLE

Section 3 - 141

EFFECTIVE APRIL 1, 2018
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

ALBERTA DRUG BENEFIT LIST

SECTION 3.

INTERFERON BETA-1B

accompany the Special Authorization Request Form.

Continued coverage may be approved for up to 12 months. Patients may receive up to 100 days' supply of interferon beta-1b per prescription at their pharmacy.

Restarting After an Interruption in Therapy Greater Than 12 Months

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

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

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

<table>
<thead>
<tr>
<th>9.6 MIU / VIAL</th>
<th>INJECTION</th>
<th>BAI</th>
<th>$ 99.3593</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002169649</td>
<td>BETASERON (0.3 MG)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>00002337819</td>
<td>EXTAVIA (0.3 MG)</td>
<td>NOV</td>
<td>$ 99.3593</td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>125 MCG / ML</th>
<th>INHALATION UNIT DOSE SOLUTION</th>
<th>PMS-IPRATROPIUM</th>
<th>PMS</th>
<th>$ 0.3295</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002231135</td>
<td></td>
<td>PMS-IPRATROPIUM</td>
<td>PMS</td>
<td>$ 0.3295</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>250 MCG / ML</th>
<th>INHALATION UNIT DOSE SOLUTION</th>
<th>PMS-IPRATROPIUM (1ML)</th>
<th>PMS</th>
<th>$ 0.6590</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002231244</td>
<td></td>
<td>PMS-IPRATROPIUM (2ML)</td>
<td>PMS</td>
<td>$ 0.6590</td>
</tr>
<tr>
<td>00002216221</td>
<td>TEVA-IPRATROPIUM STERINEBS</td>
<td>TEV</td>
<td></td>
<td>$ 0.6590</td>
</tr>
</tbody>
</table>

ITRACONAZOLE

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

"For the treatment of oral and/or esophageal candidiasis in immunocompromised patients who are intolerant to fluconazole, or who have failed fluconazole as evidenced by significant clinical deterioration due to the fungal infection during a course of therapy or no resolution after a full course of therapy."*

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

<table>
<thead>
<tr>
<th>10 MG / ML</th>
<th>ORAL SOLUTION</th>
<th>JAI</th>
<th>$ 0.8222</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002231347</td>
<td>SPORANOX</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
IVACAFTOR

Special authorization coverage may be provided for the treatment of cystic fibrosis (CF) in patients age 6 years and older who have a G551D mutation in the Cystic Fibrosis Transmembrane conductance Regulator (CFTR) gene.

For coverage, this drug must be prescribed by a prescriber affiliated with one of the following Alberta Cystic Fibrosis Clinics:
- Cystic Fibrosis Clinic, Adult: Kaye Edmonton Clinic
- Cystic Fibrosis Services - Adult Outpatient: Foothills Medical Centre
- Cystic Fibrosis Clinic, Pediatric: Stollery Children's Hospital
- Pediatric Cystic Fibrosis Clinic: Alberta Children's Hospital

Initial coverage may be approved for up to 150mg every 12 hours for 6 months. Patients will be limited to receiving a one-month supply per prescription at their pharmacy.

Renewal Criteria

The sweat chloride test will be repeated at the next routine review appointment after starting ivacaftor to determine whether sweat chloride levels are reducing and to check compliance with the drug regimen. The sweat chloride level will then be re-checked 6 months after starting treatment to determine whether the full reduction (as detailed below) has been achieved. Thereafter sweat chloride levels will be checked annually.

For continued coverage of up to 150mg every 12 hours beyond the initial 6-month authorization, the patient will be considered to have responded to treatment if either:

a) The patient's sweat chloride test falls below 60mmol/litre; OR
b) The patient's sweat chloride test falls by at least 30%

c) The patient's sweat chloride test falls by at least 30%; OR
d) The patient demonstrates a sustained absolute improvement in FEV1 of at least 5%. In this instance FEV1 will be compared with the baseline pre-treatment level one month and three months after starting treatment.

Following this assessment, continued coverage of up to 150mg every 12 hours may be approved for a period of 12 months. Patients will be limited to receiving a one-month supply per prescription at their pharmacy.

If the expected reduction in sweat chloride does not occur, the patient's CF clinician will first explore any problems in following the recommended dosing schedule for ivacaftor. The patient's sweat chloride will then be retested around one week later and funding discontinued if the patient does not meet the above criteria.

All requests (including renewal requests) for ivacaftor must be completed using the Ivacaftor Special Authorization Request Form (ABC 60004).

<table>
<thead>
<tr>
<th>150 MG</th>
<th>ORAL</th>
<th>TABLET</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002397412</td>
<td>KALYDECO</td>
<td>VER</td>
</tr>
</tbody>
</table>

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

"For adjunctive therapy in patients with refractory partial-onset seizures who meet all of the following criteria:
- Are currently receiving two or more antiepileptic medications, AND
- Have failed or demonstrated intolerance to three other antiepileptic medications, AND
- Therapy must be initiated by a Neurologist.

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

Special authorization may be granted for six months.

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

Each of these products is eligible for auto-renewal.

<table>
<thead>
<tr>
<th>Strength</th>
<th>Formulation</th>
<th>Manufacturer</th>
<th>Unit Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>50 MG</td>
<td>ORAL TABLET</td>
<td>UCB</td>
<td>$2.4093</td>
</tr>
<tr>
<td>100 MG</td>
<td>ORAL TABLET</td>
<td>UCB</td>
<td>$3.4477</td>
</tr>
<tr>
<td>150 MG</td>
<td>ORAL TABLET</td>
<td>UCB</td>
<td>$4.4862</td>
</tr>
<tr>
<td>200 MG</td>
<td>ORAL TABLET</td>
<td>UCB</td>
<td>$5.5247</td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>Strength</th>
<th>Formulation</th>
<th>Manufacturer</th>
<th>Unit Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>60 MG / SYR</td>
<td>INJECTION SYRINGE</td>
<td>ISP</td>
<td>$1195.8951</td>
</tr>
<tr>
<td>90 MG / SYR</td>
<td>INJECTION SYRINGE</td>
<td>ISP</td>
<td>$1595.2501</td>
</tr>
<tr>
<td>120 MG / SYR</td>
<td>INJECTION SYRINGE</td>
<td>ISP</td>
<td>$1996.7757</td>
</tr>
</tbody>
</table>
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.

<table>
<thead>
<tr>
<th>3.75 MG / VIAL INJECTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>00000884502 LUPRON DEPOT ABV $ 357.6000</td>
</tr>
<tr>
<td>5 MG / ML INJECTION</td>
</tr>
<tr>
<td>00000727695 LUPRON ABV $ 67.6464</td>
</tr>
<tr>
<td>7.5 MG / VIAL INJECTION</td>
</tr>
<tr>
<td>00000836273 LUPRON DEPOT ABV $ 387.9700</td>
</tr>
<tr>
<td>11.25 MG / VIAL INJECTION</td>
</tr>
<tr>
<td>00002239834 LUPRON DEPOT ABV $ 1065.4400</td>
</tr>
<tr>
<td>22.5 MG / VIAL INJECTION</td>
</tr>
<tr>
<td>00002230248 LUPRON DEPOT ABV $ 1071.0000</td>
</tr>
</tbody>
</table>

LEVOCARNITINE
"For the treatment of primary carnitine deficiency. Information is required regarding the total plasma carnitine levels."

"For the treatment of patients with an inborn error of metabolism that results in secondary carnitine deficiency. Information is required regarding the patient's diagnosis."

"Special authorization may be granted for 6 months."

In order to comply with the first criteria: Information is required regarding pre-treatment total plasma carnitine levels.

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

<table>
<thead>
<tr>
<th>330 MG ORAL TABLET</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002144328 CARNITOR SGM $ 1.3470</td>
</tr>
<tr>
<td>100 MG / ML ORAL SOLUTION</td>
</tr>
<tr>
<td>00002144336 CARNITOR SGM $ 0.4079</td>
</tr>
<tr>
<td>200 MG / ML INJECTION</td>
</tr>
<tr>
<td>00002144344 CARNITOR SGM $ 12.8977</td>
</tr>
</tbody>
</table>
LINAGLIPTIN
The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

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

As add-on therapy for the treatment of Type 2 diabetes in patients with intolerance to and/or inadequate glycemic control on:
- a sufficient trial (i.e. a minimum of 6 months) of metformin, AND
- a sulfonylurea, AND
- for whom insulin is not an option.

Or, for whom these products are contraindicated.

Special authorization may be granted for 24 months.

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

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

All requests for linagliptin must be completed using the DPP-4/SGLT2 Inhibitors Special Authorization Request Form (ABC 60012).

5 MG ORAL TABLET

| 00002370921 TRAJENTA | BOE | $    2.6035 |
LINAGLIPTIN/ METFORMIN HCL
SPECIAL AUTHORIZATION

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

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

As add-on therapy for the treatment of Type 2 diabetes in patients with intolerance to and/or inadequate glycemic control on:
- a sufficient trial (i.e. a minimum of 6 months) of metformin, AND
- a sulfonylurea, AND
- for whom insulin is not an option.

Or, for whom these products are contraindicated.

Special authorization may be granted for 24 months.

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

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

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

<table>
<thead>
<tr>
<th>2.5 MG * 500 MG ORAL TABLET</th>
<th>BOE</th>
<th>$ 1.3617</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002403250 JENTADUETO</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2.5 MG * 850 MG ORAL TABLET</th>
<th>BOE</th>
<th>$ 1.3617</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002403269 JENTADUETO</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2.5 MG * 1,000 MG ORAL TABLET</th>
<th>BOE</th>
<th>$ 1.3617</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002403277 JENTADUETO</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
LINEZOLID
(Refer to Section 1 - Restricted Benefits of the Alberta Drug Benefit List for coverage of the product when prescribed by a Specialist in Infectious Diseases or a designated prescriber.)

"For the treatment of:

1) Vancomycin-resistant enterococcus infections or

2) Methicillin-resistant Staphylococcus aureus (MRSA)/methicillin-resistant coagulase-negative Staphylococcus infections in patients who are unresponsive to or intolerant of vancomycin or

3) Susceptible organisms in patients severely intolerant or allergic to all other appropriate alternatives (e.g. beta-lactam antibiotics, clindamycin, trimethoprim/sulfamethoxazole and vancomycin) or to facilitate patient discharge from hospital where it otherwise would not be possible.

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

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

In order to comply with the above criteria, information is required regarding the type of infection and organisms involved. Information is also required regarding previous antibiotic therapy that has been utilized and the patient's response to therapy and the first line agents the organism is resistant to or why other first-line therapies cannot be used in this patient. The specialist in Infectious Diseases that recommended this drug is also required.

<table>
<thead>
<tr>
<th>600 MG</th>
<th>ORAL</th>
<th>TABLET</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>00002426552</td>
<td>APO-LINEZOLID</td>
<td>APX</td>
<td>37.0500</td>
<td></td>
</tr>
<tr>
<td>00002422689</td>
<td>SANDOZ LINEZOLID</td>
<td>SDZ</td>
<td>37.0500</td>
<td></td>
</tr>
<tr>
<td>0000243684</td>
<td>ZYVOXAM</td>
<td>PFI</td>
<td>75.7024</td>
<td></td>
</tr>
</tbody>
</table>
MEGESTROL ACETATE
"For the treatment of non-cancer indications (e.g. cachexia in HIV/AIDS patients and cancer patients)."

Special authorization may be granted for 6 months."

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

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

<table>
<thead>
<tr>
<th>40 MG ORAL TABLET</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002195917 MEGESTROL AAP</td>
</tr>
</tbody>
</table>

"For the treatment of non-cancer indications (e.g. cachexia in HIV/AIDS patients and cancer patients)."

Special authorization may be granted for 6 months."

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

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

<table>
<thead>
<tr>
<th>160 MG ORAL TABLET</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002195925 MEGESTROL AAP</td>
</tr>
</tbody>
</table>

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

"1) For second-line therapy of infections due to gram-negative organisms producing inducible beta-lactamases or extended spectrum beta-lactamases where there is resistance to first-line agents or

2) For therapy for infections involving multi-resistant Pseudomonas aeruginosa, where there is documented susceptibility to meropenem or

3) For use in other Health Canada approved indications, in consultation with a specialist in Infectious Diseases."*

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

In order to comply with all of the above criteria, information is required regarding the type of infection and organisms involved. Also, where the criteria restrict coverage of the requested drug to non-first line therapy, information is required regarding previous first-line antibiotic therapy that has been utilized, the patient's response to therapy, and the first line agents the organism is resistant to or why other first-line therapies cannot be used in this patient. Also, where applicable, the specialist in Infectious Diseases that recommended this drug is required.

<table>
<thead>
<tr>
<th>500 MG / VIAL INJECTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>0000221848 MERREM AZC</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>1 G / VIAL INJECTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002436507 MEROPENEM FOR INJECTION USP STM</td>
</tr>
<tr>
<td>00002218496 MERREM AZC</td>
</tr>
</tbody>
</table>
ALBERTA DRUG BENEFIT LIST
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

METHYL PREDNISOLONE 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.

<table>
<thead>
<tr>
<th>2.5 MG / ML * 2.5 MG / ML * 100 MG / ML * 50 MG / ML</th>
<th>TOPICAL LOTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>00000195057</td>
<td>PFI $ 0.2838</td>
</tr>
</tbody>
</table>

MIRABEGRON
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.

Coverage cannot be provided for mirabegron when this medication is intended for use in combination with other overactive bladder agents."

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

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

<table>
<thead>
<tr>
<th>25 MG ORAL EXTENDED-RELEASE TABLET</th>
<th>50 MG ORAL EXTENDED-RELEASE TABLET</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002402874 MYRBETRIQ</td>
<td>00002402882 MYRBETRIQ</td>
</tr>
<tr>
<td>ASP $ 1.4600</td>
<td>ASP $ 1.4600</td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>100 MG ORAL TABLET</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002285398 APO-MODAFINIL</td>
</tr>
<tr>
<td>00002430487 AURO-MODAFINIL</td>
</tr>
<tr>
<td>00002432560 MAR-MODAFINIL</td>
</tr>
<tr>
<td>00002420260 TEVA-MODAFINIL</td>
</tr>
<tr>
<td>00002239665 ALERTEC</td>
</tr>
</tbody>
</table>

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

UNIT OF ISSUE - REFER TO PRICE POLICY
Section 3 - 150
EFFECTIVE APRIL 1, 2018
MONTELUKAST SODIUM
(Refer to 48:10.24 of the Alberta Drug Benefit List for coverage of patients 6 to 18 years of age inclusive).

"For the prophylaxis and chronic treatment of asthma in patients over the age of 18 who meet one of the following criteria:
a) when used as adjunctive therapy in patients who do not respond adequately to high doses of inhaled glucocorticosteroids and long-acting beta 2 agonists. Patients must be unable to use long-acting beta 2 agonists or have demonstrated persistent symptoms while on long-acting beta 2 agonists, or
b) cannot operate inhaler devices."

"For the prophylaxis of exercise-induced bronchoconstriction in patients over the age of 18 where tachyphylaxis exists for long-acting beta 2 agonists."

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

In order to comply with the first criteria, information should indicate either
a) current use of inhaled steroids and contraindications or poor response to long-acting beta 2 agonists (e.g. salmeterol or formoterol) or,
b) the nature of the patient's difficulties with using inhaler devices.

In order to comply with the second criteria, information should include the nature of the patient's response to long-acting beta 2 agonists (e.g. salmeterol or formoterol).

All requests (including renewal requests) for montelukast must be completed using the Montelukast/Zafirlukast Special Authorization Request Form (ABC 60039).

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

<table>
<thead>
<tr>
<th>10 MG (BASE)</th>
<th>ORAL TABLET</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>00002374609</td>
<td>APO-MONTELUKAST</td>
<td>APX</td>
</tr>
<tr>
<td>00002401274</td>
<td>AURO-MONTELUKAST</td>
<td>AUR</td>
</tr>
<tr>
<td>00002391422</td>
<td>JAMP-MONTELUKAST</td>
<td>JPC</td>
</tr>
<tr>
<td>00002399997</td>
<td>MAR-MONTELUKAST</td>
<td>MAR</td>
</tr>
<tr>
<td>00002408643</td>
<td>MINT-MONTELUKAST</td>
<td>MPI</td>
</tr>
<tr>
<td>00002379333</td>
<td>MONTELUKAST</td>
<td>SNS</td>
</tr>
<tr>
<td>00002382474</td>
<td>MONTELUKAST</td>
<td>SIV</td>
</tr>
<tr>
<td>00002379236</td>
<td>MONTELUKAST SODIUM</td>
<td>SIV</td>
</tr>
<tr>
<td>00002373947</td>
<td>PMS-MONTELUKAST FC</td>
<td>PMS</td>
</tr>
<tr>
<td>00002389517</td>
<td>RAN-MONTELUKAST</td>
<td>RAN</td>
</tr>
<tr>
<td>00002328593</td>
<td>SANDOZ MONTELUKAST</td>
<td>SDZ</td>
</tr>
<tr>
<td>00002355523</td>
<td>TEVA-MONTELUKAST</td>
<td>TEV</td>
</tr>
<tr>
<td>00002382117</td>
<td>SINGULAIR</td>
<td>MFC</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>5 MG (BASE)</th>
<th>ORAL CHEWABLE TABLET</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>00002377616</td>
<td>APO-MONTELUKAST</td>
<td>APX</td>
</tr>
<tr>
<td>00002399873</td>
<td>MAR-MONTELUKAST</td>
<td>MAR</td>
</tr>
<tr>
<td>00002408635</td>
<td>MINT-MONTELUKAST</td>
<td>MPI</td>
</tr>
<tr>
<td>00002379325</td>
<td>MONTELUKAST</td>
<td>SNS</td>
</tr>
<tr>
<td>00002382466</td>
<td>MONTELUKAST</td>
<td>SIV</td>
</tr>
<tr>
<td>00002354985</td>
<td>PMS-MONTELUKAST</td>
<td>PMS</td>
</tr>
<tr>
<td>00002330393</td>
<td>SANDOZ MONTELUKAST</td>
<td>SDZ</td>
</tr>
<tr>
<td>00002355515</td>
<td>TEVA-MONTELUKAST</td>
<td>TEV</td>
</tr>
<tr>
<td>00002382116</td>
<td>SINGULAIR</td>
<td>MFC</td>
</tr>
</tbody>
</table>

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

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

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

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

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

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

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

<table>
<thead>
<tr>
<th>Unit of Issue</th>
<th>Manufacturer</th>
<th>Product Name</th>
<th>Unit Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 MG (BASE)</td>
<td>TEVA-NARATRIPTAN</td>
<td>$11.9041</td>
<td></td>
</tr>
<tr>
<td>2.5 MG (BASE)</td>
<td>SANDOZ NARATRIPTAN</td>
<td>$6.1436</td>
<td></td>
</tr>
<tr>
<td>2 MG (BASE)</td>
<td>TEVA-NARATRIPTAN</td>
<td>$6.1436</td>
<td></td>
</tr>
<tr>
<td>2.5 MG (BASE)</td>
<td>TEVA-NARATRIPTAN</td>
<td>$15.5017</td>
<td></td>
</tr>
</tbody>
</table>

The DBL is not a prescribing or a diagnostic tool. Prescribers should refer to drug monographs and utilize professional judgment.
NATALIZUMAB
Relapsing Remitting Multiple Sclerosis (RRMS):

Special authorization coverage may be provided for the treatment of relapsing remitting multiple sclerosis (RRMS) to reduce the frequency of clinical relapses, to decrease the number and volume of active brain lesions identified on magnetic resonance imaging (MRI) scans and to delay the progression of physical disability, in adult patients (18 years of age or older) who are refractory or intolerant to at least ONE of the following:
- interferon beta
- glatiramer acetate
- dimethyl fumarate
- teriflunomide.

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

Definition of 'refractory'
-Development of neutralizing antibodies to interferon beta.

-When the above MS DMTs (interferon beta, glatiramer acetate, dimethyl fumarate, teriflunomide) are taken at the recommended doses for a full and adequate course of treatment, within a consecutive 12-month period while the patient was on the MS DMT, the patient has:

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

2) Experienced at least two relapses* of MS confirmed by the presence of neurologic deficits on examination.
   i. The first qualifying clinical relapse must have begun at least one month after treatment initiation.
   ii. Both qualifying relapses must be classified with a relapse severity of moderate, severe or very severe**.

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

**Relapse severity: with moderate relapses modification or more time is required to carry out activities of daily living; with severe relapses there is inability to carry out some activities of daily living; with very severe relapses activities of daily living must be completed by others.

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

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

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

2) The patient must have active disease which is defined as at least two relapses* of MS during the previous two years or in the two years prior to starting an MS DMT. In most cases this will be satisfied by the 'refractory' to treatment criterion but if a patient failed interferon beta, glatiramer acetate, dimethyl fumarate, or teriflunomide more than one year earlier, ongoing active disease must be confirmed.

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

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

Coverage of natalizumab will not be approved if the patient was deemed to be refractory to natalizumab in the past, i.e., has not met the 'responder' criteria below in 'Continued Coverage'.

Following assessment of the request, coverage may be approved for up to 13 doses of 300 mg (i.e., one dose administered every 4 weeks for a period up to 12 months). Patients will be limited to receiving one dose (4 weeks supply) of natalizumab per prescription at their pharmacy.

Continued Coverage

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

1) The patient must be assessed by a registered MS Neurologist;

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

3) The registered MS Neurologist must provide a current updated EDSS score. The patient must not have an EDSS score of 7.0 or above sustained for one year or more;

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

4) At the first renewal there must be evidence that neutralizing antibodies to natalizumab are absent.

5) The registered MS Neurologist must confirm in writing that the patient is a 'responder' who has experienced no more than one inflammatory event in the last year (defined as either a clinical relapse or gadolinium-enhancing lesion). In instances where a patient has had four or more clinical relapses in the year prior to starting treatment, there must be at least a 50% reduction in relapse rate over the entire treatment period.

Following assessment of the request, continued coverage may be approved for maintenance therapy of 300 mg every 4 weeks for a period up to 12 months. Patients will be limited to receiving one dose of natalizumab per prescription at their pharmacy.

Restarting After an Interruption in Therapy Greater Than 12 Months

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

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

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

20 MG / ML  INJECTION
00002286386  TYSABRI  BIO  $ 172.8052

NINTEDANIB ESILATE
"Initial approval criteria:

Adult patients with a diagnosis of mild to moderate idiopathic pulmonary fibrosis (IPF):
- Diagnosis confirmed by a respirologist and a high-resolution CT scan within the previous 24 months.
- All other causes of restrictive lung disease (e.g. collagen vascular disorder or hypersensitivity pneumonitis) should be excluded.
- Mild to moderate IPF is defined as forced vital capacity (FVC) greater than or equal to 50% of predicted.
- Patient is under the care of a physician with experience in IPF.

Initial approval period: 7 months (allow 4 weeks for repeat pulmonary function tests)

Initial renewal criteria (at 6 months):

Patients must NOT demonstrate progression of disease defined as an absolute decline in percent predicted FVC of greater than or equal to 10% from initiation of therapy until renewal (initial 6 month treatment period). If a patient has experienced progression as defined above, then the results should be validated with a confirmatory pulmonary function test conducted 4 weeks later.

Approval period: 6 months

Second and subsequent renewals (at 12 months and thereafter):

Patients must NOT demonstrate progression of disease defined as an absolute decline in percent predicted FVC of greater than or equal to 10% within any 12 month period. If a patient has experienced progression as defined above, then the results should be validated with a confirmatory pulmonary function test conducted 4 weeks later.

Approval period: 12 months

Exclusion Criteria:
Combination use of pirfenidone and nintedanib will not be funded.

Notes:
Patients who have experienced intolerance or failure to pirfenidone or nintedanib will be considered for the alternate agent provided that the patient continues to meet the above coverage criteria."

All requests for nintedanib must be completed using the Nintedanib/Pirfenidone Special Authorization Request Form (ABC 60051).

100 MG (BASE)  ORAL  CAPSULE
00002443066  OFEV  BOE  $ 27.7507

150 MG (BASE)  ORAL  CAPSULE
00002443074  OFEV  BOE  $ 55.5015
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.

<table>
<thead>
<tr>
<th>Unit of Issue</th>
<th>Product Description</th>
<th>Manufacturer</th>
<th>Unit Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>50 MCG / ML (BASE)</td>
<td>OCTREOTIDE ACETATE OMEGA</td>
<td>OMG</td>
<td>$1.7465</td>
</tr>
<tr>
<td>00002248639</td>
<td>SANDOSTATIN</td>
<td>NOV</td>
<td>$5.1460</td>
</tr>
<tr>
<td>100 MCG / ML (BASE)</td>
<td>OCTREOTIDE ACETATE OMEGA</td>
<td>OMG</td>
<td>$3.2970</td>
</tr>
<tr>
<td>00002248640</td>
<td>SANDOSTATIN</td>
<td>NOV</td>
<td>$9.7135</td>
</tr>
<tr>
<td>200 MCG / ML (BASE)</td>
<td>OCTREOTIDE ACETATE OMEGA</td>
<td>OMG</td>
<td>$6.3420</td>
</tr>
<tr>
<td>00002248642</td>
<td>SANDOSTATIN</td>
<td>NOV</td>
<td>$18.6861</td>
</tr>
<tr>
<td>500 MCG / ML (BASE)</td>
<td>OCTREOTIDE ACETATE OMEGA</td>
<td>OMG</td>
<td>$15.4945</td>
</tr>
<tr>
<td>00002248641</td>
<td>SANDOSTATIN LAR</td>
<td>NOV</td>
<td>$1315.7400</td>
</tr>
<tr>
<td>10 MG / VIAL (BASE)</td>
<td>OCTREOTIDE ACETATE OMEGA</td>
<td>OMG</td>
<td>$1699.8900</td>
</tr>
<tr>
<td>00002239324</td>
<td>SANDOSTATIN LAR</td>
<td>NOV</td>
<td>$2180.9400</td>
</tr>
</tbody>
</table>
| 20 MG / VIAL (BASE) | SANDOSTATIN LAR | NOV | $156 EFFECTIVE APRIL 1, 2018
OMALIZUMAB

Asthma

"Special authorization coverage may be provided for adults and adolescents (12 years of age and above) with severe persistent asthma who are identified as having severe disease despite optimized standard therapy. Optimized standard therapy defined by a full trial of, and documented compliance with:

- high dose inhaled corticosteroid (budesonide 1600 micrograms per day or fluticasone propionate 1000 micrograms per day or equivalent) for at least twelve (12) months; AND,
- long-acting beta-2 agonist therapy (at least salmeterol 50 micrograms daily or 24 micrograms of formoterol fumarate daily) for at least twelve (12) months; AND,
- Therapeutic trial with systemic corticosteroids (at least 10mg per day prednisolone (or equivalent)) for at least 4 weeks in the previous twelve (12) months, unless contraindicated or not tolerated.

For coverage, the drug must be initiated and monitored by a respirologist or clinical immunologist or allergist and meet the following clinical criteria (Initial Coverage or Continued Coverage, as appropriate). Patients will be limited to receiving a one (1) month supply of omalizumab per prescription at their pharmacy.

INITIAL COVERAGE:
Special authorization requests must meet all of the following criteria for initial approval:

1) Confirmation of severe persistent asthma through recent clinical and physiologic review with exclusion of other obstructive airways processes contributing to symptoms of severe asthma (i.e. psychogenic dyspnea; cardiac dyspnea);

2) Must be a non-smoker;

3) Confirmation of IgE mediated allergy to a perennial allergen by clinical history and allergy skin testing;

4) Baseline IgE level greater than/equal to 30 IU/mL and less than/equal to 700 IU/mL;

5) A weight between 20kg and 150kg;

6) An Asthma Control Questionnaire (ACQ-5) of at least 1.25, on at least two occasions over the past 6 months in a stable state;

7) Must provide documentation:
   - Spirometry measurement of FEV1;
   - Asthma Quality of Life Questionnaire (AQLQ - Juniper) score;
   - Number of exacerbations of asthma within the previous twelve (12) month period that resulted in:
     - an emergency room visit or hospitalization;
     - physician visits resulting in oral corticosteroids or an increased dose of oral corticosteroids;
     - chronic use (greater than 50% of the year) of oral corticosteroids;

8) One (1) or more severe exacerbations of asthma requiring a hospital admission or Emergency Room visit within the previous year while on systemic corticosteroids; OR
   - One (1) or more severe exacerbations of asthma requiring a hospital admission or Emergency Room visit requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least three (3) days, or parenteral corticosteroids); OR
   - Three (3) or more severe exacerbations of asthma within the previous year which required a physician visit and resulted in courses (or chronic use greater than 50% of the year), or increased dose of systemic corticosteroids.

Initial coverage may be approved for twenty-eight (28) weeks of up to 375 mg administered every 2 weeks based on the recommended dose and dosage adjustment outlined in the Health The DBL is not a prescribing or a diagnostic tool. Prescribers should refer to drug monographs and utilize professional judgment.
OMALIZUMAB

Canada approved Product Monograph.

CONTINUED MAINTENANCE TREATMENT:
A patient must be assessed for response to initial coverage of omalizumab with a minimum of twenty-four (24) weeks of therapy with omalizumab, and this assessment must be submitted to Alberta Blue Cross no later than four (4) weeks from the date of assessment.

The assessment must be done by a respirologist or clinical immunologist or allergist or such other clinicians as the Minister may designate. If the following criteria are met, special authorization may be granted for a further twelve (12) month period. Continued coverage may be considered if the following criteria are met at the end of each additional twelve (12) month period:

1) Demonstrated that the patient has an Improvement in FEV1 greater than 12% (and for adults a minimum greater than 200 mL) from initiation of therapy; OR
   Unchanged FEV1 with a clinically meaningful Improvement in Asthma Quality of Life Questionnaire score from baseline (greater than/equal to 0.5 mean from baseline); AND
   - a decrease in the ACQ-5 of at least 0.5; OR
   - a ACQ-5 score of less than/equal to 1.

2) Patients must demonstrate at least a 25% reduction in the number of exacerbations, which required oral corticosteroids from the twelve (12) months prior to initiation of omalizumab that required systemic corticosteroids; OR
   For patients that were on chronic (greater than 50% of the year) courses of oral corticosteroids in the twelve (12) months prior to initiation of omalizumab, tapering of oral corticosteroid use by at least 25% from baseline.

3) A reduction in the number of exacerbations that have led to a hospital admission or emergency room visits, compared to the twelve (12) months prior to the commencement of omalizumab.

All requests (including renewal requests) for omalizumab for Asthma must be completed using the Omalizumab for Asthma Special Authorization Request Form (ABC 60020).

Chronic Idiopathic Urticaria

"For the treatment of adults and adolescents (12 years of age and above) with moderate to severe chronic idiopathic urticaria (CIU), defined as having a baseline Urticaria Activity Score over 7 days (UAS7) of greater than or equal to 16, who remain symptomatic (presence of hives and/or associated itching) despite optimum management with available oral therapies. Oral therapies should include a therapeutic trial with H1 antihistamines, unless contraindicated or not tolerated.

For coverage, the drug must be initiated and monitored by a Specialist in Dermatology, Clinical Immunology or Allergy.

Coverage may be approved for a period of 24 weeks at a maximum dose of 300 mg every 4 weeks.
Patients will be limited to receiving a one-month supply of omalizumab per prescription at their pharmacy.
Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

Continued coverage of a further 24-week treatment period may be considered if the patient has experienced:
- complete symptom control (i.e., UAS7 of 0) for less than 12 consecutive weeks; OR
- partial symptom control, with a reduction in baseline UAS7 of greater than or equal to 9.5 points.
OMALIZUMAB
Treatment cessation should be considered for patients who experience complete symptom control for at least 12 consecutive weeks at the end of a 24-week treatment period.

In patients where treatment is discontinued due to temporary symptom control, treatment re-initiation should be considered should CIU symptoms reappear."

All requests (including renewal requests) for omalizumab for Chronic Idiopathic Urticaria must be completed using the Omalizumab for Chronic Idiopathic Urticaria Special Authorization Request Form (ABC 60056).

<table>
<thead>
<tr>
<th>150 MG / VIAL</th>
<th>INJECTION</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>00002260565</td>
<td>XOLAIR</td>
<td>NOV $ 626.5200</td>
</tr>
</tbody>
</table>

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

PRODUCT IS NOT INTERCHANGEABLE

Section 3 - 159

EFFECTIVE APRIL 1, 2018
OMBITASVIR/ PARITAPREVIR/ RITONAVIR/ DASABUVIR SODIUM MONOHYDRATE

**The special authorization criteria outlined below remain part of the Alberta Drug Benefit List to enable patients who initiated therapy with Holkira Pak prior to April 1, 2017 to complete their course of treatment. No new patients will be approved to initiate Holkira Pak therapy after March 31, 2017.**

For treatment naive1 and treatment experienced2 adult patients with chronic hepatitis C genotype 1 infection, with compensated liver disease, (including compensated cirrhosis)3 according to the following criteria:

- Prescribed by a hepatologist, gastroenterologist, infectious disease specialist or a designated prescriber.
- Lab-confirmed hepatitis C genotype 1, subtype 1a or 1b
- Patient has a quantitative HCV RNA value within the last 6 months
- Fibrosis stage F2 or greater (Metavir scale or equivalent)

Duration of therapy reimbursed:

Genotype 1 Patient Population - Duration of therapy:

Genotype 1a:
- Treatment naive or experienced, non-cirrhotic: 12 weeks in combination with RBV
- Treatment naive or experienced (prior relapsers and partial responders), cirrhotic: 12 weeks in combination with RBV
- Treatment experienced (prior null response), cirrhotic: 24 weeks in combination with RBV

OR

Genotype 1b:
- Treatment naive or experienced, non-cirrhotic: 12 weeks
- Treatment naive or experienced, cirrhotic: 12 weeks in combination with RBV

OR

Unknown Genotype 1 Subtype or Mixed Genotype 1:
- Treatment naive or experienced, non-cirrhotic or cirrhotic: 12 weeks in combination with RBV

Exclusion criteria:
- Patients currently being treated with another HCV antiviral agent
- Patients who have received a previous trial of the drug product (Re-treatment requests will NOT be considered)
- Decompensated patients
- No funding for other Genotypes except as noted in the above funding criteria for Genotype 1
- Patients who have received previous NS3/4A protease inhibitor-based regimens (i.e., boceprevir, telaprevir, and simeprevir-based regimens).
- Patients who have received previous sofosbuvir-based regimens (i.e. including ledispasvir/sofosbuvir)

NOTES:
1. Treatment naive is defined as no prior exposure to any interferon, RBV, or other approved or experimental HCV-specific direct-acting antiviral agent at the time of treatment initiation.

2. Treatment experienced patients are defined as those who have previously been treated with PeglNF/RBV and did NOT receive adequate response.

3. Compensated cirrhosis is defined as cirrhosis with a Child Pugh Score =A (5-6).

4. HIV-HCV co-infected patients with Genotype 1 may be considered as per criteria listed above.
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

OMBITASVIR/ PARITAPREVIR/ RITONAVIR/ DASABUVIR SODIUM MONOHYDRATE

All requests (including renewal requests) for ombitasvir/paritaprevir/ritonavir+dasabuvir must be completed using the Ombitasvir/Paritaprevir/Ritonavir+Dasabuvir Special Authorization Request Form (ABC 60026).

<table>
<thead>
<tr>
<th>12.5 MG * 75 MG * 50 MG * 250 MG (BASE)</th>
<th>ORAL TABLET</th>
<th>ABV</th>
<th>$ 166.2500</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002436027</td>
<td>HOLKIRA PAK</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

PALIPERIDONE PALMITATE

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

AND who meet at least one of the following criteria:

- Experiences extra-pyramidal symptoms with either an oral or depot first generation antipsychotic agent that precludes the use of a first generation antipsychotic depot product; OR

- Is refractory to trials of at least two other antipsychotic therapies (Note: one trial must include a first generation antipsychotic agent)

Special Authorization may be granted for six months."

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

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

<table>
<thead>
<tr>
<th>50 MG / SYR (BASE)</th>
<th>INJECTION SYRINGE</th>
<th>JAI</th>
<th>$ 311.4300</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002354217</td>
<td>INVEGA SUSTENNA (0.5 ML SYR)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>75 MG / SYR (BASE)</th>
<th>INJECTION SYRINGE</th>
<th>JAI</th>
<th>$ 467.1800</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002354225</td>
<td>INVEGA SUSTENNA (0.75 ML SYR)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>100 MG / SYR (BASE)</th>
<th>INJECTION SYRINGE</th>
<th>JAI</th>
<th>$ 467.1800</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002354233</td>
<td>INVEGA SUSTENNA (1 ML SYR)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>150 MG / SYR (BASE)</th>
<th>INJECTION SYRINGE</th>
<th>JAI</th>
<th>$ 622.8900</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002354241</td>
<td>INVEGA SUSTENNA (1.5 ML SYR)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

PEGFILGRASTIM

"In patients with non-myeloid malignancies, receiving myelosuppressive anti-neoplastic drugs with curative intent, to decrease the incidence of infection, as manifested by febrile neutropenia."

All requests for pegfilgrastim must be completed using the Filgrastim/Pegfilgrastim/Plerixafor Special Authorization Request Form (ABC 60013).

Please note: Coverage cannot be considered for palliative patients.

<table>
<thead>
<tr>
<th>6 MG / SYR</th>
<th>INJECTION SYRINGE</th>
<th>AMG</th>
<th>$ 2504.9700</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002249790</td>
<td>NEULASTA (0.6 ML SYRINGE)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The DBL is not a prescribing or a diagnostic tool. Prescribers should refer to drug monographs and utilize professional judgment.
**PEGINTERFERON ALFA-2A**

**The Special Authorization Criteria outlined below remain part of the Alberta Drug Benefit List to enable patients who initiated therapy with Pegasys for Chronic Hepatitis C prior to December 31, 2017 to complete their course of treatment. No new patients will be approved to initiate Pegasys therapy for the treatment of Chronic Hepatitis C after January 2, 2018.**

(Refer to 08:18.20 of the Alberta Drug Benefit List for coverage of peginterferon alfa-2a for the treatment of Chronic Hepatitis B.)

Chronic Hepatitis C

"For the treatment of chronic hepatitis C in adult patients with evidence of active liver disease, who qualify for treatment with Pegasys RBV (peginterferon alfa-2a/ribavirin) but who are intolerant to ribavirin.

All Chronic Hepatitis C Patients Prior to Initiation of Therapy:

- To determine treatment duration and prognosis, HCV genotype testing is required for all patients.
- At least three weeks before anticipated start date of therapy, please submit to Alberta Blue Cross a Peginterferon Alfa-2a for Chronic Hepatitis C Special Authorization Request Form (ABC 60045), along with appropriate lab results. In order to meet the requirements of provincial privacy legislation, the patient's signature must be affixed to each completed form.

All Chronic Hepatitis C Patients (with the Exception of Advanced Fibrosis or Cirrhosis Patients):

Prior to initiation of therapy:

- Patients must have a baseline serum sample stored for future viral load testing in the event that the week 12 HCV RNA test is positive.

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

- Patients may receive an initial approval for 14 weeks of coverage.

At 12 weeks of treatment:

- HCV RNA testing is required for all patients at the 12th week of treatment.
- If the HCV RNA test is positive, viral load testing is required on the previously stored baseline serum sample, and the 12 week serum sample, for evaluation of continued coverage.

Renewal approval period (for patients meeting criteria):

- Patients who respond to therapy, as measured by a reduction of viral load by at least 2 logs (100 fold) or HCV RNA not detected at 12 weeks, may be approved for an additional 34 weeks of coverage (total 48 weeks).

All Chronic Hepatitis C Patients with Advanced Fibrosis or Cirrhosis:

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

- Patients with advanced fibrosis or cirrhosis may receive approval for 48 weeks of coverage.

Consideration for therapy in chronic hepatitis C patients who have previously received therapy:

- Consideration for therapy in patients who have previously received therapy may be given for patients who meet at least one of the following criteria:
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

ALBERTA DRUG BENEFIT LIST

PEGINTERFERON ALFA-2A
- 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 presence of active liver disease is required. Information must include the patient's pre-treatment serum HCV RNA (by PCR) status. Information is also required regarding whether liver enzymes (ALT/AST) are elevated, or the results of a liver biopsy, or the results of transient elastography. All requests for peginterferon alfa-2a for Chronic Hepatitis C must be completed using the Peginterferon Alfa-2a for Chronic Hepatitis C Special Authorization Request Form (ABC 60045). In order to meet the requirements of provincial privacy legislation, the patient's signature must be affixed to each completed form.

<table>
<thead>
<tr>
<th>180 MCG / SYR</th>
<th>INJECTION</th>
<th>SYRINGE</th>
<th>HLR</th>
<th>$ 413.0900</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002248077</td>
<td>PEGASYS</td>
<td>(0.5 ML SYRINGE)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
PEGINTERFERON BETA-1A

"Special authorization coverage may be provided for the reduction of the frequency and severity of clinical relapses and reduction of the number and volume of active brain lesions, identified on MRI scans, in ambulatory patients with relapsing remitting multiple sclerosis.

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

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

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

2) The patient must have active disease which is defined as at least two relapses* of MS during the previous two years or in the two years prior to starting an MS disease modifying therapy (DMT).

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

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

Coverage may be approved for up to 12 months. Patients will be limited to receiving a one-month supply of peg-interferon beta-1a per prescription at their pharmacy for the first 12 months of coverage.

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

1) The patient must be assessed by a registered MS Neurologist;

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

3) The registered MS Neurologist must provide a current updated EDSS score. The patient must not have an EDSS score of 7.0 or above sustained for one year or more.

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

Continued coverage may be approved for up to 12 months. Patients may receive up to 100 days' supply of peg-interferon beta-1a per prescription at their pharmacy.

Restarting After an Interruption in Therapy Greater Than 12 Months
In order to be eligible for coverage, after an interruption in therapy greater than 12 months, the patient must meet the following criteria:

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

All requests (including renewal requests) for peg-interferon beta-1a must be completed using
PEGINTERFERON BETA-1A
the Dimethyl Fumarate/Glatiramer Acetate/Interferon Beta-1a/Interferon Beta-1b/Peginterferon Beta-1a/Teriflunomide Special Authorization Request Form (ABC 60001).

| 125 MCG / SYR INJECTION SYRINGE | 00002444399 PLEGRIDY | BIO | $ 856.2600 |

The DBL is not a prescribing or a diagnostic tool. Prescribers should refer to drug monographs and utilize professional judgment.
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

PEGINTERFERON BETA-1A/ PEGINTERFERON BETA-1A

"Special authorization coverage may be provided for the reduction of the frequency and severity of clinical relapses and reduction of the number and volume of active brain lesions, identified on MRI scans, in ambulatory patients with relapsing remitting multiple sclerosis.

Coverage

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

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

Initial Coverage

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

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

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

Coverage may be approved for up to 12 months. Patients will be limited to receiving a one-month supply of peg-interferon beta-1a per prescription at their pharmacy for the first 12 months of coverage.

Continued Coverage

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

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

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

Continued coverage may be approved for up to 12 months. Patients may receive up to 100 days' supply of peg-interferon beta-1a per prescription at their pharmacy.

Restarting After an Interruption in Therapy Greater Than 12 Months

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

1) At least one relapse* per 12 month period; or

The DBL is not a prescribing or a diagnostic tool. Prescribers should refer to drug monographs and utilize professional judgment.
Peginterferon Beta-1a/ Peginterferon Beta-1a

2) At least two relapses* during the previous 24 month period.

All requests (including renewal requests) for peg-interferon beta-1a must be completed using the Dimethyl Fumarate/Glatiramer Acetate/Interferon Beta-1a/Interferon Beta-1b/Peginterferon Beta-1a/Teriflunomide Special Authorization Request Form (ABC 60001).

| 63 MCG / SYR * 94 MCG / SYR INJECTION SYRINGE | 00002444402 PLEGRIDY BIO | $ 856.2600 |

**Perampanel**

"For adjunctive therapy in patients with refractory partial-onset seizures who meet all of the following criteria:
- Are currently receiving two or more antiepileptic medications, AND
- Have failed or demonstrated intolerance to three other antiepileptic medications, AND
- Therapy must be initiated by a Neurologist.

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

Special authorization may be granted for six months.

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

Each of these products is eligible for auto-renewal.

| 2 MG ORAL TABLET | 00002404516 FYCOMPA EIS | $ 9.4500 |
| 4 MG ORAL TABLET | 00002404524 FYCOMPA EIS | $ 9.4500 |
| 6 MG ORAL TABLET | 00002404532 FYCOMPA EIS | $ 9.4500 |
| 8 MG ORAL TABLET | 00002404540 FYCOMPA EIS | $ 9.4500 |
| 10 MG ORAL TABLET | 00002404559 FYCOMPA EIS | $ 9.4500 |
| 12 MG ORAL TABLET | 00002404567 FYCOMPA EIS | $ 9.4500 |
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.

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

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

<table>
<thead>
<tr>
<th>15 MG (BASE) ORAL TABLET</th>
<th>30 MG (BASE) ORAL TABLET</th>
<th>45 MG (BASE) ORAL TABLET</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACCEL-PIOGLITAZONE</td>
<td>ACCEL-PIOGLITAZONE</td>
<td>ACCEL-PIOGLITAZONE</td>
</tr>
<tr>
<td>00002303442  ACP $ 0.3170</td>
<td>00002303450  ACP $ 0.4550</td>
<td>00002303469  ACP $ 0.6900</td>
</tr>
<tr>
<td>VAN-PIOGLITAZONE</td>
<td>VAN-PIOGLITAZONE</td>
<td>VAN-PIOGLITAZONE</td>
</tr>
<tr>
<td>00002434121  VAN $ 0.3330</td>
<td>00002434148  VAN $ 0.4736</td>
<td>00002434156  VAN $ 0.7187</td>
</tr>
<tr>
<td>ACTOS TAK</td>
<td>ACTOS TAK</td>
<td>ACTOS TAK</td>
</tr>
<tr>
<td>00002242572  TAK $ 2.3518</td>
<td>00002242573  TAK $ 3.2949</td>
<td>00002242574  TAK $ 4.9542</td>
</tr>
</tbody>
</table>

The DBL is not a prescribing or a diagnostic tool. Prescribers should refer to drug monographs and utilize professional judgment.
PIPERACILLIN SODIUM/ TAZOBACTAM SODIUM
(Refer to Section 1 - Restricted Benefits of the Alberta Drug Benefit List for coverage of the product when prescribed by a Specialist in Infectious Diseases or Hematology, or a designated prescriber.)

"For the treatment of:

1) Second-line therapy of intra-abdominal sepsis where there are serious adverse events due to first-line therapy or documented failure of first-line therapy (e.g. ampicillin + gentamicin + metronidazole), as defined by clinical deterioration after 72 h of antibiotic therapy or lack of improvement after completion of antibiotic therapy or

2) Second-line therapy of severe polymicrobial skin and skin structure infections (e.g. limb threatening diabetic foot) or

3) Therapy of severe ventilator-associated pneumonia where Pseudomonas and Staphylococcus aureus coverage is needed, or

4) Therapy for infections involving multi-resistant Pseudomonas aeruginosa from pulmonary secretions in cystic fibrosis patients, lung transplant patients or patients with bronchiectasis, where there is documented susceptibility to piperacillin/tazobactam sodium, or

5) For use in other Health Canada approved indications, in consultation with a specialist in Infectious Diseases."

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

In order to comply with all of the above criteria, information is required regarding the type of infection and organisms involved. Also, where the criteria restrict coverage of the requested drug to non-first line therapy, information is required regarding previous first-line antibiotic therapy that has been utilized, the patient's response to therapy, and the first line agents the organism is resistant to or why other first-line therapies cannot be used in this patient. Also, where applicable, the specialist in Infectious Diseases that recommended this drug is required.

<table>
<thead>
<tr>
<th>2 G / VIAL (BASE)</th>
<th>250 MG / VIAL (BASE)</th>
<th>INJECTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002308444</td>
<td>PIPERACILLIN AND TAZOBACTAM</td>
<td>APX</td>
</tr>
<tr>
<td>00002362619</td>
<td>PIPERACILLIN AND TAZOBACTAM</td>
<td>STM</td>
</tr>
<tr>
<td>00002401312</td>
<td>PIPERACILLIN AND TAZOBACTAM</td>
<td>TGT</td>
</tr>
<tr>
<td>00002299623</td>
<td>PIPERACILLIN SODIUM/TAZOBACTAM SODIUM</td>
<td>SDZ</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>3 G / VIAL (BASE)</th>
<th>375 MG / VIAL (BASE)</th>
<th>INJECTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002308452</td>
<td>PIPERACILLIN AND TAZOBACTAM</td>
<td>APX</td>
</tr>
<tr>
<td>00002362627</td>
<td>PIPERACILLIN AND TAZOBACTAM</td>
<td>STM</td>
</tr>
<tr>
<td>00002401320</td>
<td>PIPERACILLIN AND TAZOBACTAM</td>
<td>TGT</td>
</tr>
<tr>
<td>00002299631</td>
<td>PIPERACILLIN SODIUM/TAZOBACTAM SODIUM</td>
<td>SDZ</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>4 G / VIAL (BASE)</th>
<th>500 MG / VIAL (BASE)</th>
<th>INJECTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002308460</td>
<td>PIPERACILLIN AND TAZOBACTAM</td>
<td>APX</td>
</tr>
<tr>
<td>00002362635</td>
<td>PIPERACILLIN AND TAZOBACTAM</td>
<td>STM</td>
</tr>
<tr>
<td>00002401339</td>
<td>PIPERACILLIN AND TAZOBACTAM</td>
<td>TGT</td>
</tr>
<tr>
<td>00002299658</td>
<td>PIPERACILLIN SODIUM/TAZOBACTAM SODIUM</td>
<td>SDZ</td>
</tr>
</tbody>
</table>

| 00002370174         | PIPERACILLIN/TAZOBACTAM | TEV | $8.3458 |
PIRFENIDONE

"Initial approval criteria:

Adult patients with a diagnosis of mild to moderate idiopathic pulmonary fibrosis (IPF):
- Diagnosis confirmed by a respirologist and a high-resolution CT scan within the previous 24 months.
- All other causes of restrictive lung disease (e.g. collagen vascular disorder or hypersensitivity pneumonitis) should be excluded.
- Mild to moderate IPF is defined as forced vital capacity (FVC) greater than or equal to 50% of predicted.
- Patient is under the care of a physician with experience in IPF.

Initial approval period: 7 months (allow 4 weeks for repeat pulmonary function tests)

Initial renewal criteria (at 6 months):

Patients must NOT demonstrate progression of disease defined as an absolute decline in percent predicted FVC of greater than or equal to 10% from initiation of therapy until renewal (initial 6 month treatment period). If a patient has experienced progression as defined above, then the results should be validated with a confirmatory pulmonary function test conducted 4 weeks later.

Approval period: 6 months

Second and subsequent renewals (at 12 months and thereafter):

Patients must NOT demonstrate progression of disease defined as an absolute decline in percent predicted FVC of greater than or equal to 10% within any 12 month period. If a patient has experienced progression as defined above, then the results should be validated with a confirmatory pulmonary function test conducted 4 weeks later.

Approval period: 12 months

Exclusion Criteria:

Combination use of pirfenidone and nintedanib will not be funded.

Notes:

Patients who have experienced intolerance or failure to pirfenidone or nintedanib will be considered for the alternate agent provided that the patient continues to meet the above coverage criteria."

All requests for pirfenidone must be completed using the Nintedanib/Pirfenidone Special Authorization Request Form (ABC 60051).

| 267 MG ORAL CAPSULE | 00002393751 | ESBRIET HLR | $ 13.4105 |
PLERIXAFOR
"For the treatment of patients with Non-Hodgkin’s lymphoma (NHL) or multiple myeloma (MM) undergoing Peripheral Blood Progenitor Cell (PBPC) collection and therapy, in combination with filgrastim, when prescribed by a designated prescriber."

Coverage may be approved for a maximum of 4 doses (0.24mg/kg given daily) for a single mobilization attempt.

All requests for Plerixafor must be completed using the Filgrastim/Pegfilgrastim/Plerixafor Special Authorization Request Form (ABC 60013).

Special authorization may be granted for 12 months.

<table>
<thead>
<tr>
<th>20 MG / ML INJECTION</th>
<th>MOZOBIL</th>
<th>SAV</th>
<th>$ 6295.833</th>
</tr>
</thead>
</table>

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

FIRST-LINE DRUG PRODUCT(S): BROMOCRIPTINE

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

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

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

<table>
<thead>
<tr>
<th>0.075 MG ORAL TABLET</th>
<th>NORPROLAC</th>
<th>FEI</th>
<th>$ 1.1485</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002223767</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>0.15 MG ORAL TABLET</th>
<th>NORPROLAC</th>
<th>FEI</th>
<th>$ 1.7177</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002223775</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
RALOXIFENE HCL

Osteoporosis:

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

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

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

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

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

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

<table>
<thead>
<tr>
<th>60 MG ORAL TABLET</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>00002358840 ACT RALOXIFENE</td>
<td>APH $ 0.4583</td>
</tr>
<tr>
<td>00002279215 APO-RALOXIFENE</td>
<td>APX $ 0.4583</td>
</tr>
<tr>
<td>00002239028 EVISTA</td>
<td>LIL $ 1.9198</td>
</tr>
</tbody>
</table>
RIBAVIRIN

200 MG ORAL TABLET

- **MODERIBA**
  - **00002436396**
    - **ABV**
    - $0.0100

Genotype 1 Chronic Hepatitis C:

"For the treatment of chronic hepatitis C genotype 1, in accordance with the ombitasvir/paritaprevir/ritonavir/dasabuvir criteria, in patients who qualify for treatment with the drug product."

(Refer to Section 3 of the Alberta Drug Benefit List for coverage of ribavirin in combination with ombitasvir/paritaprevir/ritonavir/dasabuvir for the treatment of Genotype 1 Chronic Hepatitis C.)

- **IBAVYR**
  - **00002439212**
    - **PPH**
    - $7.6915

For use within an Alberta Drug Benefit List (ADBL) funded combination therapy regimen for the treatment of chronic hepatitis C according to specific eligibility criteria corresponding to the regimen in which it is being administered. Use of ribavirin outside of an ADBL hepatitis C funded regimen will not be reimbursed.

(Refer to Section 3 of the Alberta Drug Benefit List for specific eligibility criteria corresponding to the regimen in which ribavirin is being administered for the treatment of Chronic Hepatitis C.)

400 MG ORAL TABLET

- **MODERIBA**
  - **00002436418**
    - **ABV**
    - $0.0100

Genotype 1 Chronic Hepatitis C:

"For the treatment of chronic hepatitis C genotype 1, in accordance with the ombitasvir/paritaprevir/ritonavir/dasabuvir criteria, in patients who qualify for treatment with the drug product."

(Refer to Section 3 of the Alberta Drug Benefit List for coverage of ribavirin in combination with ombitasvir/paritaprevir/ritonavir/dasabuvir for the treatment of Genotype 1 Chronic Hepatitis C.)

- **IBAVYR**
  - **00002425890**
    - **PPH**
    - $15.3831

For use within an Alberta Drug Benefit List (ADBL) funded combination therapy regimen for the treatment of chronic hepatitis C according to specific eligibility criteria corresponding to the regimen in which it is being administered. Use of ribavirin outside of an ADBL hepatitis C funded regimen will not be reimbursed.

(Refer to Section 3 of the Alberta Drug Benefit List for specific eligibility criteria corresponding to the regimen in which ribavirin is being administered for the treatment of Chronic Hepatitis C.)

600 MG ORAL TABLET

- **MODERIBA**
  - **00002436426**
    - **ABV**
    - $0.0100

Genotype 1 Chronic Hepatitis C:

"For the treatment of chronic hepatitis C genotype 1, in accordance with the ombitasvir/paritaprevir/ritonavir/dasabuvir criteria, in patients who qualify for treatment with the drug product."

(Refer to Section 3 of the Alberta Drug Benefit List for coverage of ribavirin in combination with ombitasvir/paritaprevir/ritonavir/dasabuvir for the treatment of Genotype 1 Chronic Hepatitis C.)

- **IBAVYR**
  - **00002425904**
    - **PPH**
    - $23.0746

For use within an Alberta Drug Benefit List (ADBL) funded combination therapy regimen for the treatment of chronic hepatitis C according to specific eligibility criteria corresponding to the regimen in which it is being administered. Use of ribavirin outside of an ADBL hepatitis C funded regimen will not be reimbursed.

(Refer to Section 3 of the Alberta Drug Benefit List for specific eligibility criteria corresponding to the regimen in which ribavirin is being administered for the treatment of Chronic Hepatitis C.)
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

ALBERTA DRUG BENEFIT LIST

RIBAVIRIN

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

"For susceptible infections when prescribed in consultation with a Specialist in Infectious Diseases.

Special authorization may be granted for 6 months."

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

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

<table>
<thead>
<tr>
<th>150 MG ORAL CAPSULE</th>
<th>MYCOBUTIN</th>
<th>PFI</th>
<th>$</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002063786</td>
<td></td>
<td></td>
<td>5.3993</td>
</tr>
</tbody>
</table>

RIFAXIMIN

"For reducing the risk of recurrent Hepatic Encephalopathy (HE) (i.e. 2 or more episodes), in patients with a diagnosis of cirrhosis of the liver or presence of portal hypertension. Patients must have tried lactulose and been unable to achieve adequate control of HE recurrence with lactulose alone. Rifaximin must be used in combination with a maximal tolerated dose of lactulose.

Special authorization may be granted for 6 months."

This product is eligible for auto-renewal.

<table>
<thead>
<tr>
<th>550 MG ORAL TABLET</th>
<th>ZAXINE</th>
<th>SLX</th>
<th>$</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002410702</td>
<td></td>
<td></td>
<td>7.8400</td>
</tr>
</tbody>
</table>

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."

<table>
<thead>
<tr>
<th>50 MG ORAL TABLET</th>
<th></th>
<th></th>
<th>$</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002352583</td>
<td>APO-RILUZOLE</td>
<td>APX</td>
<td>3.4361</td>
</tr>
<tr>
<td>00002390299</td>
<td>MYLAN-RILUZOLE</td>
<td>MYP</td>
<td>3.4361</td>
</tr>
<tr>
<td>00002242763</td>
<td>RILUTEK</td>
<td>SAV</td>
<td>10.0542</td>
</tr>
</tbody>
</table>

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

UNIT OF ISSUE - REFER TO PRICE POLICY

Section 3 - 174

EFFECTIVE APRIL 1, 2018
RISEDRONATE SODIUM

Osteoporosis:

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

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

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

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

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

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

Paget's Disease:

"For the treatment of Paget's disease. Special Authorization for this criteria may be granted to a maximum of 2 months. Renewal requests may be considered following an observation period of at least 2 months."

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

<table>
<thead>
<tr>
<th>5 MG ORAL TABLET</th>
<th>TEVA-RISEDRONATE</th>
<th>TEV</th>
<th>$ 1.6729</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002298376</td>
<td>TEVA-RISEDRONATE</td>
<td>TEV</td>
<td>$ 1.6729</td>
</tr>
<tr>
<td>00002242518</td>
<td>ACTONEL</td>
<td>ASC</td>
<td>$ 2.0068</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>30 MG ORAL TABLET</th>
<th>TEVA-RISEDRONATE</th>
<th>TEV</th>
<th>$ 10.8388</th>
</tr>
</thead>
</table>
**RISPERIDONE**

"For the management of the manifestations of schizophrenia and related psychotic disorders in patients who demonstrate a pattern of significant non-compliance that compromises therapeutic success and who possess clinical evidence of previous successful treatment with risperidone or paliperidone therapy;

AND who meet at least one of the following criteria:

- Experiences extra-pyramidal symptoms with either an oral or depot first generation antipsychotic agent that precludes the use of a first generation antipsychotic depot product; OR
- Is refractory to trials of at least two other antipsychotic therapies (Note: one trial must include a first generation antipsychotic agent)

Special Authorization may be granted for six months."

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

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

<table>
<thead>
<tr>
<th>25 MG / VIAL INJECTION</th>
<th>RISPERDAL CONSTA</th>
<th>JAI</th>
<th>$</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002255707</td>
<td>RISPERDAL CONSTA</td>
<td>JAI</td>
<td>$ 169.5900</td>
</tr>
<tr>
<td>37.5 MG / VIAL INJECTION</td>
<td>RISPERDAL CONSTA</td>
<td>JAI</td>
<td>$ 254.3600</td>
</tr>
<tr>
<td>00002255723</td>
<td>RISPERDAL CONSTA</td>
<td>JAI</td>
<td>$ 339.1500</td>
</tr>
<tr>
<td>50 MG / VIAL INJECTION</td>
<td>RISPERDAL CONSTA</td>
<td>JAI</td>
<td>$</td>
</tr>
<tr>
<td>00002255758</td>
<td>RISPERDAL CONSTA</td>
<td>JAI</td>
<td>$</td>
</tr>
</tbody>
</table>
RITUXIMAB

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
- 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.

Subsequent courses of therapy cannot be considered prior to 24 weeks elapsing from the initial dose of the previous course of therapy.""

All requests (including renewal requests) for rituximab for Rheumatoid Arthritis must be completed using the Rituximab for Rheumatoid Arthritis Special Authorization Request Form (ABC 60046).

Granulomatosis with Polyangiitis (GPA) or Microscopic Polyangiitis (MPA):
RITUXIMAB
"For use in combination with glucocorticoids for the induction of remission of severely active granulomatosis with polyangiitis (GPA, also known as Wegener’s granulomatosis) or microscopic polyangiitis (MPA) in adult patients who have:
- Severe active disease that is life- or organ-threatening. The organ(s) and how the organ(s) is (are) threatened must be specified; AND
- A positive serum assay for either proteinase 3-ANCA (anti-neutrophil cytoplasmic antibody) or myeloperoxidase-ANCA. A copy of the lab report must be provided; AND
- Cyclophosphamide cannot be used for ONE of the following reasons:
  a) The patient has failed a minimum of six intravenous pulses of cyclophosphamide; OR
  b) The patient has failed three months of oral cyclophosphamide therapy; OR
  c) The patient has a severe intolerance or an allergy to cyclophosphamide; OR
  d) Cyclophosphamide is contraindicated; OR
  e) The patient has received a cumulative lifetime dose of at least 25 grams of cyclophosphamide.

- Coverage may be approved for a maximum of 375 mg per square metre of body surface area weekly for 4 weeks.
- Patients will be limited to receiving two doses of rituximab per prescription at their pharmacy.
- For relapse following a remission, coverage may be provided for patients who experience a flare of severe active disease that is life- or organ-threatening; or, who experience worsening symptoms in 2 or more organs even if not life-threatening. Note: For relapse following a rituximab-induced remission, additional coverage may be approved no sooner than 6 months after previous rituximab treatment."

All requests (including renewal requests) for Rituxan for Granulomatosis with Polyangiitis (GPA) or Microscopic Polyangiitis (MPA) must be completed using the Rituxan for Granulomatosis with Polyangiitis/Microscopic Polyangiitis Special Authorization Request Form (ABC 60018).

10 MG / ML INJECTION

| 00002241927 RITUXAN HLR | $ 47.4712 |

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

UNIT OF ISSUE - REFER TO PRICE POLICY  Section 3  
EFFECTIVE APRIL 1, 2018
RIVAROXABAN
NON-VALVULAR ATRIAL FIBRILLATION

SPECIAL AUTHORIZATION (step therapy approval process)

FIRST-LINE DRUG PRODUCT(S): WARFARIN

Coverage

Members of Alberta Government Sponsored Drug Plans who are at-risk with non-valvular atrial fibrillation (AF) who require the Drug Products for the prevention of stroke and systemic embolism AND in whom one of the following is also present:

- Inadequate Anticoagulation following a Reasonable Trial on Warfarin; OR
- Anticoagulation with warfarin is contraindicated or not possible due to inability to regularly monitor via International Normalized Ratio (INR) testing (i.e. no access to INR testing services at a laboratory, clinic, pharmacy, and at home).

At-risk patients with atrial fibrillation are defined as those with a CHADS2 score of greater than or equal to 1. Although the ROCKET-AF trial included patients with higher CHADS2 scores (greater than or equal to 2), other landmark studies with the other newer oral anticoagulants demonstrated a therapeutic benefit in patients with a CHADS2 score of 1. Coverage may be considered for an antiplatelet regimen or oral anticoagulation for patients with a CHADS2 score of 1.

Exclusion from Coverage:
- Patients with impaired renal function (creatinine clearance or estimated glomerular filtration rate <30 mL/min) OR
- Greater than or equal to 75 years of age and without Documented Stable Renal Function; OR
- hemodynamically significant rheumatic valvular heart disease, especially mitral stenosis; OR
- prosthetic heart valves.

Definitions:
- Documented Stable Renal Function is defined as creatinine clearance or estimated glomerular filtration rate that is maintained for at least 3 months (i.e. 30-49 mL/min for 15 mg once daily dosing or greater than or equal to 50 mL/Min for 20 mg once daily dosing).
- Inadequate anticoagulation is defined as INR testing results that are outside the desired INR range for at least 35% of the tests during the monitoring period (i.e. adequate anticoagulation is defined as INR test results that are within the desired INR range for at least 65% of the tests during the monitoring period).
- Reasonable Trial on Warfarin is defined as at least 2 months of therapy.

OTHER CRITERIA:
- Since renal impairment can increase bleeding risk, renal function should be regularly monitored. Other factors that increase bleeding risk should also be assessed and monitored (see Drug Product monograph).
- Patients starting the Drug Product should have ready access to appropriate medical services to manage a major bleeding event.
- There is currently no data to support that the Drug Product provides adequate anticoagulation in patients with rheumatic valvular disease or those with prosthetic heart valves, so Drug Product is not recommended in these populations.

Special Authorization may be granted for 24 months.

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.
RIVAROXABAN
UP - First-line therapy ineffective
UQ - First-line therapy not tolerated

VENOUS THROMBOEMBOLIC EVENTS
SPECIAL AUTHORIZATION

COVERAGE:

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

OTHER CRITERIA:

The recommended dose of rivaroxaban for patients initiating DVT or PE treatment is 15 mg twice daily for 3 weeks, followed by 20 mg once daily.

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

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

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

15 MG ORAL TABLET
00002378604 XARELTO BAI $ 2.8700
RIVAROXABAN
NON-VALVULAR ATRIAL FIBRILLATION

SPECIAL AUTHORIZATION (step therapy approval process)

FIRST-LINE DRUG PRODUCT(S): WARFARIN

Coverage

Members of Alberta Government Sponsored Drug Plans who are at-risk with non-valvular atrial fibrillation (AF) who require the Drug Products for the prevention of stroke and systemic embolism AND in whom one of the following is also present:

- Inadequate Anticoagulation following a Reasonable Trial on Warfarin; OR
- Anticoagulation with warfarin is contraindicated or not possible due to inability to regularly monitor via International Normalized Ratio (INR) testing (i.e. no access to INR testing services at a laboratory, clinic, pharmacy, and at home).

At-risk patients with atrial fibrillation are defined as those with a CHADS2 score of greater than or equal to 1. Although the ROCKET-AF trial included patients with higher CHADS2 scores (greater than or equal to 2), other landmark studies with the other newer oral anticoagulants demonstrated a therapeutic benefit in patients with a CHADS2 score of 1. Coverage may be considered for an antiplatelet regimen or oral anticoagulation for patients with a CHADS2 score of 1.

Exclusion from Coverage:
- Patients with impaired renal function (creatinine clearance or estimated glomerular filtration rate <30 mL/min) OR
- Greater than or equal to 75 years of age and without Documented Stable Renal Function; OR
- hemodynamically significant rheumatic valvular heart disease, especially mitral stenosis; OR
- prosthetic heart valves.

Definitions:
- Documented Stable Renal Function is defined as creatinine clearance or estimated glomerular filtration rate that is maintained for at least 3 months (i.e. 30-49 mL/min for 15 mg once daily dosing or greater than or equal to 50 mL/Min for 20 mg once daily dosing).
- Inadequate anticoagulation is defined as INR testing results that are outside the desired INR range for at least 35% of the tests during the monitoring period (i.e. adequate anticoagulation is defined as INR test results that are within the desired INR range for at least 65% of the tests during the monitoring period).
- Reasonable Trial on Warfarin is defined as at least 2 months of therapy.

OTHER CRITERIA:
- Since renal impairment can increase bleeding risk, renal function should be regularly monitored. Other factors that increase bleeding risk should also be assessed and monitored (see Drug Product monograph).
- Patients starting the Drug Product should have ready access to appropriate medical services to manage a major bleeding event.
- There is currently no data to support that the Drug Product provides adequate anticoagulation in patients with rheumatic valvular disease or those with prosthetic heart valves, so Drug Product is not recommended in these populations.

Special Authorization may be granted for 24 months.

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

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

### VENOUS THROMBOEMBOLIC EVENTS

### SPECIAL AUTHORIZATION

### COVERAGE:

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

### OTHER CRITERIA:

The recommended dose of rivaroxaban for patients initiating DVT or PE treatment is 15 mg twice daily for 3 weeks, followed by 20 mg once daily.

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

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

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

<table>
<thead>
<tr>
<th>20 MG ORAL TABLET</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002378612 XARELTO BAI $ 2.8700</td>
</tr>
</tbody>
</table>

### RIVASTIGMINE HYDROGEN TARTRATE

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

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

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

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

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

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

<table>
<thead>
<tr>
<th>1.5 MG (BASE) ORAL CAPSULE</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002336715 APO-RIVASTIGMINE APX $ 0.6514</td>
</tr>
<tr>
<td>00002401614 MED-RIVASTIGMINE GMP $ 0.6514</td>
</tr>
<tr>
<td>00002324563 SANDOZ RIVASTIGMINE SDZ $ 0.6514</td>
</tr>
<tr>
<td>00002242115 EXELON NOV $ 2.7080</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>3 MG (BASE) ORAL CAPSULE</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002336723 APO-RIVASTIGMINE APX $ 0.6514</td>
</tr>
<tr>
<td>00002401622 MED-RIVASTIGMINE GMP $ 0.6514</td>
</tr>
<tr>
<td>00002324571 SANDOZ RIVASTIGMINE SDZ $ 0.6514</td>
</tr>
<tr>
<td>00002242116 EXELON NOV $ 2.7080</td>
</tr>
</tbody>
</table>

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

4.5 MG (BASE) ORAL CAPSULE
- 00002336731 APO-RIVASTIGMINE APX $ 0.6514
- 00002401630 MED-RIVASTIGMINE GMP $ 0.6514
- 00002324598 SANDOZ RIVASTIGMINE SDZ $ 0.6514
- 00002242117 EXELON NOV $ 2.7080

6 MG (BASE) ORAL CAPSULE
- 00002336758 APO-RIVASTIGMINE APX $ 0.6514
- 00002401649 MED-RIVASTIGMINE GMP $ 0.6514
- 00002324601 SANDOZ RIVASTIGMINE SDZ $ 0.6514
- 00002242118 EXELON NOV $ 2.7080

2 MG / ML (BASE) ORAL SOLUTION
- 00002245240 EXELON NOV $ 1.4236

RIZATRIPTAN BENZOATE

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

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

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

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

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

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

5 MG (BASE) ORAL TABLET
- 00002393468 APO-RIZATRIPTAN APX $ 3.7050
- 00002380455 JAMP-RIZATRIPTAN JPC $ 3.7050
- 00002429233 JAMP-RIZATRIPTAN IR JPC $ 3.7050
- 00002428512 VAN-RIZATRIPTAN VAN $ 3.7050

10 MG (BASE) ORAL TABLET
- 00002381702 ACT RIZATRIPTAN APH $ 3.7050
- 00002393476 APO-RIZATRIPTAN APX $ 3.7050
- 00002441444 AURO-RIZATRIPTAN AUR $ 3.7050
- 00002380463 JAMP-RIZATRIPTAN JPC $ 3.7050
- 00002429241 JAMP-RIZATRIPTAN IR JPC $ 3.7050
- 00002379678 MAR-RIZATRIPTAN MAR $ 3.7050
- 00002428520 VAN-RIZATRIPTAN VAN $ 3.7050
- 00002240521 MAXALT MFC $ 16.5163

5 MG (BASE) ORAL DISINTEGRATING TABLET
- 00002374730 ACT RIZATRIPTAN ODT APH $ 3.7050
- 00002393484 APO-RIZATRIPTAN RPD APX $ 3.7050
- 00002379198 MYLAN-RIZATRIPTAN ODT MYP $ 3.7050
- 00002436604 NAT-RIZATRIPTAN ODT NTP $ 3.7050
- 00002393360 PMS-RIZATRIPTAN RDT PMS $ 3.7050
- 00002442906 RIZATRIPTAN ODT SNS $ 3.7050
- 00002446111 RIZATRIPTAN ODT SIV $ 3.7050
- 00002351870 SANDOZ RIZATRIPTAN ODT SDZ $ 3.7050
- 00002396661 TEVA-RIZATRIPTAN ODT TEV $ 3.7050
- 00002240518 MAXALT RPD MFC $ 16.5163

The DBL is not a prescribing or a diagnostic tool. Prescribers should refer to drug monographs and utilize professional judgment.
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

ALBERTA DRUG BENEFIT LIST

RIZATRIPTAN BENZOATE

10 MG (BASE) ORAL DISINTEGRATING TABLET

<table>
<thead>
<tr>
<th>Item Number</th>
<th>Product Name</th>
<th>Manufacturer</th>
<th>Unit Quantity</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002374749</td>
<td>ACT RIZATRIPTAN ODT</td>
<td>APH</td>
<td>$</td>
<td>3.7050</td>
</tr>
<tr>
<td>00002393492</td>
<td>APO-RIZATRIPTAN RPD</td>
<td>APX</td>
<td>$</td>
<td>3.7050</td>
</tr>
<tr>
<td>00002379201</td>
<td>MYLAN-RIZATRIPTAN ODT</td>
<td>MYP</td>
<td>$</td>
<td>3.7050</td>
</tr>
<tr>
<td>00002436612</td>
<td>NAT-RIZATRIPTAN ODT</td>
<td>NTP</td>
<td>$</td>
<td>3.7050</td>
</tr>
<tr>
<td>00002393379</td>
<td>PMS-RIZATRIPTAN RDT</td>
<td>PMS</td>
<td>$</td>
<td>3.7050</td>
</tr>
<tr>
<td>00002442914</td>
<td>RIZATRIPTAN ODT</td>
<td>SNS</td>
<td>$</td>
<td>3.7050</td>
</tr>
<tr>
<td>00002446138</td>
<td>RIZATRIPTAN ODT</td>
<td>SIV</td>
<td>$</td>
<td>3.7050</td>
</tr>
<tr>
<td>00002351889</td>
<td>SANDOZ RIZATRIPTAN ODT</td>
<td>SDZ</td>
<td>$</td>
<td>3.7050</td>
</tr>
<tr>
<td>00002396688</td>
<td>TEVA-RIZATRIPTAN ODT</td>
<td>TEV</td>
<td>$</td>
<td>3.7050</td>
</tr>
<tr>
<td>00002448505</td>
<td>VAN-RIZATRIPTAN ODT</td>
<td>VAN</td>
<td>$</td>
<td>3.7050</td>
</tr>
<tr>
<td>00002403366</td>
<td>MAXALT RPD</td>
<td>MFC</td>
<td>$</td>
<td>16.5163</td>
</tr>
</tbody>
</table>

ROSIGLITAZONE MALEATE

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

FIRST-LINE DRUG PRODUCT(S): METFORMIN

"For the treatment of Type 2 diabetes in patients who have an inadequate response to a sufficient trial (i.e. a minimum of 6 months) of metformin or who are intolerant to metformin (e.g. dermatologic reactions) or for whom the product is contraindicated."

Special authorization may be granted for 24 months.

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

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

2 MG (BASE) ORAL TABLET

<table>
<thead>
<tr>
<th>Item Number</th>
<th>Product Name</th>
<th>Manufacturer</th>
<th>Unit Quantity</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002403366</td>
<td>APO-ROSIGLITAZONE</td>
<td>APX</td>
<td>$</td>
<td>1.0316</td>
</tr>
<tr>
<td>00002241112</td>
<td>AVANDIA</td>
<td>GSK</td>
<td>$</td>
<td>1.4260</td>
</tr>
</tbody>
</table>

4 MG (BASE) ORAL TABLET

<table>
<thead>
<tr>
<th>Item Number</th>
<th>Product Name</th>
<th>Manufacturer</th>
<th>Unit Quantity</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002403374</td>
<td>APO-ROSIGLITAZONE</td>
<td>APX</td>
<td>$</td>
<td>1.6188</td>
</tr>
<tr>
<td>00002241113</td>
<td>AVANDIA</td>
<td>GSK</td>
<td>$</td>
<td>2.2400</td>
</tr>
</tbody>
</table>

8 MG (BASE) ORAL TABLET

<table>
<thead>
<tr>
<th>Item Number</th>
<th>Product Name</th>
<th>Manufacturer</th>
<th>Unit Quantity</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002403382</td>
<td>APO-ROSIGLITAZONE</td>
<td>APX</td>
<td>$</td>
<td>2.3150</td>
</tr>
<tr>
<td>00002241114</td>
<td>AVANDIA</td>
<td>GSK</td>
<td>$</td>
<td>3.1813</td>
</tr>
</tbody>
</table>

ROTIGOTINE

"For adjunctive therapy to levodopa for the treatment of patients with advanced stage Parkinson's disease (APD).

Special authorization may be granted for six months."

This product is eligible for auto-renewal.

2 MG/24HR TRANSDERMAL PATCH

<table>
<thead>
<tr>
<th>Item Number</th>
<th>Product Name</th>
<th>Manufacturer</th>
<th>Unit Quantity</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002403900</td>
<td>NEUPRO</td>
<td>UCB</td>
<td>$</td>
<td>3.5400</td>
</tr>
</tbody>
</table>

4 MG/24HR TRANSDERMAL PATCH

<table>
<thead>
<tr>
<th>Item Number</th>
<th>Product Name</th>
<th>Manufacturer</th>
<th>Unit Quantity</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002403927</td>
<td>NEUPRO</td>
<td>UCB</td>
<td>$</td>
<td>6.5000</td>
</tr>
</tbody>
</table>

6 MG/24HR TRANSDERMAL PATCH

<table>
<thead>
<tr>
<th>Item Number</th>
<th>Product Name</th>
<th>Manufacturer</th>
<th>Unit Quantity</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002403935</td>
<td>NEUPRO</td>
<td>UCB</td>
<td>$</td>
<td>7.2700</td>
</tr>
</tbody>
</table>

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

UNIT OF ISSUE - REFER TO PRICE POLICY

Section 3 • 184

EFFECTIVE APRIL 1, 2018
## CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

### ROTIGOTINE
8 MG/24HR TRANSDERMAL PATCH

<table>
<thead>
<tr>
<th>Product Code</th>
<th>Manufacturer</th>
<th>Quantity</th>
<th>Unit</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002403943</td>
<td>UCB</td>
<td></td>
<td></td>
<td>7.2700</td>
</tr>
</tbody>
</table>

### RUFINAMIDE
"For the treatment of seizures associated with Lennox-Gastaut Syndrome (LGS) in patients who meet the following criteria:
- are currently taking two or more anti-epileptic drugs (AEDs) without optimal seizure control;
AND
- have failed or demonstrated intolerance to adequate trials of both lamotrigine AND topiramate;
AND
- therapy must be initiated by a Neurologist.

Special authorization may be granted for six months."

This product is eligible for auto-renewal.

<table>
<thead>
<tr>
<th>Quantity</th>
<th>Unit</th>
<th>Manufacturer</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>100 MG</td>
<td>ORAL TABLET</td>
<td>EIS</td>
<td>0.7182</td>
</tr>
<tr>
<td>200 MG</td>
<td>ORAL TABLET</td>
<td>EIS</td>
<td>1.4364</td>
</tr>
<tr>
<td>400 MG</td>
<td>ORAL TABLET</td>
<td>EIS</td>
<td>3.1298</td>
</tr>
</tbody>
</table>

### SACUBITRIL/ VALSARTAN
"For the treatment of heart failure (HF) in patients with the following criteria:

1) reduced left ventricular ejection fraction (LVEF) (< 40%)
And
2) New York Heart Association (NYHA) class II or III HF symptoms despite at least FOUR weeks of treatment with:
- a stable dose of an angiotensin-converting enzyme inhibitor (ACEI) or an angiotensin II receptor antagonist (ARB)
- in combination with a beta-blocker and other recommended therapies, including an aldosterone antagonist (if tolerable)
And
3) who have Plasma B-type natriuretic peptide (BNP) >= 150 pg/mL or N-terminal prohormone B-type natriuretic peptide (NT-proBNP) >= 600 pg/mL; or
- if the patient has been hospitalized for HF within the past 12 months and has plasma BNP >= 100 pg/mL or NT-proBNP >= 400 pg/mL levels

For coverage, this drug must be initiated by a Specialist in Cardiology or Internal Medicine, and the initial request must be completed by the Specialist.

Special authorization may be granted for six months."

This product is eligible for auto-renewal.

All requests (including renewal requests) for sacubitril+valsartan must be completed using the Eplerenone/Sacubitril+Valsartan Special Authorization Request Form (ABC 60050).
The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

ASTHMA

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

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

"Special authorization may be granted for 24 months."

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

UP - First-line therapy ineffective

All requests for salmeterol xinafoate + fluticasone propionate must be completed using the Long-Acting Fixed-Dose Combination Products for Asthma/COPD Special Authorization Request Form (ABC 60025).

| 25 MCG / DOSE (BASE) * 125 MCG / DOSE INHALATION METERED DOSE AEROSOL | 00002245126  | ADVAIR 125  | GSK | $ 0.8425 |

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

ASTHMA

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

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

"Special authorization may be granted for 24 months."

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

UP - First-line therapy ineffective

All requests for salmeterol xinafoate + fluticasone propionate must be completed using the Long-Acting Fixed-Dose Combination Products for Asthma/COPD Special Authorization Request Form (ABC 60025).

| 25 MCG / DOSE (BASE) * 250 MCG / DOSE INHALATION METERED DOSE AEROSOL | 00002245127  | ADVAIR 250  | GSK | $ 1.1960 |
**SALMETEROL XINAFOATE/ FLUTICASONE PROPIONATE**

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

**ASTHMA**

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

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

"Special authorization may be granted for 24 months."

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

**UP - First-line therapy ineffective**

All requests for salmeterol xinafoate + fluticasone propionate must be completed using the Long-Acting Fixed-Dose Combination Products for Asthma/COPD Special Authorization Request Form (ABC 60025).

**50 MCG / DOSE (BASE)  * 100 MCG / DOSE  INHALATION  METERED INHALATION POWDER**

<table>
<thead>
<tr>
<th>Code</th>
<th>Quantity</th>
<th>Description</th>
<th>Manufacturer</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002240835</td>
<td>ADVAIR 100 DISKUS</td>
<td>GSK</td>
<td>$1.4075</td>
<td></td>
</tr>
</tbody>
</table>
SALMETEROL XINAFOATE/ FLUTICASONE PROPIONATE
The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

ASTHMA
FIRST-LINE DRUG PRODUCT(S): INHALED CORTICOSTEROID (ICS)
"For the treatment of asthma in patients uncontrolled on inhaled steroid therapy."

CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD)
FIRST-LINE DRUG PRODUCT(S): LONG-ACTING BRONCHODILATOR (I.E., LONG-ACTING BETA-2 AGONIST [LABA] OR LONG-ACTING MUSCARINIC ANTAGONIST [LAMA])
"For the long-term maintenance treatment of airflow obstruction in patients with moderate to severe (i.e., FEV1 < 80% predicted) chronic obstructive pulmonary disease (COPD), who have an inadequate response to a long-acting bronchodilator (long-acting beta-2 agonist [LABA] or long-acting muscarinic antagonist [LAMA])."
"For the long-term maintenance treatment of airflow obstruction in patients with severe (i.e., FEV1 < 50% predicted) chronic obstructive pulmonary disease (COPD)."
"Special authorization may be granted for 24 months."

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

UP - First-line therapy ineffective

All requests for salmeterol xinafoate + fluticasone propionate must be completed using the Long-Acting Fixed-Dose Combination Products for Asthma/COPD Special Authorization Request Form (ABC 60025).

50 MCG / DOSE (BASE) * 250 MCG / DOSE INHALATION METERED INHALATION POWDER
00002240836 ADVAIR 250 DISKUS GSK $ 1.6850

The DBL is not a prescribing or a diagnostic tool. Prescribers should refer to drug monographs and utilize professional judgment.
UNIT OF ISSUE - REFER TO PRICE POLICY Section 3 188 EFFECTIVE APRIL 1, 2018
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

ALBERTA DRUG BENEFIT LIST

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

ASTHMA

FIRST-LINE DRUG PRODUCT(S): INHALED CORTICOSTEROID (ICS)
"For the treatment of asthma in patients uncontrolled on inhaled steroid therapy."

CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD)

FIRST-LINE DRUG PRODUCT(S): LONG-ACTING BRONCHODILATOR (I.E., LONG-ACTING BETA-2 AGONIST [LABA] OR LONG-ACTING MUSCARINIC ANTAGONIST [LAMA])
"For the long-term maintenance treatment of airflow obstruction in patients with moderate to severe (i.e., FEV1 < 80% predicted) chronic obstructive pulmonary disease (COPD), who have an inadequate response to a long-acting bronchodilator (long-acting beta-2 agonist [LABA] or long-acting muscarinic antagonist [LAMA])."

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

"Special authorization may be granted for 24 months."

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

UP - First-line therapy ineffective

All requests for salmeterol xinafoate + fluticasone propionate must be completed using the Long-Acting Fixed-Dose Combination Products for Asthma/COPD Special Authorization Request Form (ABC 60025).

<table>
<thead>
<tr>
<th>50 MCG / DOSE (BASE)</th>
<th>500 MCG / DOSE INHALATION METERED INHALATION POWDER</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002240837</td>
<td>ADVAIR 500 DISKUS</td>
</tr>
<tr>
<td></td>
<td>GSK</td>
</tr>
<tr>
<td></td>
<td>$ 2.3920</td>
</tr>
</tbody>
</table>

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

PRODUCT IS NOT INTERCHANGEABLE

Section 3 -189

EFFECTIVE APRIL 1, 2018
SAXAGLIPTIN HCL

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

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

As add-on therapy for the treatment of Type 2 diabetes in patients with intolerance to and/or inadequate glycemic control on:
- a sufficient trial (i.e. a minimum of 6 months) of metformin, AND
- a sulfonylurea, AND
- for whom insulin is not an option.

Or, for whom these products are contraindicated.

Special authorization may be granted for 24 months.

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

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

All requests for saxagliptin must be completed using the DPP-4/SGLT2 Inhibitors Special Authorization Request Form (ABC 60012).

<table>
<thead>
<tr>
<th></th>
<th>ORAL TABLET</th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>2.5 MG</td>
<td>ONGLYZA</td>
<td>AZC</td>
<td>$ 2.4410</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5 MG (BASE)</td>
<td>ONGLYZA</td>
<td>AZC</td>
<td>$ 2.9260</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

UNIT OF ISSUE - REFER TO PRICE POLICY

Section 3 - 190

EFFECTIVE APRIL 1, 2018
SAXAGLIPTIN HCL/ METFORMIN HCL
The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

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

As add-on therapy for the treatment of Type 2 diabetes in patients with intolerance to and/or inadequate glycemic control on:
- a sufficient trial (i.e. a minimum of 6 months) of metformin, AND
- a sulfonylurea, AND
- for whom insulin is not an option.

Or, for whom these products are contraindicated.

Special authorization may be granted for 24 months.

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

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

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

<table>
<thead>
<tr>
<th>Strength</th>
<th>Product Code</th>
<th>Product Name</th>
<th>Code</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.5 MG (BASE) * 500 MG ORAL TABLET</td>
<td>00002389169</td>
<td>KOMBOGLYZE</td>
<td>AZC</td>
<td>$1.2700</td>
</tr>
<tr>
<td>2.5 MG (BASE) * 850 MG ORAL TABLET</td>
<td>00002389177</td>
<td>KOMBOGLYZE</td>
<td>AZC</td>
<td>$1.2700</td>
</tr>
<tr>
<td>2.5 MG (BASE) * 1,000 MG ORAL TABLET</td>
<td>00002389185</td>
<td>KOMBOGLYZE</td>
<td>AZC</td>
<td>$1.2700</td>
</tr>
</tbody>
</table>
SEUKINUMAB

"Special authorization coverage may be provided for the reduction in signs and symptoms of severe, debilitating plaque psoriasis in patients who:
- Have a total PASI of 10 or more and a DLQI of more than 10, OR
- Who have significant involvement of the face, palms of the hands, soles of the feet or genital region; AND
- Who are refractory or intolerant to:
  - Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory, OR
  - Cyclosporine (6 weeks treatment); AND
  - Phototherapy (unless restricted by geographic location)

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

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

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

Initial coverage may be approved for 12 weeks as follows:
- Four weekly doses of 300 mg of secukinumab at weeks 0, 1, 2 and 3, followed by monthly dosing at weeks 4, 8 and 12.
- Patients will be limited to receiving two doses of secukinumab per prescription at their pharmacy during the initial 3 weeks, then one dose per prescription thereafter. Each 300 mg dose is provided as two subcutaneous injections of 150 mg.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of the initial coverage period.
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond seven doses, the patient must meet all of the following criteria:
1) The patient must be assessed by a Dermatology Specialist after the initial seven doses to determine response.
2) The Dermatology Specialist must confirm, in writing, that the patient is a 'responder' that meets the following criteria:
   - Greater than or equal to 75% reduction in PASI score, OR
   - Greater than or equal to 50% reduction in PASI score AND improvement of greater than or equal to 5 points in the DLQI.

Following this assessment, continued coverage may be considered for one 300 mg dose of secukinumab every month for a period of 12 months. Ongoing coverage may be considered if the patient is re-assessed by a Dermatology Specialist every 12 months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above."

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

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

150 MG / ML INJECTION SYRINGE
00002438070 COSENTYX NOV $ 822.5000

SILTUXIMAB
"For the treatment of multicentric Castleman's disease (MCD) in patients who are human immunodeficiency virus (HIV) negative and human herpes virus-8 (HHV-8) negative and who have an ECOG performance status of less than or equal to 2.

Initial coverage may be approved for a period of 6 months.

Continued coverage may be approved for a period of 12 months for patients who continue to meet initial coverage criteria.

Coverage for siltuximab will be provided for one intravenous dose of 11 mg/kg every 3 weeks. Patients will be limited to receiving one dose of siltuximab per prescription at their pharmacy."

100 MG / VIAL INJECTION
00002435128 SYLVANT JAI $ 697.7000
400 MG / VIAL INJECTION
00002435136 SYLVANT JAI $ 2790.8000
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

ALBERTA DRUG BENEFIT LIST

SIMEPREVIR SODIUM

"For use in combination with peginterferon alfa/ribavirin, for the treatment of genotype 1 chronic hepatitis C (CHC), in adults (18 years of age or older) with compensated liver disease and detectable levels of hepatitis C virus (HCV) RNA in the last six months, and a fibrosis stage of F2, F3, or F4 and; who have either not received previous therapy with peginterferon alfa/ribavirin or have failed previous therapy with peginterferon alfa/ribavirin following prior null response, partial response or relapse.

Failure of previous therapy with peginterferon alfa/ribavirin is defined as:
- prior null response: less than 2 logs (100 fold) reduction in HCV RNA after 12 weeks of treatment.
- partial response: a decrease in HCV RNA viral load greater than or equal to 2 logs (100 fold) by treatment week 12, but failure to achieve a sustained virologic response (SVR).
- relapse: undetectable HCV RNA at end of previous therapy with subsequently detectable HCV RNA.

Coverage cannot be considered for:
- treatment of CHC other than genotype 1;
- treatment as monotherapy;
- patients with the NS3 Q80K polymorphism;
- patients with decompensated liver disease (Child Pugh score greater than 6), including a history of the presence of clinical ascites, bleeding varices or hepatic encephalopathy;
- patients who previously received a prior full therapeutic course with an HCV NS3/4A protease inhibitor (e.g., retreatment);
- extensions beyond the stated duration (as stated below).

The following dosing guidelines must be met:
1) Simeprevir must be given in combination with peginterferon alfa/ribavirin.
2) Simeprevir dosing is 150 mg once a day as response guided therapy described below.
3) Futility (stopping) rule applies to all patients: Discontinue all therapy if HCV RNA is greater than or equal to 25 IU/mL at week 4, or if HCV RNA is detectable at week 12 or 24.

Initial approval period (for patients meeting criteria):
- All patients may receive an initial approval for 6 weeks of treatment coverage (6 weeks of simeprevir in combination with peginterferon alfa/ribavirin).

Renewal approval periods (for patients meeting criteria):

At treatment week 4:
- HCV RNA testing is required for all patients at the 4th week of treatment to determine the length of treatment.
- If HCV RNA is greater than or equal to 25 IU/mL, triple therapy should be discontinued.
- If HCV RNA is undetectable or detectable but less than 25 IU/mL, an additional 6 weeks of simeprevir may be approved (for a total of 12 weeks) plus an additional 8 weeks of peginterferon alfa/ribavirin.

At treatment week 12:
- HCV RNA testing is required for all patients at the 12th week of treatment. If HCV RNA is detectable at week 12, discontinue peginterferon alfa/ribavirin (treatment with simeprevir is complete at week 12).

For treatment naive patients and prior relapers:
- If HCV RNA was undetectable at week 4, and is undetectable at week 12, peginterferon alfa/ribavirin may be approved for an additional 10 weeks (total treatment is 24 weeks).
- If HCV RNA was detectable but less than 25 IU/mL at week 4, and is undetectable at week 12, peginterferon alfa/ribavirin may be approved for an additional 12 weeks.

For prior partial and null responders:
- If HCV RNA was undetectable or detectable but less than 25 IU/mL at week 4, and is undetectable at week 12, peginterferon alfa/ribavirin maybe approved for an additional 12 weeks.

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

UNIT OF ISSUE - REFER TO PRICE POLICY
Section 3 - 194
EFFECTIVE APRIL 1, 2018
SIMPREVIR SODIUM

At treatment week 24:
- HCV RNA testing is required for all patients at the 24th week of treatment. If HCV RNA is detectable at week 24, discontinue peginterferon alfa/ribavirin treatment.

For treatment naive patients and prior relapsers:
- If HCV RNA was detectable but less than 25 IU/mL at week 4, and undetectable at weeks 12 and 24, peginterferon alfa/ribavirin may be approved for an additional 22 weeks (total 48 weeks).

For prior partial and null responders:
- If HCV RNA was undetectable or detectable but less than 25 IU/mL at week 4, and undetectable at weeks 12 and 24, peginterferon alfa/ribavirin may be approved for an additional 22 weeks (total 48 weeks).

Confirmation of the diagnosis of genotype 1 chronic hepatitis C and presence of active liver disease is required. Information must include confirmation of compensated liver disease and the patient's pre-treatment serum HCV RNA (by PCR) status. Information is also required regarding the patient's fibrosis stage and confirmation of whether the patient has Q80K polymorphism for those patients with subtype 1a HCV. All requests for simprevir + peginterferon alfa/ribavirin must be completed using the Simeprevir + Peginterferon Alfa/Ribavirin Special Authorization Request Form (ABC 60016). In order to meet the requirements of provincial privacy legislation, the patient's signature must be affixed to each completed form.

150 MG (BASE) ORAL CAPSULE
00002416441 GALEXOS JAI $ 434.5500
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.

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

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

All requests for sitagliptin must be completed using the DPP-4/SGLT2 Inhibitors Special Authorization Request Form (ABC 60012).

<table>
<thead>
<tr>
<th>25 MG ORAL TABLET</th>
<th>JANUVIA</th>
<th>MFC</th>
<th>$ 3.0694</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002388839</td>
<td>JANUVIA</td>
<td>MFC</td>
<td>$ 3.0694</td>
</tr>
<tr>
<td>50 MG ORAL TABLET</td>
<td>JANUVIA</td>
<td>MFC</td>
<td>$ 3.0694</td>
</tr>
<tr>
<td>00002388847</td>
<td>JANUVIA</td>
<td>MFC</td>
<td>$ 3.0694</td>
</tr>
<tr>
<td>100 MG ORAL TABLET</td>
<td>JANUVIA</td>
<td>MFC</td>
<td>$ 3.0694</td>
</tr>
<tr>
<td>00002303922</td>
<td>JANUVIA</td>
<td>MFC</td>
<td>$ 3.0694</td>
</tr>
</tbody>
</table>

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

UNIT OF ISSUE - REFER TO PRICE POLICY

Section 3 - 196

EFFECTIVE APRIL 1, 2018
SITAGLIPTIN PHOSPHATE MONOHYDRATE/ METFORMIN HCL

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

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

As add-on therapy for the treatment of Type 2 diabetes in patients with intolerance to and/or inadequate glycemic control on:
- a sufficient trial (i.e. a minimum of 6 months) of metformin, AND
- a sulfonylurea, AND
- for whom insulin is not an option.

Or, for whom these products are contraindicated.

Special authorization may be granted for 24 months.

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

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

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

<table>
<thead>
<tr>
<th>50 MG (BASE) * 500 MG ORAL TABLET</th>
<th>MFC</th>
<th>$1.6633</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002333856 JANUMET</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>50 MG (BASE) * 850 MG ORAL TABLET</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002333864 JANUMET</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>50 MG (BASE) * 1,000 MG ORAL TABLET</th>
<th>MFC</th>
<th>$1.6633</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002333872 JANUMET</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>50 MG (BASE) * 500 MG EXTENDED-RELEASE TABLET</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002416786 JANUMET XR</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>50 MG (BASE) * 1,000 MG EXTENDED-RELEASE TABLET</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002416794 JANUMET XR</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>100 MG (BASE) * 1,000 MG EXTENDED-RELEASE TABLET</th>
<th>MFC</th>
<th>$3.3039</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002416808 JANUMET XR</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

PRODUCT IS NOT INTERCHANGEABLE

Section 3 - 197
EFFECTIVE APRIL 1, 2018
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

ALBERTA DRUG BENEFIT LIST

SOFOBUVIR

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

I) Prescribed by a hepatologist, gastroenterologist, infectious disease specialist, or a designated prescriber;
AND
II) Laboratory confirmed hepatitis C genotype 2 or genotype 3;
AND
III) Laboratory confirmed quantitative HCV RNA value within the last 6 months;
AND
IV) Fibrosis (2) stage of F0 or greater (Metavir scale or equivalent).

Duration of therapy reimbursed:
- Treatment-naive or treatment experienced genotype 2, without cirrhosis or with compensated cirrhosis (3): 12 weeks in combination with ribavirin
- Treatment-naive or treatment-experienced genotype 3, without cirrhosis: 12 weeks in combination with daclatasvir
- Treatment-naive or treatment-experienced genotype 3, without cirrhosis or with compensated cirrhosis (3), or with decompensated cirrhosis (4), or post-liver transplant: 24 weeks in combination with ribavirin

Exclusion criteria:
- Patients currently being treated with another HCV antiviral agent
- Retreatment for failure or re-infection in patients who have received an adequate prior course of an HCV direct-acting antiviral drug regimen may be considered on an exceptional case-by-case basis
- Combination therapy with elbasvir/grazoprevir will not be considered

Notes:
1. Treatment-experienced are those who failed prior therapy with an interferon-based regimen, including regimens containing an HCV protease inhibitor.
2. Fibrosis score test is optional. Acceptable methods include liver biopsy, transient elastography (FibroScan), fibrotest and serum biomarker panels (such as AST-to-Platelet Ratio Index or Fibrosis-4 score) either alone or in combination.
3. Compensated cirrhosis is defined as cirrhosis with Child-Turcotte-Pugh A (i.e. score 5 to 6) and d
4. Decompensated cirrhosis is defined as cirrhosis with Child-Turcotte-Pugh B or C (i.e. score 7 or above).
5. Health care professionals are advised to refer to the product monograph and prescribing guidelines for appropriate use of the drug product, including use in special populations.

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

400 MG  ORAL  TABLET
00002418355  SOVALDI  GIL  $ 654.7619

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

UNIT OF ISSUE - REFER TO PRICE POLICY  Section 3 -198  EFFECTIVE APRIL 1, 2018
SOFOBUVIR/ LEDIPASVIR
For treatment-naive or treatment-experienced (1) adult patients with chronic hepatitis C (CHC) infection who meet all of the following criteria:
I) Prescribed by a hepatologist, gastroenterologist, infectious disease specialist, or a designated prescriber;
AND
II) Laboratory confirmed hepatitis C genotype 1;
AND
III) Laboratory confirmed quantitative HCV RNA value within the last 6 months;
AND
IV) Fibrosis (2) stage of F0 or greater (Metavir scale or equivalent).

Duration of therapy reimbursed:
- Treatment-naive, without cirrhosis, recent quantitative hepatitis C viral load less than 6 M IU/mL: 8 weeks or 12 weeks (3)
- Treatment-naive, without cirrhosis, viral load greater than or equal to 6 M IU/mL: 12 weeks
- Treatment-naive, with compensated cirrhosis (4): 12 weeks
- Treatment-experienced, without cirrhosis: 12 weeks
- Treatment-naive or treatment-experienced with decompensated cirrhosis (5): 12 weeks in combination with ribavirin
- Treatment-naive or treatment-experienced liver transplant recipients, without cirrhosis or with compensated cirrhosis (4): 12 weeks in combination with ribavirin
- Treatment-experienced, with compensated cirrhosis (4): 24 weeks

Exclusion criteria:
- Patients currently being treated with another HCV antiviral agent
- Retreatment for failure or re-infection in patients who have received an adequate prior course of an HCV direct-acting antiviral drug regimen may be considered on an exceptional case-by-case basis

Notes:
1. Treatment-experienced are those who failed prior therapy with an interferon-based regimen, including regimens containing an HCV protease inhibitor.
2. Fibrosis score test is optional. Acceptable methods include liver biopsy, transient elastography (FibroScan), fibrotest and serum biomarker panels (such as AST-to-Platelet Ratio Index or Fibrosis-4 score) either alone or in combination.
3. For this population cohort, evidence has shown that the SVR rates with 8-week and 12-week treatment regimens are similar. Treatment regimens of up to 12 weeks are recognized by Health Canada as an approved treatment option. 12-week treatment regimens may be considered for patients with advanced liver fibrosis.
4. Compensated cirrhosis is defined as cirrhosis with Child-Turcotte-Pugh A (i.e. score 5 to 6).
5. Decompensated cirrhosis is defined as cirrhosis with Child-Turcotte-Pugh B or C (i.e. score 7 or above).
6. Health care professionals are advised to refer to the product monograph and prescribing guidelines for appropriate use of the drug product, including use in special populations.

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

400 MG * 90 MG ORAL TABLET
00002432226 HARVONI GIL $ 797.6190

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

For treatment-naive or treatment-experienced (1) adult patients with chronic hepatitis C (CHC) infection who meet all of the following criteria:
I) Prescribed by a hepatologist, gastroenterologist, infectious disease specialist, or a designated prescriber;
AND
II) Laboratory confirmed hepatitis C genotype 1, 2, 3, 4, 5, 6 or mixed genotypes;
AND
III) Laboratory confirmed quantitative HCV RNA value within the last 6 months;
AND
IV) Fibrosis (2) stage of F0 or greater (Metavir scale or equivalent).

Duration of therapy reimbursed:
- Treatment-naive or treatment-experienced, without cirrhosis or with compensated cirrhosis (3): 12 weeks
- Treatment-naive or treatment-experienced, with decompensated cirrhosis (4): 12 weeks in combination with ribavirin

Exclusion criteria:
- Patients currently being treated with another HCV antiviral agent
- Retreatment for failure or re-infection in patients who have received an adequate prior course of an HCV direct-acting antiviral drug regimen may be considered on an exceptional case-by-case basis

Notes:
1. Treatment-experienced is defined as those who failed prior therapy with an interferon-based regimen, including regimens containing an HCV protease inhibitor.
2. Fibrosis score test is optional. Acceptable methods include liver biopsy, transient elastography (FibroScan), fibrotest and serum biomarker panels (such as AST-to-Platelet Ratio Index or Fibrosis-4 score) either alone or in combination.
3. Compensated cirrhosis is defined as cirrhosis with Child-Turcotte-Pugh A (i.e. score 5 to 6).
4. Decompensated cirrhosis is defined as cirrhosis with Child-Turcotte-Pugh B or C (i.e. score 7 or above).
5. Health care professionals are advised to refer to the product monograph and prescribing guidelines for appropriate use of the drug product, including use in special populations.

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

400 MG * 100 MG ORAL TABLET

| 00002456370 | EPCLUSA | GIL | $ 714.2857 |
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."

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

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

<table>
<thead>
<tr>
<th>5 MG ORAL TABLET</th>
<th>AURO-SOLIFENACIN</th>
<th>AUR</th>
<th>$ 0.3041</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002446375</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>00002424339</td>
<td>JAMP-SOLIFENACIN</td>
<td>JPC</td>
<td>$ 0.3041</td>
</tr>
<tr>
<td>00002428911</td>
<td>MED-SOLIFENACIN</td>
<td>GMP</td>
<td>$ 0.3041</td>
</tr>
<tr>
<td>00002443171</td>
<td>MINT-SOLIFENACIN</td>
<td>MPI</td>
<td>$ 0.3041</td>
</tr>
<tr>
<td>00002417723</td>
<td>PMS-SOLIFENACIN</td>
<td>PMS</td>
<td>$ 0.3041</td>
</tr>
<tr>
<td>00002437988</td>
<td>RAN-SOLIFENACIN</td>
<td>RAN</td>
<td>$ 0.3041</td>
</tr>
<tr>
<td>00002399032</td>
<td>SANDOZ SOLIFENACIN</td>
<td>SDZ</td>
<td>$ 0.3041</td>
</tr>
<tr>
<td>00002458241</td>
<td>SOLIFENACIN</td>
<td>SNS</td>
<td>$ 0.3041</td>
</tr>
<tr>
<td>00002448335</td>
<td>SOLIFENACIN SUCCINATE</td>
<td>MDA</td>
<td>$ 0.3041</td>
</tr>
<tr>
<td>00002397900</td>
<td>TEVA-SOLIFENACIN</td>
<td>TEV</td>
<td>$ 0.3041</td>
</tr>
<tr>
<td>00002277263</td>
<td>VESICARE</td>
<td>ASP</td>
<td>$ 1.5135</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>10 MG ORAL TABLET</th>
<th>AURO-SOLIFENACIN</th>
<th>AUR</th>
<th>$ 0.3041</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002446383</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>00002424347</td>
<td>JAMP-SOLIFENACIN</td>
<td>JPC</td>
<td>$ 0.3041</td>
</tr>
<tr>
<td>00002428938</td>
<td>MED-SOLIFENACIN</td>
<td>GMP</td>
<td>$ 0.3041</td>
</tr>
<tr>
<td>00002443198</td>
<td>MINT-SOLIFENACIN</td>
<td>MPI</td>
<td>$ 0.3041</td>
</tr>
<tr>
<td>00002417731</td>
<td>PMS-SOLIFENACIN</td>
<td>PMS</td>
<td>$ 0.3041</td>
</tr>
<tr>
<td>00002399032</td>
<td>SANDOZ SOLIFENACIN</td>
<td>SDZ</td>
<td>$ 0.3041</td>
</tr>
<tr>
<td>00002458268</td>
<td>SOLIFENACIN</td>
<td>SNS</td>
<td>$ 0.3041</td>
</tr>
<tr>
<td>00002448343</td>
<td>SOLIFENACIN SUCCINATE</td>
<td>MDA</td>
<td>$ 0.3041</td>
</tr>
<tr>
<td>00002397919</td>
<td>TEVA-SOLIFENACIN</td>
<td>TEV</td>
<td>$ 0.3041</td>
</tr>
<tr>
<td>00002277271</td>
<td>VESICARE</td>
<td>ASP</td>
<td>$ 1.5135</td>
</tr>
</tbody>
</table>

SOMATROPIN

"For replacement of endogenous growth hormone in adults with severe growth hormone deficiency. Information is required regarding the results of either a diagnostic insulin tolerance test or a glucagon stimulation test. Growth hormone values less than 3 mcg/litre are indicative of severe growth hormone deficiency.

Special authorization may be granted for 6 months."

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

<table>
<thead>
<tr>
<th>0.6 MG / SYR INJECTION</th>
<th>GENOTROPIN MINIQUICK</th>
<th>PFI</th>
<th>$ 16.7400</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002401762</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>0.8 MG / SYR INJECTION</th>
<th>GENOTROPIN MINIQUICK</th>
<th>PFI</th>
<th>$ 22.3200</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002401770</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>1 MG / SYR INJECTION</th>
<th>GENOTROPIN MINIQUICK</th>
<th>PFI</th>
<th>$ 27.9000</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002401789</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## SOMATROPIN

"For replacement of endogenous growth hormone in adults with severe growth hormone deficiency. Information is required regarding the results of either a diagnostic insulin tolerance test or a glucagon stimulation test. Growth hormone values less than 3 mcg/litre are indicative of severe growth hormone deficiency.

Special authorization may be granted for 6 months."

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

<table>
<thead>
<tr>
<th>Type</th>
<th>Unit</th>
<th>Code</th>
<th>Brand</th>
<th>Manufacturer</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 MG / VIAL INJECTION</td>
<td></td>
<td>00002243077</td>
<td>HUMATROPE</td>
<td>LIL</td>
<td>$ 280.0200</td>
</tr>
<tr>
<td>12 MG / VIAL INJECTION</td>
<td></td>
<td>00002243078</td>
<td>HUMATROPE</td>
<td>LIL</td>
<td>$ 560.0400</td>
</tr>
</tbody>
</table>

## SOMATROPIN R-DNA ORIGIN

"For replacement of endogenous growth hormone in adults with severe growth hormone deficiency. Information is required regarding the results of either a diagnostic insulin tolerance test or a glucagon stimulation test. Growth hormone values less than 3 mcg/litre are indicative of severe growth hormone deficiency.

Special authorization may be granted for 6 months."

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

<table>
<thead>
<tr>
<th>Type</th>
<th>Unit</th>
<th>Code</th>
<th>Brand</th>
<th>Manufacturer</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.3 MG / VIAL INJECTION</td>
<td></td>
<td>00002325063</td>
<td>OMNITROPE</td>
<td>SDZ</td>
<td>$ 103.8667</td>
</tr>
<tr>
<td>5 MG / VIAL INJECTION</td>
<td></td>
<td>00002215136</td>
<td>SAIZEN</td>
<td>SRO</td>
<td>$ 147.0735</td>
</tr>
<tr>
<td>5.83 MG / ML INJECTION</td>
<td></td>
<td>000022350122</td>
<td>SAIZEN</td>
<td>SRO</td>
<td>$ 264.9150</td>
</tr>
<tr>
<td>6.7 MG / ML INJECTION</td>
<td></td>
<td>00002325071</td>
<td>OMNITROPE</td>
<td>SDZ</td>
<td>$ 207.7333</td>
</tr>
<tr>
<td>8 MG / ML INJECTION</td>
<td></td>
<td>00002350130</td>
<td>SAIZEN (1.5 ML)</td>
<td>SRO</td>
<td>$ 353.2200</td>
</tr>
<tr>
<td></td>
<td></td>
<td>00002350149</td>
<td>SAIZEN (2.5 ML)</td>
<td>SRO</td>
<td>$ 353.2200</td>
</tr>
<tr>
<td>8.8 MG / VIAL INJECTION</td>
<td></td>
<td>00002272083</td>
<td>SAIZEN</td>
<td>SRO</td>
<td>$ 353.2504</td>
</tr>
</tbody>
</table>
STIRIPENTOL

"For use in combination with clobazam and valproate as adjunctive therapy of refractory generalized tonic-clonic seizures in patients with severe myoclonic epilepsy in infancy (Dravet Syndrome), whose seizures are not adequately controlled with clobazam and valproate alone.

This medication must be prescribed in consultation with a Neurologist.

Special authorization may be granted for 6 months."

Each of these products is eligible for auto-renewal.

<table>
<thead>
<tr>
<th>250 MG</th>
<th>ORAL</th>
<th>CAPSULE</th>
</tr>
</thead>
<tbody>
<tr>
<td>0002398958</td>
<td>DIACOMIT</td>
<td>BCF</td>
</tr>
<tr>
<td>500 MG</td>
<td>ORAL</td>
<td>CAPSULE</td>
</tr>
<tr>
<td>0002398966</td>
<td>DIACOMIT</td>
<td>BCF</td>
</tr>
<tr>
<td>250 MG</td>
<td>ORAL</td>
<td>POWDER PACKET</td>
</tr>
<tr>
<td>0002398974</td>
<td>DIACOMIT</td>
<td>BCF</td>
</tr>
</tbody>
</table>

SUMATRIPTAN HEMISULFATE

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

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

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

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

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

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

<table>
<thead>
<tr>
<th>5 MG</th>
<th>DOSE (BASE)</th>
<th>NASAL</th>
<th>UNIT DOSE SPRAY</th>
</tr>
</thead>
<tbody>
<tr>
<td>0002230418</td>
<td>IMITREX</td>
<td>GSK</td>
<td>$15.2588</td>
</tr>
<tr>
<td>20 MG</td>
<td>DOSE (BASE)</td>
<td>NASAL</td>
<td>UNIT DOSE SPRAY</td>
</tr>
<tr>
<td>0002230420</td>
<td>IMITREX</td>
<td>GSK</td>
<td>$15.7028</td>
</tr>
</tbody>
</table>
SUMATRIPTAN SUCCINATE
(Refer to 28:32.28 of the Alberta Drug Benefit List for coverage of patients 18 to 64 years of age inclusive.)

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

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

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

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

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

<table>
<thead>
<tr>
<th>50 MG (BASE)</th>
<th>ORAL TABLET</th>
<th>100 MG (BASE)</th>
<th>ORAL TABLET</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002268388</td>
<td>APO-SUMATRIPTAN</td>
<td>APX</td>
<td>$2.7732</td>
</tr>
<tr>
<td>00002268914</td>
<td>MYLAN-SUMATRIPTAN</td>
<td>MYP</td>
<td>$2.7732</td>
</tr>
<tr>
<td>00002256436</td>
<td>PMS-SUMATRIPTAN</td>
<td>PMS</td>
<td>$2.7732</td>
</tr>
<tr>
<td>00002263025</td>
<td>SANDOZ SUMATRIPTAN</td>
<td>SDZ</td>
<td>$2.7732</td>
</tr>
<tr>
<td>00002286521</td>
<td>SUMATRIPTAN</td>
<td>SNS</td>
<td>$2.7732</td>
</tr>
<tr>
<td>00002385570</td>
<td>SUMATRIPTAN DF</td>
<td>SIV</td>
<td>$2.7732</td>
</tr>
<tr>
<td>00002286823</td>
<td>TEVA-SUMATRIPTAN DF</td>
<td>TEV</td>
<td>$2.7732</td>
</tr>
<tr>
<td>00002212153</td>
<td>IMITREX DF</td>
<td>GSK</td>
<td>$15.7300</td>
</tr>
<tr>
<td>00002257904</td>
<td>ACT SUMATRIPTAN</td>
<td>APH</td>
<td>$3.0549</td>
</tr>
<tr>
<td>00002268396</td>
<td>APO-SUMATRIPTAN</td>
<td>APX</td>
<td>$3.0549</td>
</tr>
<tr>
<td>00002268922</td>
<td>MYLAN-SUMATRIPTAN</td>
<td>MYP</td>
<td>$3.0549</td>
</tr>
<tr>
<td>00002256444</td>
<td>PMS-SUMATRIPTAN</td>
<td>PMS</td>
<td>$3.0549</td>
</tr>
<tr>
<td>00002263033</td>
<td>SANDOZ SUMATRIPTAN</td>
<td>SDZ</td>
<td>$3.0549</td>
</tr>
<tr>
<td>00002286548</td>
<td>SUMATRIPTAN</td>
<td>SNS</td>
<td>$3.0549</td>
</tr>
<tr>
<td>00002385589</td>
<td>SUMATRIPTAN DF</td>
<td>SIV</td>
<td>$3.0549</td>
</tr>
<tr>
<td>00002239367</td>
<td>TEVA-SUMATRIPTAN</td>
<td>TEV</td>
<td>$3.0549</td>
</tr>
<tr>
<td>00002286831</td>
<td>TEVA-SUMATRIPTAN DF</td>
<td>TEV</td>
<td>$3.0549</td>
</tr>
<tr>
<td>00002212161</td>
<td>IMITREX DF</td>
<td>GSK</td>
<td>$17.3283</td>
</tr>
<tr>
<td>00002361698</td>
<td>TARO-SUMATRIPTAN (0.5 ML)</td>
<td>TAR</td>
<td>$33.1745</td>
</tr>
<tr>
<td>00002212188</td>
<td>IMITREX (0.5 ML)</td>
<td>GSK</td>
<td>$46.0741</td>
</tr>
</tbody>
</table>

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

UNIT OF ISSUE - REFER TO PRICE POLICY
Section 3 - 204
EFFECTIVE APRIL 1, 2018
TACROLIMUS

"For use in patients 2 to 15 years of age inclusive with atopic dermatitis who are unable to tolerate or have failed topical steroid therapy."

"For use in patients 2 to 15 years of age inclusive with atopic dermatitis who require ongoing use of potent (Class 3 or higher) topical steroids."

"For use in patients 16 years of age and older with atopic dermatitis affecting face and flexures who are unable to tolerate or have failed topical steroid therapy."

"For use in patients 16 years of age and older with atopic dermatitis who require ongoing use of potent (Class 3 or higher) topical steroids over greater than 30 % of body surface area."

"Special authorization for all criteria may be granted for 6 months."

Information is required regarding the patient's diagnosis, previous medications utilized (including specific topical steroids) and the patient's response to therapy. In order to comply with the third criterion, information is also required regarding the area(s) affected. In order to comply with the fourth criterion, information is also required regarding the percentage body surface area affected.

The following product(s) are eligible for auto-renewal.

All requests for tacrolimus topical ointment must be completed using the Tacrolimus Topical Ointment Special Authorization Request Form (ABC 60047).

<table>
<thead>
<tr>
<th>0.03 % TOPOCAL OINTMENT</th>
<th>PROTOPIC</th>
<th>LEO</th>
<th>$ 2.2145</th>
</tr>
</thead>
<tbody>
<tr>
<td>000022444149</td>
<td>PROTOPIC</td>
<td>LEO</td>
<td>$ 2.2145</td>
</tr>
</tbody>
</table>

"For use in patients 16 years of age and older with atopic dermatitis affecting face and flexures who are unable to tolerate or have failed topical steroid therapy."

"For use in patients 16 years of age and older with atopic dermatitis who require ongoing use of potent (Class 3 or higher) topical steroids over greater than 30 % of body surface area."

"Special authorization for all criteria may be granted for 6 months."

Information is required regarding the patient's diagnosis, previous medications utilized (including specific topical steroids) and the patient's response to therapy. In order to comply with the first criterion, information is also required regarding the area(s) affected. In order to comply with the second criterion, information is also required regarding the percentage body surface area affected.

The following product(s) are eligible for auto-renewal.

All requests for tacrolimus topical ointment must be completed using the Tacrolimus Topical Ointment Special Authorization Request Form (ABC 60047).

<table>
<thead>
<tr>
<th>0.1 % TOPOCAL OINTMENT</th>
<th>PROTOPIC</th>
<th>LEO</th>
<th>$ 2.3510</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002244148</td>
<td>PROTOPIC</td>
<td>LEO</td>
<td>$ 2.3510</td>
</tr>
</tbody>
</table>
TERIFLUNOMIDE
SPECIAL AUTHORIZATION

Relapsing Remitting Multiple Sclerosis (RRMS):

Special authorization coverage may be provided for the reduction of the frequency and severity of clinical relapses and reduction of the number and volume of active brain lesions, identified on MRI scans, in ambulatory patients with relapsing remitting multiple sclerosis.

Coverage

For coverage, this drug must be prescribed by a registered MS Neurologist. A current assessment must be completed by a registered MS Neurologist at every request.

To register to become an MS Neurologist please complete the Registration for MS Neurologist Status Form (ABC 60002).

Initial Coverage

1) The registered MS Neurologist must confirm a diagnosis of RRMS;

2) The patient must have active disease which is defined as at least two relapses* of MS during the previous two years or in the two years prior to starting an MS disease modifying therapy (DMT).

*A relapse is defined as the appearance of new symptoms or worsening of old symptoms, lasting at least 48 hours in the absence of fever, not associated with withdrawal from steroids. Onset of clinical relapses must be separated by a period of at least one month. At least one definite gadolinium-enhancing T1 MRI lesion (not questionable faint enhancement) obtained at least 90 days after initiation of the DMT and at least 90 days before or after a relapse may substitute for one clinical relapse.

3) The patient must be ambulatory with or without aid (The registered MS Neurologist must provide a current updated Expanded Disability Status Scale (EDSS) score less than or equal to 6.5).

Coverage may be approved for up to 12 months. Patients will be limited to receiving a one-month supply of teriflunomide per prescription at their pharmacy for the first 12 months of coverage.

Continued Coverage

For continued coverage beyond the initial coverage period, the patient must meet the following criteria:

1) The patient must be assessed by a registered MS Neurologist;

2) The registered MS Neurologist must confirm a diagnosis of RRMS;

3) The registered MS Neurologist must provide a current updated EDSS score. The patient must not have an EDSS score of 7.0 or above sustained for one year or more.

Coverage of this drug may be considered in a patient with a sustained EDSS score of 7.0 or above in exceptional circumstances. For MS DMT coverage to be considered, details of the exceptional circumstance must be provided in a letter from the registered MS Neurologist and accompany the Special Authorization Request Form.

Continued coverage may be approved for up to 12 months. Patients may receive up to 100 days' supply of teriflunomide per prescription at their pharmacy.

Restarting After an Interruption in Therapy Greater Than 12 Months

The DBL is not a prescribing or a diagnostic tool. Prescribers should refer to drug monographs and utilize professional judgment.
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

TERIFLUNOMIDE
In order to be eligible for coverage, after an interruption in therapy greater than 12 months, the patient must meet the following criteria:

1) At least one relapse* per 12 month period; or
2) At least two relapses* during the previous 24 month period.

All requests (including renewal requests) for teriflunomide must be completed using the Dimethyl Fumarate/Glatiramer Acetate/Interferon Beta-1a/Interferon Beta-1b/Peginterferon Beta-1a/Teriflunomide Special Authorization Request Form (ABC 60001).

| 14 MG ORAL TABLET | 00002416328 | AUBAGIO | GZM | $ 56.3900 |

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) | ASC | $ 2.1159 |
| 24.3 MG TRANSDERMAL PATCH | 00002245972 | ANDRODERM (5 MG/DAY) | ASC | $ 4.2317 |

TESTOSTERONE UNDECANOATE
"For use in males for the treatment of congenital and acquired primary and secondary hypogonadism."

"Coverage cannot be considered when used for the treatment of androgen decline in the aging male (ADAM)."

"Special authorization may be granted for 6 months."

The following product(s) are eligible for auto-renewal.

| 40 MG ORAL CAPSULE | 00002322498 | PMS-TESTOSTERONE | PMS | $ 0.4700 |
| 00002421186 | TARO-TESTOSTERONE | TAR | $ 0.4700 |

TETRABENAZINE
"For the treatment of hyperkinetic movement disorders when prescribed by specialists in Neurology, Psychiatry, or Geriatric Medicine.

Special authorization may be granted for 6 months."

The following product(s) are eligible for auto-renewal.

| 25 MG ORAL TABLET | 00002407590 | APO-TETRABENAZINE | APX | $ 3.3746 |
| 00002402424 | PMS-TETRABENAZINE | PMS | $ 3.3746 |
| 00002410338 | TETRABENAZINE | STM | $ 3.3746 |
| 00002199270 | NITOMAN | VCL | $ 7.2138 |
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

TICAGRELOR
(Refer to 20:12.18 of the Alberta Drug Benefit List for coverage of ticagrelor when prescribed by a specialist in Cardiology, Cardiac Surgery, Cardiovascular & Thoracic Surgery, Internal Medicine or General Surgery.)

For the treatment of Acute Coronary Syndrome, defined as unstable angina or myocardial infarction, when initiated in hospital in consultation with a Specialist in Cardiology, Cardiac Surgery, Cardiovascular & Thoracic Surgery, Internal Medicine or General Surgery. Treatment must be in combination with low dose ASA. Special authorization may be granted for 6 months.*

*Special Authorization is only required when the initiating prescriber is not a Specialist in Cardiology, Cardiac Surgery, Cardiovascular & Thoracic Surgery, Internal Medicine or General Surgery.

The following product(s) are eligible for auto-renewal.

| 90 MG ORAL TABLET | 00002368544 | BRILINTA | AZC | $ 1.5470 |

TIOTROPIUM BROMIDE MONOHYDRATE/ OLODATEROL HYDROCHLORIDE
The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD)

FIRST-LINE DRUG PRODUCT(S): LONG-ACTING BRONCHODILATOR (I.E., LONG-ACTING BETA-2 AGONIST [LABA] OR LONG-ACTING MUSCARINIC ANTAGONIST [LAMA])

"For the long-term maintenance treatment of airflow obstruction in patients with moderate to severe (i.e., FEV1 < 80% predicted) chronic obstructive pulmonary disease (COPD), who have an inadequate response to a long-acting bronchodilator (long-acting beta-2 agonist [LABA] or long-acting muscarinic antagonist [LAMA])."

"For the long-term maintenance treatment of airflow obstruction in patients with severe (i.e., FEV1 < 50% predicted) chronic obstructive pulmonary disease (COPD)."

"Special authorization may be granted for 24 months."

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

UP - First-line therapy ineffective

All requests for tiotropium bromide monohydrate + olodaterol hydrochloride must be completed using the Long-Acting Fixed-Dose Combination Products for Asthma/COPD Special Authorization Request Form (ABC 60025).

| 2.5 MCG / DOSE * 2.5 MCG / DOSE INHALATION SOLUTION | 00002441888 | INSPIOLTO RESPIMAT | BOE | $ 1.0363 |

The DBL is not a prescribing or a diagnostic tool. Prescribers should refer to drug monographs and utilize professional judgment.

UNIT OF ISSUE - REFER TO PRICE POLICY  Section 3·208  EFFECTIVE APRIL 1, 2018
TOCILIZUMAB

Rheumatoid Arthritis:

"Special authorization coverage may be provided for use in combination with methotrexate for the reduction in signs and symptoms of severely active Rheumatoid Arthritis (RA) in adult patients (18 years of age or older) who are refractory or intolerant to:

- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- Methotrexate with other disease modifying anti-rheumatic agent(s) (minimum 4-month trial). [e.g., methotrexate with hydroxychloroquine or methotrexate with sulfasalazine]; AND
- Leflunomide (minimum 10 week trial at 20 mg daily)

Special authorization coverage of this agent may be provided for use as monotherapy in adult patients for whom methotrexate is contraindicated and/or for those patients who have experienced serious adverse effects.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for 16 weeks as follows:
  - Tocilizumab intravenous infusion: one dose of 4 mg/kg or 8 mg/kg (up to a maximum of 800 mg per dose) of tocilizumab administered at 0, 4, 8, 12 and 16 weeks (total of 5 doses). Patients will be limited to receiving one dose of intravenous tocilizumab per prescription at their pharmacy.
  - Tocilizumab subcutaneous injection: for patients weighing less than 100 kg, initial coverage may be approved for one 162 mg dose of tocilizumab administered every other week, up to weekly based on clinical response. For patients weighing 100 kg or more, initial coverage may be approved for one 162 mg dose of tocilizumab administered every week. Patients will be limited to receiving a one-month supply of subcutaneous tocilizumab per prescription at their pharmacy.
  - Patients will be permitted to switch from one biologic agent to another (with the exception of anakinra) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
  - Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
  - Patients will not be permitted to switch from anakinra to other biologic agents except under exceptional circumstances.
  - Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond the initial 16 weeks, the patient must meet the following criteria:
1) The patient must be assessed by an RA Specialist after 16 weeks, but no longer than 20 weeks after treatment to determine response.
2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets
TOCILIZUMAB

the following criteria:
- ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND
- An improvement of 0.22 in HAQ score [reported to two (2) decimal places].

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be approved for a period of 12 months. Coverage for tocilizumab will be provided for one intravenous dose of 4 mg/kg to 8 mg/kg (up to a maximum of 800 mg per dose) every 4 weeks, or one 162 mg subcutaneous dose administered every one to two weeks (based on weight and clinical response). Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:

1) The patient has been assessed by an RA Specialist to determine response;
2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
   - Confirmation of maintenance of ACR20, OR
   - Maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.
3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above."

All requests (including renewal requests) for tocilizumab for Rheumatoid Arthritis must be completed using the Abatacept/Adalimumab/Anakinra/Certolizumab/Etanercept/Golimumab/Infliximab/Tocilizumab/Tofacitinib for Rheumatoid Arthritis Special Authorization Request Form (ABC 60027).

Systemic Juvenile Idiopathic Arthritis:

"Special authorization coverage may be provided for the treatment of active systemic juvenile idiopathic arthritis (sJIA) in patients 2 years of age and older when all of the following conditions are met:
- the patient has a diagnosis of systemic JIA with fever (greater than 38 degrees Celsius) for at least two weeks and at least one of the following: rash of systemic JIA; serositis; lymphadenopathy; hepatomegaly; splenomegaly; AND
- the physician has ruled out other potential etiologies; AND
- the patient is refractory to one or more non-steroidal anti-inflammatory drugs (NSAIDs) and one or more systemic corticosteroids.

"Refractory" is defined as one or more of the following: lack of effect, serious adverse effects or contraindications to treatments as defined in the product monographs.

For coverage, this drug must be prescribed by a prescriber affiliated with a Pediatric Rheumatology Clinic in Edmonton or Calgary (Pediatric RA Specialist).

- Coverage may be approved for one dose of 12 mg/kg for patient weight less than 30 kg or 8 mg/kg for patient weight greater than or equal to 30 kg to a maximum of 800 mg, administered every two weeks for 12 weeks.
- Patients will be limited to receiving one month of tocilizumab per prescription at their pharmacy.

For continued coverage beyond 12 weeks, the patient must meet the following criteria:
1) The patient must be assessed by a Pediatric RA Specialist after 12 weeks, but no longer than 16 weeks after, treatment with this biologic agent to determine response.
TOCILIZUMAB

2) The Pediatric RA Specialist must confirm in writing that the patient is a responder as demonstrated by JIA ACR30 response and/or absence of fever and/or reduction in inflammatory markers [e.g., C-reactive protein (CRP) concentration of less than 15 mg/L or reduction in erythrocyte sedimentation rate (ESR)].

Following this assessment, continued coverage may be approved for one dose of 12 mg/kg for patient weight less than 30 kg or 8 mg/kg for patient weight greater than or equal to 30 kg to a maximum of 800 mg, administered every two weeks, for a maximum of twelve months. After twelve months, in order to be considered for continued coverage, the patient must meet the following criteria:

1) The patient has been re-assessed every 12 months by a Pediatric RA Specialist to determine response, AND
2) The Pediatric RA Specialist must confirm in writing that the patient has maintained a response to therapy.

All requests (including renewal requests) for tocilizumab for Systemic Juvenile Idiopathic Arthritis must be completed using the Tocilizumab for Systemic Juvenile Idiopathic Arthritis Special Authorization Request Form (ABC 60048).

Polyarticular Juvenile Idiopathic Arthritis:

"Special authorization coverage may be provided for the reduction in signs and symptoms of severely active polyarticular juvenile idiopathic arthritis (pJIA) in patients 2 years of age and older who:
- Have 5 or more active joints (defined by either swelling or limitation of motion plus pain and/or tenderness), AND
- Are refractory to one or more disease modifying anti-rheumatic agents (DMARDs) conventionally used in children (minimum three month trial).

"Refractory" is defined as one or more of the following: lack of effect, serious adverse effects (e.g., leukopenia, hepatitis) or contraindications to treatments as defined in the product monographs.

For coverage, this drug must be prescribed by a prescriber affiliated with a Pediatric Rheumatology Clinic in Edmonton or Calgary (Pediatric Rheumatology Specialist).

- Coverage may be approved for 10 mg/kg/dose for patients less than 30 kg, or 8 mg/kg/dose for patients 30 kg or greater every 4 weeks.
- Patients will be limited to receiving a one-month supply of tocilizumab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another (with the exception of abatacept) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients will not be permitted to switch from abatacept to other biologic agents except under exceptional circumstances.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage of this agent beyond 12 weeks, the patient must meet the following criteria:
1) The patient must be assessed by a Pediatric Rheumatology Specialist after 12 weeks, but no longer than 16 weeks after, treatment with this biologic agent to determine response.
2) The Pediatric Rheumatology Specialist must confirm in writing that the patient is a responder that meets the following criteria (ACR Pedi 30):
- 30% improvement from baseline in at least three of the following six response
TOCILIZUMAB
variables, with worsening of 30% or more in no more than one of the six variables. The
variables include:
i. global assessment of the severity of the disease by the Pediatric Rheumatology
Specialist,
ii. global assessment of overall well-being by the patient or parent,
iii. number of active joints (joints with swelling not due to deformity or joints with
limitation of motion with pain tenderness or both),
iv. number of joints with limitation of motion,
v. functional ability based on CHAQ scores,
vi. ESR or CRP
3) Data from all of the six variables comprising the ACR Pedi 30 and the CHAQ scores
must be reported in each request.

Following this assessment, continued coverage may be approved for 10 mg/kg/dose for
patients less than 30 kg, or 8 mg/kg/dose for patients 30 kg or greater every 4 weeks, for
a maximum of twelve months. After twelve months, in order to be considered for
continued coverage, the patient must be re-assessed every twelve months by a
Pediatric Rheumatology Specialist and must meet the following criteria:
1) The patient has been assessed by a Pediatric Rheumatology Specialist to determine
response, and
2) The Pediatric Rheumatology Specialist must confirm in writing that the patient has
maintained a response to therapy as indicated by maintenance of the ACR Pedi 30,
3) Data from all of the six variables comprising the ACR Pedi 30 and the CHAQ scores
must be reported in each request.

Once a child with pJIA has had two disease-free years, it is common clinical practice for
drug treatment to be stopped."

All requests (including renewal requests) for tocilizumab for Polyarticular Juvenile
Idiopathic Arthritis must be completed using the Adalimumab/Etanercept/Tocilizumab for
Polyarticular Juvenile Idiopathic Arthritis Special Authorization Request Form (ABC
60011).

80 MG / VIAL INJECTION
00002350092 ACTEMRA (4 ML) HLR $ 182.8000
TOCILIZUMAB

"Special authorization coverage may be provided for use in combination with methotrexate for the reduction in signs and symptoms of severely active Rheumatoid Arthritis (RA) in adult patients (18 years of age or older) who are refractory or intolerant to:

- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- Methotrexate with other disease modifying anti-rheumatic agent(s) (minimum 4-month trial). [e.g., methotrexate with hydroxychloroquine or methotrexate with sulfasalazine]; AND
- Leflunomide (minimum 10 week trial at 20 mg daily)
Special authorization coverage of this agent may be provided for use as monotherapy in adult patients for whom methotrexate is contraindicated and/or for those patients who have experienced serious adverse effects.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.

'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for 16 weeks as follows:
  - Tocilizumab intravenous infusion: one dose of 4 mg/kg or 8 mg/kg (up to a maximum of 800 mg per dose) of tocilizumab administered at 0, 4, 8, 12 and 16 weeks (total of 5 doses). Patients will be limited to receiving one dose of intravenous tocilizumab per prescription at their pharmacy.
  - Tocilizumab subcutaneous injection: for patients weighing less than 100 kg, initial coverage may be approved for one 162 mg dose of tocilizumab administered every other week, up to weekly based on clinical response. For patients weighing 100 kg or more, initial coverage may be approved for one 162 mg dose of tocilizumab administered every week. Patients will be limited to receiving a one-month supply of subcutaneous tocilizumab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another (with the exception of anakinra) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients will not be permitted to switch from anakinra to other biologic agents except under exceptional circumstances.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond the initial 16 weeks, the patient must meet the following criteria:
1) The patient must be assessed by an RA Specialist after 16 weeks, but no longer than 20 weeks after treatment to determine response.
2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
   - ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND
   - An improvement of 0.22 in HAQ score [reported to two (2) decimal places].

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.
TOCILIZUMAB

Following this assessment, continued coverage may be approved for a period of 12 months. Coverage for tocilizumab will be provided for one intravenous dose of 4 mg/kg to 8 mg/kg (up to a maximum of 800 mg per dose) every 4 weeks, or one 162 mg subcutaneous dose administered every one to two weeks (based on weight and clinical response). Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by an RA Specialist to determine response;
2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
   - Confirmation of maintenance of ACR20, OR
   - Maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.
3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

All requests (including renewal requests) for tocilizumab for Rheumatoid Arthritis must be completed using the Abatacept/Adalimumab/Anakinra/Certolizumab/Etanercept/Golimumab/Infliximab/Tocilizumab/Tofacitinib for Rheumatoid Arthritis Special Authorization Request Form (ABC 60027).

162 MG / SYR INJECTION

00002424770  ACTEMRA (0.9 ML SYRINGE)  HLR  $ 358.9050
TOCILIZUMAB

Rheumatoid Arthritis:

"Special authorization coverage may be provided for use in combination with methotrexate for the reduction in signs and symptoms of severely active Rheumatoid Arthritis (RA) in adult patients (18 years of age or older) who are refractory or intolerant to:

- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- Methotrexate with other disease modifying anti-rheumatic agent(s) (minimum 4-month trial). [e.g., methotrexate with hydroxychloroquine or methotrexate with sulfasalazine]; AND
- Leflunomide (minimum 10 week trial at 20 mg daily)

Special authorization coverage of this agent may be provided for use as monotherapy in adult patients for whom methotrexate is contraindicated and/or for those patients who have experienced serious adverse effects.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.

'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for 16 weeks as follows:
  - Tocilizumab intravenous infusion: one dose of 4 mg/kg or 8 mg/kg (up to a maximum of 800 mg per dose) of tocilizumab administered at 0, 4, 8, 12 and 16 weeks (total of 5 doses). Patients will be limited to receiving one dose of intravenous tocilizumab per prescription at their pharmacy.
  - Tocilizumab subcutaneous injection: for patients weighing less than 100 kg, initial coverage may be approved for one 162 mg dose of tocilizumab administered every other week, up to weekly based on clinical response. For patients weighing 100 kg or more, initial coverage may be approved for one 162 mg dose of tocilizumab administered every week. Patients will be limited to receiving a one-month supply of subcutaneous tocilizumab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another (with the exception of anakinra) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients will not be permitted to switch from anakinra to other biologic agents except under exceptional circumstances.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond the initial 16 weeks, the patient must meet the following criteria:
1) The patient must be assessed by an RA Specialist after 16 weeks, but no longer than 20 weeks after treatment to determine response.
2) The RA Specialist must confirm in writing that the patient is a ‘responder’ that meets
TOCILIZUMAB

the following criteria:
- ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND
- An improvement of 0.22 in HAQ score [reported to two (2) decimal places].
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be approved for a period of 12 months. Coverage for tocilizumab will be provided for one intravenous dose of 4 mg/kg to 8 mg/kg (up to a maximum of 800 mg per dose) every 4 weeks, or one 162 mg subcutaneous dose administered every one to two weeks (based on weight and clinical response). Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by an RA Specialist to determine response;
2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
   - Confirmation of maintenance of ACR20, OR
   - Maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.
3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above."

All requests (including renewal requests) for tocilizumab for Rheumatoid Arthritis must be completed using the Abatacept/Adalimumab/Anakinra/Certolizumab/Etanercept/Golimumab/Infliximab/Tocilizumab/Tofactinib for Rheumatoid Arthritis Special Authorization Request Form (ABC 60027).

Systemic Juvenile Idiopathic Arthritis:

"Special authorization coverage may be provided for the treatment of active systemic juvenile idiopathic arthritis (sJIA) in patients 2 years of age and older when all of the following conditions are met:
- the patient has a diagnosis of systemic JIA with fever (greater than 38 degrees Celsius) for at least two weeks and at least one of the following: rash of systemic JIA; serositis; lymphadenopathy; hepatomegaly; splenomegaly; AND
- the physician has ruled out other potential etiologies; AND
- the patient is refractory to one or more non-steroidal anti-inflammatory drugs (NSAIDs) and one or more systemic corticosteroids.

"Refractory" is defined as one or more of the following: lack of effect, serious adverse effects or contraindications to treatments as defined in the product monographs.

For coverage, this drug must be prescribed by a prescriber affiliated with a Pediatric Rheumatology Clinic in Edmonton or Calgary (Pediatric RA Specialist).

- Coverage may be approved for one dose of 12 mg/kg for patient weight less than 30 kg or 8 mg/kg for patient weight greater than or equal to 30 kg to a maximum of 800 mg, administered every two weeks for 12 weeks.
- Patients will be limited to receiving one month of tocilizumab per prescription at their pharmacy.

For continued coverage beyond 12 weeks, the patient must meet the following criteria:
1) The patient must be assessed by a Pediatric RA Specialist after 12 weeks, but no longer than 16 weeks after, treatment with this biologic agent to determine response.
TOCILIZUMAB

2) The Pediatric RA Specialist must confirm in writing that the patient is a responder as demonstrated by JIA ACR30 response and/or absence of fever and/or reduction in inflammatory markers [e.g., C-reactive protein (CRP) concentration of less than 15 mg/L or reduction in erythrocyte sedimentation rate (ESR)].

Following this assessment, continued coverage may be approved for one dose of 12 mg/kg for patient weight less than 30 kg or 8 mg/kg for patient weight greater than or equal to 30 kg to a maximum of 800 mg, administered every two weeks, for a maximum of twelve months. After twelve months, in order to be considered for continued coverage, the patient must meet the following criteria:
1) The patient has been re-assessed every 12 months by a Pediatric RA Specialist to determine response, AND
2) The Pediatric RA Specialist must confirm in writing that the patient has maintained a response to therapy.

All requests (including renewal requests) for tocilizumab for Systemic Juvenile Idiopathic Arthritis must be completed using the Tocilizumab for Systemic Juvenile Idiopathic Arthritis Special Authorization Request Form (ABC 60048).

Polyarticular Juvenile Idiopathic Arthritis:

"Special authorization coverage may be provided for the reduction in signs and symptoms of severely active polyarticular juvenile idiopathic arthritis (pJIA) in patients 2 years of age and older who:
- Have 5 or more active joints (defined by either swelling or limitation of motion plus pain and/or tenderness), AND
- Are refractory to one or more disease modifying anti-rheumatic agents (DMARDs) conventionally used in children (minimum three month trial).

"Refractory" is defined as one or more of the following: lack of effect, serious adverse effects (e.g., leukopenia, hepatitis) or contraindications to treatments as defined in the product monographs.

For coverage, this drug must be prescribed by a prescriber affiliated with a Pediatric Rheumatology Clinic in Edmonton or Calgary (Pediatric Rheumatology Specialist).

- Coverage may be approved for 10 mg/kg/dose for patients less than 30 kg, or 8 mg/kg/dose for patients 30 kg or greater every 4 weeks.
- Patients will be limited to receiving a one-month supply of tocilizumab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another (with the exception of abatacept) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients will not be permitted to switch from abatacept to other biologic agents except under exceptional circumstances.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage of this agent beyond 12 weeks, the patient must meet the following criteria:
1) The patient must be assessed by a Pediatric Rheumatology Specialist after 12 weeks, but no longer than 16 weeks after, treatment with this biologic agent to determine response.
2) The Pediatric Rheumatology Specialist must confirm in writing that the patient is a responder that meets the following criteria (ACR Pedi 30):
- 30% improvement from baseline in at least three of the following six response
TOCILIZUMAB
variables, with worsening of 30% or more in no more than one of the six variables. The variables include:
i. global assessment of the severity of the disease by the Pediatric Rheumatology Specialist,
ii. global assessment of overall well-being by the patient or parent,
iii. number of active joints (joints with swelling not due to deformity or joints with limitation of motion with pain tenderness or both),
iv. number of joints with limitation of motion,
v. functional ability based on CHAQ scores,
vi. ESR or CRP
3) Data from all of the six variables comprising the ACR Pedi 30 and the CHAQ scores must be reported in each request.

Following this assessment, continued coverage may be approved for 10 mg/kg/dose for patients less than 30 kg, or 8 mg/kg/dose for patients 30 kg or greater every 4 weeks, for a maximum of twelve months. After twelve months, in order to be considered for continued coverage, the patient must be re-assessed every twelve months by a Pediatric Rheumatology Specialist and must meet the following criteria:
1) The patient has been assessed by a Pediatric Rheumatology Specialist to determine response, and
2) The Pediatric Rheumatology Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by maintenance of the ACR Pedi 30,
3) Data from all of the six variables comprising the ACR Pedi 30 and the CHAQ scores must be reported in each request.

Once a child with pJIA has had two disease-free years, it is common clinical practice for drug treatment to be stopped.”

All requests (including renewal requests) for tocilizumab for Polyarticular Juvenile Idiopathic Arthritis must be completed using the Adalimumab/Etanercept/Tocilizumab for Polyarticular Juvenile Idiopathic Arthritis Special Authorization Request Form (ABC 60011).

200 MG / VIAL INJECTION
00002350106 ACTEMRA (10 ML) HLR $ 457.0000
TOCILIZUMAB

Rheumatoid Arthritis:

"Special authorization coverage may be provided for use in combination with methotrexate for the reduction in signs and symptoms of severely active Rheumatoid Arthritis (RA) in adult patients (18 years of age or older) who are refractory or intolerant to:

- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- Methotrexate with other disease modifying anti-rheumatic agent(s) (minimum 4-month trial). [e.g., methotrexate with hydroxychloroquine or methotrexate with sulfasalazine]; AND
- Leflunomide (minimum 10 week trial at 20 mg daily)

Special authorization coverage of this agent may be provided for use as monotherapy in adult patients for whom methotrexate is contraindicated and/or for those patients who have experienced serious adverse effects.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.

'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for 16 weeks as follows:
  - Tocilizumab intravenous infusion: one dose of 4 mg/kg or 8 mg/kg (up to a maximum of 800 mg per dose) of tocilizumab administered at 0, 4, 8, 12 and 16 weeks (total of 5 doses). Patients will be limited to receiving one dose of intravenous tocilizumab per prescription at their pharmacy.
  - Tocilizumab subcutaneous injection: for patients weighing less than 100 kg, initial coverage may be approved for one 162 mg dose of tocilizumab administered every other week, up to weekly based on clinical response. For patients weighing 100 kg or more, initial coverage may be approved for one 162 mg dose of tocilizumab administered every week. Patients will be limited to receiving a one-month supply of subcutaneous tocilizumab per prescription at their pharmacy.
  - Patients will be permitted to switch from one biologic agent to another (with the exception of anakinra) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
  - Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
  - Patients will not be permitted to switch from anakinra to other biologic agents except under exceptional circumstances.
  - Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond the initial 16 weeks, the patient must meet the following criteria:
1) The patient must be assessed by an RA Specialist after 16 weeks, but no longer than 20 weeks after treatment to determine response.
2) The RA Specialist must confirm in writing that the patient is a ‘responder’ that meets
TOCILIZUMAB

the following criteria:
- ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND
- An improvement of 0.22 in HAQ score [reported to two (2) decimal places].

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be approved for a period of 12 months. Coverage for tocilizumab will be provided for one intravenous dose of 4 mg/kg to 8 mg/kg (up to a maximum of 800 mg per dose) every 4 weeks, or one 162 mg subcutaneous dose administered every one to two weeks (based on weight and clinical response). Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by an RA Specialist to determine response;
2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
   - Confirmation of maintenance of ACR20, OR
   - Maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.
3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above."

All requests (including renewal requests) for tocilizumab for Rheumatoid Arthritis must be completed using the Abatacept/Adalimumab/Anakinra/Certolizumab/Etanercept/Golimumab/Infliximab/Tocilizumab/Tofacitinib for Rheumatoid Arthritis Special Authorization Request Form (ABC 60027).

Systemic Juvenile Idiopathic Arthritis:

"Special authorization coverage may be provided for the treatment of active systemic juvenile idiopathic arthritis (sJIA) in patients 2 years of age and older when all of the following conditions are met:
- the patient has a diagnosis of systemic JIA with fever (greater than 38 degrees Celsius) for at least two weeks and at least one of the following: rash of systemic JIA; serositis; lymphadenopathy; hepatomegaly; splenomegaly; AND
- the physician has ruled out other potential etiologies; AND
- the patient is refractory to one or more non-steroidal anti-inflammatory drugs (NSAIDs) and one or more systemic corticosteroids.

"Refractory" is defined as one or more of the following: lack of effect, serious adverse effects or contraindications to treatments as defined in the product monographs.

For coverage, this drug must be prescribed by a prescriber affiliated with a Pediatric Rheumatology Clinic in Edmonton or Calgary (Pediatric RA Specialist).

- Coverage may be approved for one dose of 12 mg/kg for patient weight less than 30 kg or 8 mg/kg for patient weight greater than or equal to 30 kg to a maximum of 800 mg, administered every two weeks for 12 weeks.
- Patients will be limited to receiving one month of tocilizumab per prescription at their pharmacy.

For continued coverage beyond 12 weeks, the patient must meet the following criteria:
1) The patient must be assessed by a Pediatric RA Specialist after 12 weeks, but no longer than 16 weeks after, treatment with this biologic agent to determine response.
TOCILIZUMAB

2) The Pediatric RA Specialist must confirm in writing that the patient is a responder as demonstrated by JIA ACR30 response and/or absence of fever and/or reduction in inflammatory markers [e.g., C-reactive protein (CRP) concentration of less than 15 mg/L or reduction in erythrocyte sedimentation rate (ESR)].

Following this assessment, continued coverage may be approved for one dose of 12 mg/kg for patient weight less than 30 kg or 8 mg/kg for patient weight greater than or equal to 30 kg to a maximum of 800 mg, administered every two weeks, for a maximum of twelve months. After twelve months, in order to be considered for continued coverage, the patient must meet the following criteria:
1) The patient has been re-assessed every 12 months by a Pediatric RA Specialist to determine response, AND
2) The Pediatric RA Specialist must confirm in writing that the patient has maintained a response to therapy.

All requests (including renewal requests) for tocilizumab for Systemic Juvenile Idiopathic Arthritis must be completed using the Tocilizumab for Systemic Juvenile Idiopathic Arthritis Special Authorization Request Form (ABC 60048).

400 MG / VIAL INJECTION
00002350114 ACTEMRA (20 ML) HLR $ 914.0000
TOFACITINIB CITRATE

Rheumatoid Arthritis:

"Special authorization coverage may be provided for use in combination with methotrexate for the reduction in signs and symptoms of severely active Rheumatoid Arthritis (RA) in adult patients (18 years of age or older) who are refractory or intolerant to:
- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- Methotrexate with other disease modifying anti-rheumatic agent(s) (minimum 4 month trial) [e.g., methotrexate with hydroxychloroquine or methotrexate with sulfasalazine]; AND
- Leflunomide (minimum 10 week trial at 20 mg daily).

Special authorization coverage of this agent may be provided for use as monotherapy in adult patients for whom methotrexate is contraindicated and/or for those patients who have experienced serious adverse effects.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for 5 mg twice daily for three months.
- Patients will be limited to receiving a one-month supply of tofacitinib per prescription at their pharmacy.
- Patients will not be permitted to switch back to tofacitinib if they were deemed unresponsive to therapy.

For continued coverage beyond three months, the patient must meet the following criteria:
1) The patient must be assessed by an RA Specialist after the initial three months to determine response.
2) The RA Specialist must confirm in writing that the patient is a ‘responder’ that meets the following criteria:
   - ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND
   - An improvement of 0.22 in HAQ score [reported to two (2) decimal places].

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be approved for 5 mg twice daily for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by an RA Specialist to determine response;
2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
   - confirmation of maintenance of ACR20, or
   - maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.
3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Coverage cannot be provided for tofacitinib when intended for use in combination with a biologic agent."

All requests (including renewal requests) for tofacitinib for Rheumatoid Arthritis must be completed using the
TOFACITINIB CITRATE
Abatacept/Adalimumab/Anakinra/Certolizumab/Etanercept/Golimumab/Infliximab/Tocilizumab/Tofacitinib for Rheumatoid Arthritis Special Authorization Request Form (ABC 60027).

5 MG ORAL TABLET
00002423898 XELJANZ PFI $ 23.9589

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."

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

UP - First-line therapy ineffective
UQ - First-line therapy not tolerated

2 MG ORAL EXTENDED-RELEASE CAPSULE
00002404184 MYLAN-TOLTERODINE ER MYP $ 0.4911
00002413140 SANDOZ TOLTERODINE LA SDZ $ 0.4911
00002412195 TEVA-TOLTERODINE LA TEV $ 0.4911
0000244612 DETROL LA PFI $ 2.0433

4 MG ORAL EXTENDED-RELEASE CAPSULE
00002404182 MYLAN-TOLTERODINE ER MYP $ 0.4911
00002413159 SANDOZ TOLTERODINE LA SDZ $ 0.4911
00002412209 TEVA-TOLTERODINE LA TEV $ 0.4911
0000244613 DETROL LA PFI $ 2.0433

TRETINOIN
"For the treatment of severe acne as defined by scarring acne."

Special authorization may be granted for 6 months."

The following product(s) are eligible for auto-renewal.

0.025 % TOPICAL GEL
00001926470 VITAMIN A ACID VCL $ 0.3299

0.05 % TOPICAL GEL
00001926489 VITAMIN A ACID VCL $ 0.3299

0.01 % TOPICAL CREAM
00000657204 STIEVA-A GSK $ 0.3084

0.025 % TOPICAL CREAM
00000578576 STIEVA-A GSK $ 0.3084

0.05 % TOPICAL CREAM
00000518182 STIEVA-A GSK $ 0.2100

0.01 % TOPICAL GEL
00001926462 VITAMIN A ACID VCL $ 0.3299

The DBL is not a prescribing or a diagnostic tool. Prescribers should refer to drug monographs and utilize professional judgment.

PRODUCT IS NOT INTERCHANGEABLE
Section 3 223 EFFECTIVE APRIL 1, 2018
**TROPIUM 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."

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

UP - First-line therapy ineffective
UQ - First-line therapy not tolerated

![Table: TROSEC](image)

**UMECLIDINIUM BROMIDE/ VILANTEROL TRIFENATATE**
The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD)

FIRST-LINE DRUG PRODUCT(S): LONG-ACTING BRONCHODILATOR (I.E., LONG-ACTING BETA-2 AGONIST [LABA] OR LONG-ACTING MUSCARINIC ANTAGONIST [LAMA])

"For the long-term maintenance treatment of airflow obstruction in patients with moderate to severe (i.e., FEV1 < 80% predicted) chronic obstructive pulmonary disease (COPD), who have an inadequate response to a long-acting bronchodilator (long-acting beta-2 agonist [LABA] or long-acting muscarinic antagonist [LAMA])."

"For the long-term maintenance treatment of airflow obstruction in patients with severe (i.e., FEV1 < 50% predicted) chronic obstructive pulmonary disease (COPD)."

"Special authorization may be granted for 24 months."

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

UP - First-line therapy ineffective

All requests for umeclidinium bromide + vilanterol trifenate must be completed using the Long-Acting Fixed-Dose Combination Products for Asthma/COPD Special Authorization Request Form (ABC 60025).

![Table: ANORO ELLIPTA](image)
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 (90 mg for patients weighing greater than 100 kg) at weeks 0, 4 and 16.
- Patients will be limited to receiving one dose per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage, the patient must meet all of the following criteria:
1) The patient must be assessed by a Dermatology Specialist after the initial 16 weeks of therapy to determine response.
2) The Dermatology Specialist must confirm, in writing, that the patient is a ‘responder’ that meets the following criteria:
   - Greater than or equal to 75% reduction in PASI score, OR
   - Greater than or equal to 50% reduction in PASI score AND improvement of greater than or equal to 5 points in the DLQI.

Following this assessment, continued coverage may be considered for 45 mg (90 mg for patients weighing greater than 100 kg) every 12 weeks for a period of 12 months. Ongoing coverage may be considered if the patient is re-assessed by a Dermatology Specialist every 12 months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above."

PASI and DLQI scores are required for all requests for Plaque Psoriasis including those requests for patients that have significant involvement of the face, palms, soles of feet or genital region.

All requests (including renewal requests) for ustekinumab for Plaque Psoriasis must be completed using the Adalimumab/Etanercept/Infliximab/Secukinumab/Ustekinumab for Plaque Psoriasis Special Authorization Request Form (ABC 60030).
<table>
<thead>
<tr>
<th>CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS</th>
</tr>
</thead>
</table>

**USTEKINUMAB**

<table>
<thead>
<tr>
<th>45 MG INJECTION VIAL OR SYRINGE</th>
<th>STELARA (0.5 ML VIAL OR SYRINGE)</th>
<th>JAI</th>
<th>$ 4465.5800</th>
</tr>
</thead>
<tbody>
<tr>
<td>90 MG / SYR INJECTION SYRINGE</td>
<td>STELARA (1.0 ML SYRINGE)</td>
<td>JAI</td>
<td>$ 4465.5800</td>
</tr>
</tbody>
</table>

For this product - pricing has been established on a per vial or syringe basis.

The DBL is not a prescribing or a diagnostic tool. Prescribers should refer to drug monographs and utilize professional judgment.

UNIT OF ISSUE - REFER TO PRICE POLICY  
Section 3  
EFFECTIVE APRIL 1, 2018
VANCOMYCIN HCL
(Refer to Section 1 - Restricted Benefits of the Alberta Drug Benefit List for coverage of the product when prescribed by a Specialist in Infectious Diseases or a designated prescriber.)

"For the treatment of:
1) Clostridium difficile infection 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 infection with symptoms after 2 courses of metronidazole therapy or

3) Severe Clostridium difficile infection (defined as WBC >15 X 10^9/L, serum creatinine >=1.5 times baseline, hypotension, or shock) or documented or impending toxic megacolon or

4) Clostridium difficile infection if there is intolerance or side effects to metronidazole therapy.

Special authorization for all criteria may be granted for 3 months."

*Special Authorization is only required when the prescriber prescribing the medication is not a Specialist in Infectious Diseases or a designated prescriber.

All requests (including renewal requests) for oral vancomycin must be completed using the Oral Vancomycin/Fidaxomicin Special Authorization Request Form (ABC 60014).

125 MG (BASE) ORAL CAPSULE

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>JPC</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002407744</td>
<td>JAMP-VANCOMYCIN</td>
<td></td>
<td>$5.1800</td>
</tr>
<tr>
<td>00000800430</td>
<td>VANCOCIN</td>
<td></td>
<td>$5.1800</td>
</tr>
</tbody>
</table>

The DBL is not a prescribing or a diagnostic tool. Prescribers should refer to drug monographs and utilize professional judgment.
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

ALBERTA DRUG BENEFIT LIST

VANCOMYCIN HCL
(Refer to Section 1 - Restricted Benefits of the Alberta Drug Benefit List for coverage of the product when prescribed by a Specialist in Infectious Diseases or a designated prescriber.)

"For the treatment of:

1) Clostridium difficile infection 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 infection with symptoms after 2 courses of metronidazole therapy or

3) Severe Clostridium difficile infection (defined as WBC >15 X 10^9/L, serum creatinine >=1.5 times baseline, hypotension, or shock) or documented or impending toxic megacolon or

4) Clostridium difficile infection if there is intolerance or side effects to metronidazole therapy.

Special authorization for all criteria may be granted for 3 months."*

*Special Authorization is only required when the prescriber prescribing the medication is not a Specialist in Infectious Diseases or a designated prescriber.

All requests (including renewal requests) for oral vancomycin must be completed using the Oral Vancomycin/Fidaxomicin Special Authorization Request Form (ABC 60014).

<table>
<thead>
<tr>
<th>250 MG (BASE)</th>
<th>ORAL CAPSULE</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002407752</td>
<td>JAMP-VANCOMYCIN   JPC $ 10.3600</td>
</tr>
<tr>
<td>00000788716</td>
<td>VANCOCIN       MLJ $ 10.3600</td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>0.5 MG (BASE)</th>
<th>ORAL TABLET</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002291177</td>
<td>CHAMPIX PFI $ 1.8437</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>1 MG (BASE)</th>
<th>ORAL TABLET</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002291185</td>
<td>CHAMPIX PFI $ 1.8432</td>
</tr>
</tbody>
</table>
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.

<table>
<thead>
<tr>
<th>0.5 MG * 1 MG</th>
<th>ORAL</th>
<th>TABLET</th>
<th>00002298309</th>
<th>CHAMPIX (STARTER PACK)</th>
<th>PFI</th>
<th>$ 1.8370</th>
</tr>
</thead>
</table>
VEDOLIZUMAB
Moderately to Severely Active Crohn's Disease

"Special authorization coverage may be approved for coverage of vedolizumab for the reduction in signs and symptoms and induction and maintenance of clinical remission of Moderately to Severely Active Crohn's Disease in patients who meet the following criteria:

- vedolizumab must be prescribed by a Specialist in Gastroenterology or a physician appropriately trained by the University of Alberta or the University of Calgary and recognized as a prescriber by Alberta Blue Cross for coverage for the treatment of Moderately to Severely Active Crohn's Disease patients ('Specialist').
- Patients must be 18 years of age or older to be considered for coverage of vedolizumab.
- Patients will be limited to receiving one dose of vedolizumab per prescription at their pharmacy.
- Patients may be allowed to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy (both primary loss of response and secondary loss of response) or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

Prior to initiation of vedolizumab therapy for New Patients:
'New Patients' are patients who have never been treated with vedolizumab by any health care provider.
Moderately to Severely Active Crohn's Disease:
Prior to initiation of vedolizumab therapy, New Patients must have a current Modified (without the physical exam) Harvey Bradshaw Index score of greater than or equal to 7 (New Patient's Baseline Score), AND be Refractory.

Refractory is defined as one or more of the following:
1) Serious adverse effects or reactions to the treatments specified below; OR
2) Contraindications (as defined in product monographs) to the treatments specified below; OR
3) Previous documented lack of effect at doses and for duration of all treatments specified below:
   a) mesalamine: minimum of 3 grams/day for a minimum of 6 weeks; AND refractory to, or dependent on, glucocorticoids: following at least one tapering dosing schedule of 40 mg/day, tapering by 5 mg each week to 20 mg, then tapering by 2.5 mg each week to zero, or similar. [Note: Patients who have used the above treatments in combination will not be required to be challenged with individual treatments as monotherapy]
   AND
   b) Immunosuppressive therapy as follows:
      - Azathioprine: minimum of 2 mg/kg/day for a minimum of 3 months; OR
      - 6-mercaptopurine: minimum of 1 mg/kg/day for a minimum of 3 months; OR
      - Methotrexate: minimum or 15 mg/week for a minimum of 3 months.
      OR
      - Immunosuppressive therapy discontinued at less than 3 months due to serious adverse effects or reactions.

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
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

ALBERTA DRUG BENEFIT LIST

VEDOLIZUMAB

- been treated with vedolizumab by any health care provider).
- 'Induction Dosing' means a maximum of one 300 mg dose of vedolizumab per New Patient at 0, 2 and 6 weeks (for a maximum total of three doses).
- New Patients are eligible to receive Induction Dosing only once, after which time the Maintenance Dosing for New Patients and Continued Coverage for Maintenance Dosing criteria will apply.

Maintenance Dosing:
- 'Maintenance Dosing' means one 300 mg dose of vedolizumab per patient every eight (8) weeks for a period of 12 months to:
  - New Patients following the completion of Induction Dosing; OR
  - Existing Patients, who are patients that are being treated, or have previously been treated, with vedolizumab.

Maintenance Dosing for New Patients after Completion of Induction Dosing:
- The New Patient must be assessed by a Specialist between weeks 10 and 14 after the initiation of Induction Dosing to determine response by obtaining a Modified Harvey Bradshaw Index score for patients with Moderately to Severely Active Crohn's Disease; AND
- The Specialist must confirm the Modified Harvey Bradshaw Index score shows a decrease from the New Patient's Baseline Score of greater than or equal to 3 points for patients with Moderately to Severely Active Crohn's.

Maintenance Dosing for Existing Patients:
- The patient must be assessed by a Specialist at least 4 to 8 weeks after the day the last dose of vedolizumab was administered to the patient and prior to administration of the next dose to obtain: a Modified Harvey Bradshaw Index Score (Existing Patient's Baseline Score) for Moderately to Severely Active Crohn's; AND
- these measures must be provided to Alberta Blue Cross for assessment for continued coverage for maintenance dosing.

Continued Coverage for Maintenance Dosing:
- Continued coverage may be considered for one 300 mg dose of vedolizumab per patient provided no more often than every 8 weeks for a period of 12 months, if the following criteria are met at the end of each 12 month period:
  - The New Patient or the Existing Patient must be assessed by a Specialist at least 4 to 6 weeks after the day the last dose of vedolizumab was administered to the patient and prior to the administration of the next dose to obtain a Modified Harvey Bradshaw Index Score for Moderately to Severely Active Crohn's; AND
  - For New Patients: The Specialist must confirm that the patient has maintained a greater than or equal to 3 point decrease from the New Patient's Baseline Score for Moderately to Severely Active Crohn's; OR
  - For Existing Patients: The Specialist must confirm that the patient has maintained the Existing Patient's Baseline Score."

All requests (including renewal requests) for vedolizumab for Moderately to Severely Active Crohn's Disease must be completed using the Adalimumab/Vedolizumab for Crohn's/Infliximab for Crohn's/Fistulizing Crohn's Special Authorization Request Form (ABC 60031).

Ulcerative Colitis

"Special authorization coverage may be provided for the reduction in signs and symptoms and induction and maintenance of clinical remission of Ulcerative Colitis in adult patients (18 years of age or older) with active disease (characterized by a partial Mayo score >4 prior to initiation of biologic therapy) and who are refractory or intolerant to:
- mesalamine: minimum of 4 grams/day for a minimum of 4 weeks

AND

- corticosteroids (failure to respond to prednisone 40 mg daily for 2 weeks, or; steroid dependent
VEDOLIZUMAB
i.e. failure to taper off steroids without recurrence of disease or disease requiring a second dose of steroids within 12 months of previous dose).
'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

Immunosuppressive therapy as follows may also be initiated if in the clinician's judgment a trial is warranted:
i) Azathioprine: minimum of 2 mg/kg/day for a minimum of 2 months; OR
ii) 6-mercaptopurine: minimum of 1 mg/kg/day for a minimum of 2 months

For coverage, this drug must be prescribed by a Specialist in Gastroenterology or a physician appropriately trained by the University of Alberta or the University of Calgary and recognized as a prescriber by Alberta Blue Cross ('Specialist').

Initial coverage may be approved for three doses of 300 mg of vedolizumab at 0, 2 and 6 weeks.

- Patients will be limited to receiving a one dose of vedolizumab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond three doses, the patient must meet the following criteria:
1) The patient must be assessed by a Specialist between weeks 10 and 12 after the initiation of therapy to determine response.
2) The Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
   - a decrease in the partial Mayo score of greater than or equal to 2 points

Following this assessment, continued coverage may be approved for a dose of 300 mg every 8 weeks for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by a Specialist in Gastroenterology to determine response;
2) The Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
   - a decrease in the partial Mayo score of greater than or equal to 2 points from the score prior to initiation of vedolizumab therapy.

All requests (including renewal requests) for vedolizumab for Ulcerative Colitis must be completed using the Adalimumab/Golimumab/Infliximab/Vedolizumab for Ulcerative Colitis Special Authorization Request Form (ABC 60008).

300 MG / VIAL   INJECTION
00002436841 ENTYVIO TAK $ 3290.0000

The DBL is not a prescribing or a diagnostic tool. Prescribers should refer to drug monographs and utilize professional judgment.
# ALBERTA DRUG BENEFIT LIST

## CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

### VORICONAZOLE

(Refer to Section 1 - Restricted Benefits of the Alberta Drug Benefit List for coverage of the product when prescribed by a Specialist in Infectious Diseases or a designated prescriber.)

"For the treatment of invasive aspergillosis for post-hospital discharge only."

"For treatment of culture proven invasive candidiasis with documented resistance to fluconazole."

"This medication must be prescribed in consultation with a specialist in Infectious Diseases."

*Special Authorization is only required when the prescriber prescribing the medication is not a Specialist in Infectious Diseases or a designated prescriber.

<table>
<thead>
<tr>
<th>Strength</th>
<th>Brand Name</th>
<th>Manufacturer</th>
<th>Price ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>50 MG Tablet</td>
<td>APO-VORICONAZOLE</td>
<td>APX</td>
<td>3.1958</td>
</tr>
<tr>
<td></td>
<td>SANDOZ VORICONAZOLE</td>
<td>SDZ</td>
<td>3.1958</td>
</tr>
<tr>
<td></td>
<td>TEVA-VORICONAZOLE</td>
<td>TEV</td>
<td>3.1958</td>
</tr>
<tr>
<td>200 MG Tablet</td>
<td>VFEND</td>
<td>PFI</td>
<td>13.0387</td>
</tr>
<tr>
<td>40 MG Suspension</td>
<td>VFEND</td>
<td>PFI</td>
<td>10.2850</td>
</tr>
<tr>
<td>200 MG Injection</td>
<td>VFEND</td>
<td>PFI</td>
<td>156.2700</td>
</tr>
</tbody>
</table>
ZAFIRLUKAST
(Refer to 48:10.24 of the Alberta 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 60039).

The following product(s) are eligible for auto-renewal.

| 20 MG ORAL TABLET | 00002236606 ACCOLATE | AZC | $0.7974 |
ZOLEDRONIC ACID

Osteoporosis:

"For the treatment of postmenopausal osteoporosis in women who have a high 10-year risk (i.e., greater than 20%) of experiencing a major osteoporotic fracture, as demonstrated by 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

AND

at least one of the following:

1) For whom oral bisphosphonates are contraindicated due to an abnormality of the esophagus which delays esophageal emptying;

OR

2) Who have demonstrated severe gastrointestinal intolerance to a course of therapy with either alendronate or risedronate. Severe gastrointestinal intolerance is defined as manifested by weight loss or vomiting directly attributable to the oral bisphosphonates.

OR

3) Who had an unsatisfactory response (defined as a fragility fracture despite adhering to oral alendronate or risedronate treatment fully for 1 year and evidence of a decline in BMD below pre-treatment baseline level).

Special Authorization may be granted for 12 months.

- Patients will be limited to receiving one dose of zoledronic acid per prescription at their pharmacy.

- Coverage cannot be provided for two or more osteoporosis medications (alendronate, denosumab, raloxifene, risedronate, zoledronic acid) when these medications are intended for use as combination therapy.

- Requests for other osteoporosis medications covered via special authorization will not be considered until 6 months after the last dose of denosumab 60 mg/syr injection syringe.

- Requests for other osteoporosis medications covered via special authorization will not be considered until 12 months after the last dose of zoledronic acid 0.05 mg/ml injection.

- This product is eligible for auto-renewal for the treatment of osteoporosis.

All requests for zoledronic acid for osteoporosis must be completed using the Denosumab/Zoledronic Acid for Osteoporosis Special Authorization Request Form (ABC 60007).

Paget's Disease:

"For the treatment of Paget's disease. Special Authorization for this criterion may be granted for one dose per 12 month period."

"Coverage cannot be provided for two or more medications used in the treatment of Paget's disease when these medications are intended for use in combination or when therapy with two or more medications overlap."
ZOLEDRONIC ACID

0.05 MG / ML INJECTION

<table>
<thead>
<tr>
<th>Product Code</th>
<th>Brand Name</th>
<th>Type</th>
<th>Unit Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002415100</td>
<td>TARO-ZOLEDRONIC ACID</td>
<td>TAR</td>
<td>$3.3540</td>
</tr>
<tr>
<td>00002422433</td>
<td>ZOLEDRONIC ACID</td>
<td>DRL</td>
<td>$3.3540</td>
</tr>
<tr>
<td>00002269198</td>
<td>ACLASTA</td>
<td>NOV</td>
<td>$6.9713</td>
</tr>
</tbody>
</table>

"For the treatment of tumor-induced hypercalcemia in patients with documented evidence of intolerance or lack of response to clodronate or pamidronate.

For the prevention of skeletal-related events in patients with metastatic castration-resistant prostate cancer (CRPC) with one or more bony metastases.

Special authorization may be granted for 6 months."

The following product(s) are eligible for auto-renewal.

0.8 MG / ML INJECTION

<table>
<thead>
<tr>
<th>Product Code</th>
<th>Brand Name</th>
<th>Type</th>
<th>Unit Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002415186</td>
<td>TARO-ZOLEDRONIC ACID CONCENTRATE</td>
<td>TAR</td>
<td>$38.7856</td>
</tr>
<tr>
<td>00002407639</td>
<td>ZOLEDRONIC ACID</td>
<td>TEV</td>
<td>$38.7856</td>
</tr>
<tr>
<td>00002444739</td>
<td>ZOLEDRONIC ACID</td>
<td>MDA</td>
<td>$38.7856</td>
</tr>
<tr>
<td>00002401606</td>
<td>ZOLEDRONIC ACID-Z</td>
<td>SDZ</td>
<td>$38.7856</td>
</tr>
<tr>
<td>00002422425</td>
<td>ZOLEDRONIC ACID CONCENTRATE</td>
<td>DRL</td>
<td>$38.7856</td>
</tr>
<tr>
<td>0000248296</td>
<td>ZOMETA CONCENTRATE</td>
<td>NOV</td>
<td>$115.7940</td>
</tr>
</tbody>
</table>

ZOMIG

(Refer to 28:32.28 of the Alberta Drug Benefit List for coverage of patients 18 to 64 years of age inclusive.)

"For the treatment of acute migraine attacks in patients 65 years of age and older where other standard therapy has failed."

"For the treatment of acute migraine attacks in patients 65 years of age and older who have been using zolmitriptan prior to turning 65."

"Special authorization for both criteria may be granted for 24 months."

In order to comply with the first criteria, information is required regarding previous medications utilized and the patient's response to therapy.

The following product(s) are eligible for auto-renewal.

2.5 MG ORAL TABLET

<table>
<thead>
<tr>
<th>Product Code</th>
<th>Brand Name</th>
<th>Type</th>
<th>Unit Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002380951</td>
<td>APO-ZOMITRIPTAN</td>
<td>APX</td>
<td>$3.5375</td>
</tr>
<tr>
<td>00002421623</td>
<td>JAMP-ZOMITRIPTAN</td>
<td>JPC</td>
<td>$3.5375</td>
</tr>
<tr>
<td>00002399458</td>
<td>MAR-ZOMITRIPTAN</td>
<td>MAR</td>
<td>$3.5375</td>
</tr>
<tr>
<td>00002419521</td>
<td>MINT-ZOMITRIPTAN</td>
<td>MPI</td>
<td>$3.5375</td>
</tr>
<tr>
<td>00002369036</td>
<td>MYLAN-ZOMITRIPTAN</td>
<td>MYP</td>
<td>$3.5375</td>
</tr>
<tr>
<td>00002421534</td>
<td>NAT-ZOMITRIPTAN</td>
<td>NTP</td>
<td>$3.5375</td>
</tr>
<tr>
<td>00002324229</td>
<td>PMS-ZOMITRIPTAN</td>
<td>PMS</td>
<td>$3.5375</td>
</tr>
<tr>
<td>00002362988</td>
<td>SANDOZ ZOMITRIPTAN</td>
<td>SDZ</td>
<td>$3.5375</td>
</tr>
<tr>
<td>00002313960</td>
<td>TEVA-ZOMITRIPTAN</td>
<td>TEV</td>
<td>$3.5375</td>
</tr>
<tr>
<td>00002238660</td>
<td>ZOMIG</td>
<td>AZC</td>
<td>$14.8100</td>
</tr>
</tbody>
</table>

2.5 MG ORAL DISPERSIBLE TABLET

<table>
<thead>
<tr>
<th>Product Code</th>
<th>Brand Name</th>
<th>Type</th>
<th>Unit Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002428237</td>
<td>JAMP-ZOMITRIPTAN ODT</td>
<td>JPC</td>
<td>$1.7532</td>
</tr>
<tr>
<td>00002428474</td>
<td>SEPTA-ZOMITRIPTAN-ODT</td>
<td>SEP</td>
<td>$1.7532</td>
</tr>
<tr>
<td>00002438763</td>
<td>VAN-ZOMITRIPTAN ODT</td>
<td>VAN</td>
<td>$1.7532</td>
</tr>
<tr>
<td>00002243045</td>
<td>ZOMIG RAPIMELT</td>
<td>AZC</td>
<td>$14.8100</td>
</tr>
</tbody>
</table>

5 MG / DOSE NASAL UNIT DOSE SPRAY

<table>
<thead>
<tr>
<th>Product Code</th>
<th>Brand Name</th>
<th>Type</th>
<th>Unit Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>00002248993</td>
<td>ZOMIG</td>
<td>AZC</td>
<td>$14.8100</td>
</tr>
</tbody>
</table>