Updates to the Alberta Drug Benefit List

Effective February 1, 2020

Alberta Government
Inquiries should be directed to:

**Pharmacy Services**  
Alberta Blue Cross  
10009 108 Street NW  
Edmonton AB  T5J 3C5

Telephone Number:  
(780) 498-8370 (Edmonton)  
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(780) 498-8406  
1-877-305-9911 (Toll Free)

**Website:** [https://www.alberta.ca/drug-benefit-list-and-drug-review-process.aspx](https://www.alberta.ca/drug-benefit-list-and-drug-review-process.aspx)

Administered by Alberta Blue Cross on behalf of Alberta Health.

The Drug Benefit List (DBL) is a list of drugs for which coverage may be provided to program participants. The DBL is not intended to be, and must not be used as a diagnostic or prescribing tool. Inclusion of a drug on the DBL does not mean or imply that the drug is fit or effective for any specific purpose. Prescribing professionals must always use their professional judgment and should refer to product monographs and any applicable practice guidelines when prescribing drugs. The product monograph contains information that may be required for the safe and effective use of the product.

Copies of the *Alberta Drug Benefit List* are available from Pharmacy Services, Alberta Blue Cross at the address shown above.

Binder and contents: **$42.00** ($40.00 + $2.00 G.S.T.)  
Contents only: **$36.75** ($35.00 + $1.75 G.S.T.)

A cheque or money order must accompany the request for copies.
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**Special Authorization**

The following drug product(s) will be considered for coverage by Special Authorization for patients covered under Alberta government-sponsored drug programs.

**New Drug Product(s) Available by Special Authorization**

<table>
<thead>
<tr>
<th>Trade Name / Strength / Form</th>
<th>Generic Description</th>
<th>DIN</th>
<th>MFR</th>
</tr>
</thead>
<tbody>
<tr>
<td>SKYRIZI 75 MG / SYRINGE INJECTION</td>
<td>RISANKIZUMAB</td>
<td>00002487454</td>
<td>ABV</td>
</tr>
</tbody>
</table>

**New Drug Product(s) Available by Step Therapy / Special Authorization**

<table>
<thead>
<tr>
<th>Trade Name / Strength / Form</th>
<th>Generic Description</th>
<th>DIN</th>
<th>MFR</th>
</tr>
</thead>
<tbody>
<tr>
<td>TRELEGY ELLIPTA 100 MCG / DOSE / 62.5 MCG / DOSE / 25 MCG / DOSE INHALATION METERED INHALATION POWDER</td>
<td>FLUTICASONE Furoate / UMECLIDINUM BROMIDE / VILANTEROL TRIFENATATE</td>
<td>00002474522</td>
<td>GSK</td>
</tr>
</tbody>
</table>

**New Drug Product(s) Available by Restricted Benefit / Special Authorization**

<table>
<thead>
<tr>
<th>Trade Name / Strength / Form</th>
<th>Generic Description</th>
<th>DIN</th>
<th>MFR</th>
</tr>
</thead>
<tbody>
<tr>
<td>CRESEMBA 100 MG CAPSULE</td>
<td>ISAVUCONAZONIUM SULFATE</td>
<td>00002483971</td>
<td>AVP</td>
</tr>
<tr>
<td>CRESEMBA 200 MG / VIAL INJECTION</td>
<td>ISAVUCONAZONIUM SULFATE</td>
<td>00002483998</td>
<td>AVP</td>
</tr>
</tbody>
</table>

**Additional Brand(s) and/or Strength(s) of Drug Product(s) Available by Special Authorization**

<table>
<thead>
<tr>
<th>Trade Name / Strength / Form</th>
<th>Generic Description</th>
<th>DIN</th>
<th>MFR</th>
</tr>
</thead>
<tbody>
<tr>
<td>JAMP RIVASTIGMINE 1.5 MG CAPSULE</td>
<td>RIVASTIGMINE HYDROGEN TARTRATE</td>
<td>00002485362</td>
<td>JPC</td>
</tr>
<tr>
<td>JAMP RIVASTIGMINE 3 MG CAPSULE</td>
<td>RIVASTIGMINE HYDROGEN TARTRATE</td>
<td>00002485370</td>
<td>JPC</td>
</tr>
<tr>
<td>JAMP RIVASTIGMINE 4.5 MG CAPSULE</td>
<td>RIVASTIGMINE HYDROGEN TARTRATE</td>
<td>00002485389</td>
<td>JPC</td>
</tr>
<tr>
<td>JAMP RIVASTIGMINE 6 MG CAPSULE</td>
<td>RIVASTIGMINE HYDROGEN TARTRATE</td>
<td>00002485397</td>
<td>JPC</td>
</tr>
<tr>
<td>MINT-LACOSAMIDE 50 MG TABLET</td>
<td>LACOSAMIDE</td>
<td>00002490544</td>
<td>MPI</td>
</tr>
<tr>
<td>MINT-LACOSAMIDE 100 MG TABLET</td>
<td>LACOSAMIDE</td>
<td>00002490552</td>
<td>MPI</td>
</tr>
<tr>
<td>MINT-LACOSAMIDE 150 MG TABLET</td>
<td>LACOSAMIDE</td>
<td>00002490560</td>
<td>MPI</td>
</tr>
<tr>
<td>MINT-LACOSAMIDE 200 MG TABLET</td>
<td>LACOSAMIDE</td>
<td>00002490579</td>
<td>MPI</td>
</tr>
<tr>
<td>MYLAN-FINGOLIMOD 0.5 MG CAPSULE</td>
<td>FINGOLIMOD HYDROCHLORIDE</td>
<td>00002469715</td>
<td>MYP</td>
</tr>
<tr>
<td>PMS-FINGOLIMOD 0.5 MG CAPSULE</td>
<td>FINGOLIMOD HYDROCHLORIDE</td>
<td>00002469782</td>
<td>PMS</td>
</tr>
<tr>
<td>SANDOZ FINGOLIMOD 0.5 MG CAPSULE</td>
<td>FINGOLIMOD HYDROCHLORIDE</td>
<td>00002482606</td>
<td>SDZ</td>
</tr>
<tr>
<td>TEVA-FINGOLIMOD 0.5 MG CAPSULE</td>
<td>FINGOLIMOD HYDROCHLORIDE</td>
<td>00002469561</td>
<td>TEV</td>
</tr>
</tbody>
</table>

EFFECTIVE FEBRUARY 1, 2020
# Updates to the Alberta Drug Benefit List

**Effective February 1, 2020**

## Drug Product(s) with Changes to Criteria for Coverage

<table>
<thead>
<tr>
<th>Trade Name / Strength / Form</th>
<th>Generic Description</th>
<th>DIN</th>
<th>MFR</th>
</tr>
</thead>
<tbody>
<tr>
<td>APTIOM 200 MG TABLET</td>
<td>ESLICARBAZEPINE ACETATE</td>
<td>00002426862</td>
<td>SUN</td>
</tr>
<tr>
<td>APTIOM 400 MG TABLET</td>
<td>ESLICARBAZEPINE ACETATE</td>
<td>00002426870</td>
<td>SUN</td>
</tr>
<tr>
<td>APTIOM 600 MG TABLET</td>
<td>ESLICARBAZEPINE ACETATE</td>
<td>00002426889</td>
<td>SUN</td>
</tr>
<tr>
<td>APTIOM 800 MG TABLET</td>
<td>ESLICARBAZEPINE ACETATE</td>
<td>00002426897</td>
<td>SUN</td>
</tr>
<tr>
<td>ENBREL 25 MG / VIAL INJECTION</td>
<td>ETANERCEPT</td>
<td>00002242903</td>
<td>AMG</td>
</tr>
<tr>
<td>ENBREL 50 MG / SYRINGE INJECTION</td>
<td>ETANERCEPT</td>
<td>00002274728</td>
<td>AMG</td>
</tr>
<tr>
<td>FYCOMPA 2 MG TABLET</td>
<td>PERAMPANEL</td>
<td>00002404516</td>
<td>EIS</td>
</tr>
<tr>
<td>FYCOMPA 4 MG TABLET</td>
<td>PERAMPANEL</td>
<td>00002404524</td>
<td>EIS</td>
</tr>
<tr>
<td>FYCOMPA 6 MG TABLET</td>
<td>PERAMPANEL</td>
<td>00002404532</td>
<td>EIS</td>
</tr>
<tr>
<td>FYCOMPA 8 MG TABLET</td>
<td>PERAMPANEL</td>
<td>00002404540</td>
<td>EIS</td>
</tr>
<tr>
<td>FYCOMPA 10 MG TABLET</td>
<td>PERAMPANEL</td>
<td>00002404559</td>
<td>EIS</td>
</tr>
<tr>
<td>FYCOMPA 12 MG TABLET</td>
<td>PERAMPANEL</td>
<td>00002404567</td>
<td>EIS</td>
</tr>
<tr>
<td>HUMIRA (40 MG / 0.8 ML) 40 MG / SYRINGE INJECTION</td>
<td>ADALIMUMAB</td>
<td>00002258595</td>
<td>ABV</td>
</tr>
<tr>
<td>STELARA (0.5 ML) 45 MG VIAL OR SYRINGE INJECTION</td>
<td>USTEKINUMAB</td>
<td>00002320673</td>
<td>JAI</td>
</tr>
<tr>
<td>STELARA (0.1 ML SYRINGE) 90 MG SYRINGE INJECTION</td>
<td>USTEKINUMAB</td>
<td>00002320681</td>
<td>JAI</td>
</tr>
</tbody>
</table>

## Restricted Benefit(s)

### Additional Brand(s) and/or Strength(s) of Drug Product(s) Available by Restricted Benefit

<table>
<thead>
<tr>
<th>Trade Name / Strength / Form</th>
<th>Generic Description</th>
<th>DIN</th>
<th>MFR</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACCEL-LEFLUNOMIDE 10 MG TABLET</td>
<td>LEFLUNOMIDE</td>
<td>00002478862</td>
<td>ACP</td>
</tr>
<tr>
<td>ACCEL-LEFLUNOMIDE 20 MG TABLET</td>
<td>LEFLUNOMIDE</td>
<td>00002478870</td>
<td>ACP</td>
</tr>
</tbody>
</table>

### Added Product(s)

<table>
<thead>
<tr>
<th>Trade Name / Strength / Form</th>
<th>Generic Description</th>
<th>DIN</th>
<th>MFR</th>
</tr>
</thead>
<tbody>
<tr>
<td>IPRATROPIUM BROMIDE / SALBUTAMOL SULPHATE 0.2 MG / ML / 1 MG / ML INHALATION SOLUTION</td>
<td>IPRATROPIUM BROMIDE/ SALBUTAMOL SULFATE</td>
<td>00002483394</td>
<td>MDA</td>
</tr>
<tr>
<td>JAMP DUTASTERIDE 0.5 MG CAPSULE</td>
<td>DUTASTERIDE</td>
<td>00002484870</td>
<td>JPC</td>
</tr>
<tr>
<td>JAMP-CHOLESTYRAMINE 4 G / ORAL POWDER PACKET</td>
<td>CHOLESTYRAMINE RESIN</td>
<td>00002478595</td>
<td>JPC</td>
</tr>
<tr>
<td>MED-LATANOPROST-TIMOLOL 0.005 % / 0.5 % OPHTHALMIC SOLUTION</td>
<td>LATANOPROST/ TIMOLOL MALEATE</td>
<td>00002454505</td>
<td>GMP</td>
</tr>
<tr>
<td>RIVA-DAPSONE 100 MG TABLET</td>
<td>DAPSONE</td>
<td>00002489058</td>
<td>RIV</td>
</tr>
</tbody>
</table>
UPDATES TO THE ALBERTA DRUG BENEFIT LIST

Added Product(s), continued

<table>
<thead>
<tr>
<th>Trade Name / Strength / Form</th>
<th>Generic Description</th>
<th>DIN</th>
<th>MFR</th>
</tr>
</thead>
<tbody>
<tr>
<td>RIVA-LEVETIRACETAM 250 MG TABLET</td>
<td>LEVETIRACETAM</td>
<td>00002482274</td>
<td>RIV</td>
</tr>
<tr>
<td>RIVA-LEVETIRACETAM 500 MG TABLET</td>
<td>LEVETIRACETAM</td>
<td>00002482282</td>
<td>RIV</td>
</tr>
<tr>
<td>RIVA-LEVETIRACETAM 750 MG TABLET</td>
<td>LEVETIRACETAM</td>
<td>00002482290</td>
<td>RIV</td>
</tr>
<tr>
<td>VALSARTAN HCT 320 MG / 12.5 MG TABLET</td>
<td>VALSARTAN/HYDROCHLORTHIAZIDE</td>
<td>00002384760</td>
<td>SIV</td>
</tr>
</tbody>
</table>

New Established Interchangeable (IC) Grouping(s)

The following IC Grouping(s) have been established and LCA pricing will be applied effective March 1, 2020.

<table>
<thead>
<tr>
<th>Generic Description</th>
<th>Strength / Form</th>
<th>New LCA Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>FINGOLIMOD HYDROCHLORIDE</td>
<td>0.5 MG CAPSULE</td>
<td>21.7381</td>
</tr>
</tbody>
</table>

Least Cost Alternative (LCA) Price Change(s)

The following established IC Grouping(s) are affected and a revised LCA price has been established. Groupings affected by a price change, will be effective March 1, 2020.

Please review the online Alberta Drug Benefit List at https://www.ab.bluecross.ca/dbl/idbl_main1.php for further information.

<table>
<thead>
<tr>
<th>Generic Description</th>
<th>Strength / Form</th>
<th>New LCA Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>CHOLESTYRAMINE RESIN</td>
<td>4 G / ORAL POWDER PACKET</td>
<td>0.3693</td>
</tr>
<tr>
<td>DAPSONE</td>
<td>100 MG TABLET</td>
<td>0.7031</td>
</tr>
<tr>
<td>IPRATROPIUM BROMIDE/ SALBUTAMOL SULFATE</td>
<td>0.2 MG / ML / 1 MG / ML INHALATION SOLUTION</td>
<td>0.3226</td>
</tr>
</tbody>
</table>

Product(s) with a Price Change

The following product(s) had a Price Change. The previous higher price will be recognized until February 29, 2020. For products within an established IC Grouping, the LCA price may apply.

<table>
<thead>
<tr>
<th>Trade Name / Strength / Form</th>
<th>Generic Description</th>
<th>DIN</th>
<th>MFR</th>
</tr>
</thead>
<tbody>
<tr>
<td>CHOLESTYRAMINE-ODAN 4 G / ORAL POWDER PACKET</td>
<td>CHOLESTYRAMINE RESIN</td>
<td>00002455609</td>
<td>ODN</td>
</tr>
<tr>
<td>MAR-DAPSONE 100 MG TABLET</td>
<td>DAPSONE</td>
<td>00002481227</td>
<td>MAR</td>
</tr>
<tr>
<td>METHADOSE 10 MG / ML ORAL LIQUID</td>
<td>METHADONE HCL</td>
<td>00002394596</td>
<td>MAL</td>
</tr>
<tr>
<td>METHADOSE SUGAR FREE 10 MG / ML ORAL LIQUID</td>
<td>METHADONE HCL</td>
<td>00002394618</td>
<td>MAL</td>
</tr>
<tr>
<td>OLESTYR LIGHT 4 G / ORAL POWDER PACKET</td>
<td>CHOLESTYRAMINE RESIN</td>
<td>00000890960</td>
<td>PMS</td>
</tr>
<tr>
<td>OLESTYR REGULAR 4 G / ORAL POWDER PACKET</td>
<td>CHOLESTYRAMINE RESIN</td>
<td>00002210320</td>
<td>PMS</td>
</tr>
</tbody>
</table>
### Product(s) with a Price Change, continued

<table>
<thead>
<tr>
<th>Trade Name / Strength / Form</th>
<th>Generic Description</th>
<th>DIN</th>
<th>MFR</th>
</tr>
</thead>
<tbody>
<tr>
<td>TEVA-COMBO STERINEBS 0.2 MG / ML / 1 MG / ML INHALATION SOLUTION</td>
<td>IPRATROPIUM BROMIDE/ SALBUTAMOL SULFATE</td>
<td>00002272695</td>
<td>TEV</td>
</tr>
</tbody>
</table>

### Discontinued Listing(s)

Notification of discontinuation has been received from the manufacturer(s). The Alberta government-sponsored drug programs previously covered the following drug product(s). Effective February 1, 2020, the listed product(s) will no longer be a benefit and will not be considered for coverage by Special Authorization. A transition period will be applied and, as of March 1, 2020 claims will no longer pay for these product(s).

<table>
<thead>
<tr>
<th>Trade Name / Strength / Form</th>
<th>Generic Description</th>
<th>DIN</th>
<th>MFR</th>
</tr>
</thead>
<tbody>
<tr>
<td>APO-ALENDRONATE 10 MG TABLET</td>
<td>ALENDRONATE SODIUM</td>
<td>00002248728</td>
<td>APO</td>
</tr>
<tr>
<td>APO-HYDROMORPHONE CR 3 MG CONTROLLED-RELEASE CAPSULE</td>
<td>HYDROMORPHONE HCL</td>
<td>00002476614</td>
<td>APO</td>
</tr>
<tr>
<td>APO-HYDROMORPHONE CR 4.5 MG CONTROLLED-RELEASE CAPSULE</td>
<td>HYDROMORPHONE HCL</td>
<td>00002476622</td>
<td>APO</td>
</tr>
<tr>
<td>APO-HYDROMORPHONE CR 6 MG CONTROLLED-RELEASE CAPSULE</td>
<td>HYDROMORPHONE HCL</td>
<td>00002476630</td>
<td>APO</td>
</tr>
<tr>
<td>APO-HYDROMORPHONE CR 9 MG CONTROLLED-RELEASE CAPSULE</td>
<td>HYDROMORPHONE HCL</td>
<td>00002476649</td>
<td>APO</td>
</tr>
<tr>
<td>APO-HYDROMORPHONE CR 12 MG CONTROLLED-RELEASE CAPSULE</td>
<td>HYDROMORPHONE HCL</td>
<td>00002476657</td>
<td>APO</td>
</tr>
<tr>
<td>APO-HYDROMORPHONE CR 18 MG CONTROLLED-RELEASE CAPSULE</td>
<td>HYDROMORPHONE HCL</td>
<td>00002476665</td>
<td>APO</td>
</tr>
<tr>
<td>APO-HYDROMORPHONE CR 24 MG CONTROLLED-RELEASE CAPSULE</td>
<td>HYDROMORPHONE HCL</td>
<td>00002476673</td>
<td>APO</td>
</tr>
<tr>
<td>APO-HYDROMORPHONE CR 30 MG CONTROLLED-RELEASE CAPSULE</td>
<td>HYDROMORPHONE HCL</td>
<td>00002476681</td>
<td>APO</td>
</tr>
<tr>
<td>COMBIVENT UDV 0.2 MG / ML / 1 MG / ML INHALATION SOLUTION</td>
<td>IPRATROPIUM BROMIDE/ SALBUTAMOL SULFATE</td>
<td>00002231675</td>
<td>BOE</td>
</tr>
<tr>
<td>LOSEC 10 MG SUSTAINED-RELEASE TABLET</td>
<td>OMEPRAZOLE</td>
<td>00002230737</td>
<td>AZC</td>
</tr>
<tr>
<td>MYLAN-MINOCYCLINE 50 MG CAPSULE</td>
<td>MINOCYCLINE HCL</td>
<td>00002230735</td>
<td>MYP</td>
</tr>
<tr>
<td>MYLAN-MINOCYCLINE 100 MG CAPSULE</td>
<td>MINOCYCLINE HCL</td>
<td>00002230736</td>
<td>MYP</td>
</tr>
<tr>
<td>SANDOZ ALENDRONATE 10 MG TABLET</td>
<td>ALENDRONATE SODIUM</td>
<td>00002288087</td>
<td>SDZ</td>
</tr>
<tr>
<td>SANDOZ CEFPROZIL 500 MG TABLET</td>
<td>CEFPROZIL</td>
<td>00002302187</td>
<td>SDZ</td>
</tr>
<tr>
<td>SANDOZ DILTIAZEM T 360 MG EXTENDED-RELEASE CAPSULE</td>
<td>DILTIAZEM HCL</td>
<td>00002245922</td>
<td>SDZ</td>
</tr>
<tr>
<td>SANDOZ PAROXETINE 20 MG TABLET</td>
<td>PAROXETINE HCL</td>
<td>00002431785</td>
<td>SDZ</td>
</tr>
<tr>
<td>TEVA-ARIPIPRAZOLE 5 MG TABLET</td>
<td>ARIPIPRAZOLE</td>
<td>00002464152</td>
<td>TEV</td>
</tr>
<tr>
<td>TEVA-LISINOPRIL (TYPE P) 20 MG TABLET</td>
<td>LISINOPRIL</td>
<td>00002285096</td>
<td>TEV</td>
</tr>
</tbody>
</table>
PART 2

Drug Additions
### CHOLESTYRAMINE RESIN

<table>
<thead>
<tr>
<th>4 G ORAL POWDER PACKET</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>00002455609 CHOLESTYRAMINE-ODAN ODN</td>
<td>$ 0.3693</td>
</tr>
<tr>
<td>00002478595 JAMP-CHOLESTYRAMINE JPC</td>
<td>$ 0.3693</td>
</tr>
<tr>
<td>00000890960 OLESTYR LIGHT PMS</td>
<td>$ 0.3693</td>
</tr>
<tr>
<td>00002210320 OLESTYR REGULAR PMS</td>
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</table>

### DAPSONE

<table>
<thead>
<tr>
<th>100 MG ORAL TABLET</th>
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</tr>
</thead>
<tbody>
<tr>
<td>00002481227 MAR-DAPSONE MAR</td>
<td>$ 0.7031</td>
</tr>
<tr>
<td>00002489058 RIVA-DAPSONE RIV</td>
<td>$ 0.7031</td>
</tr>
<tr>
<td>00002041510 DAPSONE NTI</td>
<td>$ 1.4061</td>
</tr>
</tbody>
</table>

### DUTASTERIDE

<table>
<thead>
<tr>
<th>0.5 MG ORAL CAPSULE</th>
<th></th>
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</thead>
<tbody>
<tr>
<td>00002404206 APO-DUTASTERIDE APX</td>
<td>$ 0.3027</td>
</tr>
<tr>
<td>00002469308 AURO-DUTASTERIDE AUR</td>
<td>$ 0.3027</td>
</tr>
<tr>
<td>00002429012 DUTASTERIDE SIV</td>
<td>$ 0.3027</td>
</tr>
<tr>
<td>00002443058 DUTASTERIDE SNS</td>
<td>$ 0.3027</td>
</tr>
<tr>
<td>00002484870 JAMP DUTASTERIDE JPC</td>
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### IPRATROPIUM BROMIDE/ SALBUTAMOL SULFATE

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<td>00002483394 IPRATROPIUM BROMIDE/SALBUTAMOL SULPHATE MDA</td>
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<td>00002272695 TEVA-COMBO STERINEBS TEV</td>
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### ISAVUCONAZONIUM SULFATE

This product is a benefit when prescribed by a Specialist in Infectious Diseases or a designated prescriber.

(Refer to Section 3 - Criteria for Special Authorization of Select Drug Products of the Alberta Drug Benefit List for eligibility when the prescriber prescribing the medication is not a Specialist in Infectious Diseases or a designated prescriber.)

<table>
<thead>
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<td>200 MG / VIAL INJECTION</td>
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### LATANOPROST/ TIMOLOL MALEATE

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<tr>
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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 FEBRUARY 1, 2020
**LEFLUNOMIDE**

RESTRICTED BENEFIT - This product is a benefit for the treatment of rheumatoid arthritis when the initial prescription is prescribed by a Specialist in Rheumatology or Internal Medicine.

### 10 MG ORAL TABLET

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**LEVETIRACETAM**

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PRODUCT IS NOT INTERCHANGEABLE

EFFECTIVE FEBRUARY 1, 2020
## METHADONE HCL

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## VALSARTAN/ HYDROCHLOROTHIAZIDE

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PART 3

Special Authorization
ADALIMUMAB
Ankylosing Spondylitis

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

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

- who are refractory or intolerant to:

at least TWO of the following
- Brenzys (etanercept)
- Cimzia (certolizumab pegol)
- Cosentyx (secukinumab)
- Erelzi (etanercept)
- Inflectra (infliximab)
- Renflexis (infliximab)

- Simponi (golimumab)

AND

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

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

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

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

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

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

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

Hidradenitis Suppurativa

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

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

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

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

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

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

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

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

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

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

Moderately to Severe Active Crohn’s Disease

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

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

CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

ADALIMUMAB
- 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 of 15 mg/week for a minimum of 3 months.
   OR
   - Immunosuppressive therapy discontinued at less than 3 months due to serious adverse effects or reactions;

AND
c) refractory or intolerant to at least TWO of the following:
   - Entyvio (vedolizumab)
   - Inflectra (infliximab)
   - Renflexis (infliximab).

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

Coverage Criteria for Moderately to Severely Active Crohn’s Disease
- New Patients must meet the criteria above prior to being considered for approval.
- All approvals are also subject to the following applicable criteria.

Induction Dosing for New Patients:
ADALIMUMAB

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

Maintenance Dosing:

‘Maintenance Dosing’ means one 40 mg dose of adalimumab per patient provided no more often than every other week starting at week 4 for a period of 12 months to:
- New Patients following the completion of Induction Dosing; OR
- Existing Patients, who are patients that are being treated, or have previously been treated, with adalimumab.

Maintenance Dosing for New Patients after Completion of Induction Dosing:

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

Maintenance Dosing for Existing Patients:

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

Continued Coverage for Maintenance Dosing:

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

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

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

Plaque Psoriasis

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

"Special authorization coverage may be provided for the reduction in signs and symptoms of severe, debilitating psoriasis in patients who:
- Have a total PASI of 10 or more and a DLQI of more than 10, OR
- Who have significant involvement of the face, palms of the hands, soles of the feet or genital region; AND

- Who are refractory or intolerant to:

at least THREE of the following:
- Cosentyx (secukinumab)
- Inflectra (infliximab)
- Renflexis (infliximab)
- Skyrizi (risankizumab)
- Taltz (ixekizumab);
AND

- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory, OR
- Cyclosporine (6 weeks treatment); AND
- Phototherapy (unless restricted by geographic location)

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

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

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

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

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

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

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

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

Polyarticular Juvenile Idiopathic Arthritis

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

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

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

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

Following this assessment, continued coverage may be approved for 24 mg per square meter body surface area.
ADALIMUMAB

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

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

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

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

Psoriatic Arthritis

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

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

AND

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

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

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

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

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

ADALIMUMAB
contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

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

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

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

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

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

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

at least FOUR of the following:
- Actemra (tocilizumab)
- Brenzys (etanercept)
- Cimzia (certolizumab pegol)
- Erelzi (etanercept)
- Inflectra (infliximab)
- Kevzara (sarilumab)
- Orencia (abatacept)
- Renflexis (infliximab)
- Simponi (golimumab)
- Xeljanz (tofacitinib)

AND

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

**CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

**adalimumab**

must have a trial of parenteral methotrexate before being accepted as refractory; AND
- Methotrexate with other disease modifying anti-rheumatic agent(s) (minimum 4 month trial) [e.g., methotrexate with hydroxychloroquine or methotrexate with sulfasalazine]; AND
- Leflunomide (minimum 10 week trial at 20 mg daily)

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

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

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

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

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

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

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

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

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EFFECTIVE FEBRUARY 1, 2020
ADALIMUMAB

Ulcerative Colitis

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

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

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

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

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

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

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

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

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

The DBL is not a prescribing or a diagnostic tool. Prescribers should refer to drug monographs and utilize professional judgment.
ADALIMUMAB
Special Authorization Request Form (ABC 60008).

**40 MG / SYR INJECTION SYRINGE**
- 00002258595 HUMIRA (40 MG/0.8 ML INJ SYR) ABV $ 762.5700

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

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

Special authorization may be granted for six months.

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

Each of these products is eligible for auto-renewal.

**200 MG ORAL TABLET**
- 00002426862 APTIOM SUN $ 9.8700

**400 MG ORAL TABLET**
- 00002426870 APTIOM SUN $ 9.8700

**600 MG ORAL TABLET**
- 00002426889 APTIOM SUN $ 9.8700

**800 MG ORAL TABLET**
- 00002426897 APTIOM SUN $ 9.8700
ETANERCEPT
25 MG / VIAL  INJECTION
00002242903  ENBREL  AMG  $ 200.7100

Ankylosing Spondylitis

***Effective March 1, 2018, all new Special Authorization requests for the treatment of Rheumatoid Arthritis or Ankylosing Spondylitis for etanercept-naive patients will be assessed for coverage with Brenzys or Erelzi. Effective June 1, 2019, all new Special Authorization requests for the treatment of Psoriatic Arthritis for etanercept-naive patients will be assessed for coverage with Erelzi. Enbrel will not be approved for new etanercept starts for patients with the indications stated above; however, coverage for Enbrel will continue for patients who are currently well maintained on Enbrel and are considered a 'responder' as defined in criteria.

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

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

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

- a BASDAI greater than or equal to 4 units, demonstrated on 2 occasions at least 8 weeks apart
- 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.
ETANERCEPT

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

- Reduction of the BASDAI score by at least 50% of the pre-treatment value or by 2 or more units, AND

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

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

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

Plaque Psoriasis

***Effective March 1, 2018, all new Special Authorization requests for the treatment of Rheumatoid Arthritis or Ankylosing Spondylitis for etanercept-naive patients will be assessed for coverage with Brenzys or Erelzi. Effective June 1, 2019, all new Special Authorization requests for the treatment of Psoriatic Arthritis for etanercept-naive patients will be assessed for coverage with Erelzi. Enbrel will not be approved for new etanercept starts for patients with the indications stated above; however, coverage for Enbrel will continue for patients who are currently well maintained on Enbrel and are considered a ‘responder’ as defined in criteria.

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

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

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

- Have a total PASI of 10 or more and a DLQI of more than 10, OR

- Who have significant involvement of the face, palms of the hands, soles of the feet or genital region; AND

- Who are refractory or intolerant to:

at least THREE of the following:

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

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

- Cyclosporine (6 weeks treatment); AND

- Phototherapy (unless restricted by geographic location)
ETANERCEPT

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/Ixekizumab/Risankizumab/Secukinumab/Ustekinumab for Plaque Psoriasis Special Authorization Request Form (ABC 60030).

Polyarticular Juvenile Idiopathic Arthritis

***Effective March 1, 2018, all new Special Authorization requests for the treatment of Rheumatoid Arthritis or Ankylosing Spondylitis for etanercept-naive patients will be assessed for coverage with Brenzys or Erelzi. Effective June 1, 2019, all new Special Authorization requests for the treatment of Psoriatic Arthritis for etanercept-naive patients will be assessed for coverage with Erelzi. Enbrel will not be approved for new etanercept starts for patients with the indications stated above; however, coverage for Enbrel will continue for patients who are currently well maintained on Enbrel and are considered a ‘responder’ as defined in criteria.

In addition, all new Special Authorization requests for the treatment of Polyarticular Juvenile Idiopathic Arthritis for etanercept-naive patients weighing 63 kg (138 pounds) or more will be
The DBL is not a prescribing or a diagnostic tool. Prescribers should refer to drug monographs and utilize professional judgment.

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**ETANERCEPT**

assessed for coverage with Erelzi. Enbrel will be approved for new etanercept starts for pediatric patients with Polyarticular Juvenile Idiopathic Arthritis weighing less than 63 kg, and coverage for Enbrel will continue for patients who are currently well maintained on Enbrel and are considered a ‘responder’ as defined in criteria.

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

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

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

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

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

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

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

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

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

Psoriatic Arthritis

***Effective March 1, 2018, all new Special Authorization requests for the treatment of Rheumatoid Arthritis or Ankylosing Spondylitis for etanercept-naive patients will be assessed for coverage with Brenzys or Erelzi. Effective June 1, 2019, all new Special Authorization requests for the treatment of Psoriatic Arthritis for etanercept-naive patients will be assessed for coverage with Erelzi. Enbrel will not be approved for new etanercept starts for patients with the indications stated above; however, coverage for Enbrel will continue for patients who are currently well maintained on Enbrel and are considered a ‘responder’ as defined in criteria.

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

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

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

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

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

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

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

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

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the...
ETANERCEPT

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

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

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

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

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

Rheumatoid Arthritis

***Effective March 1, 2018, all new Special Authorization requests for the treatment of Rheumatoid Arthritis or Ankylosing Spondylitis for etanercept-naive patients will be assessed for coverage with Brenzys or Erelzi. Effective June 1, 2019, all new Special Authorization requests for the treatment of Psoriatic Arthritis for etanercept-naive patients will be assessed for coverage with Erelzi. Enbrel will not be approved for new etanercept starts for patients with the indications stated above; however, coverage for Enbrel will continue for patients who are currently well maintained on Enbrel and are considered a 'responder' as defined in criteria.

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

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

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

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

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

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

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

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").
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- Initial coverage may be approved for 50 mg per week for 8 weeks.

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

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

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

- Patients will not be permitted to switch from anakinra to other biologic agents except under exceptional circumstances.

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

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

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

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

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

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

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

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

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

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

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

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

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

***Effective March 1, 2018, all new Special Authorization requests for the treatment of Rheumatoid Arthritis or Ankylosing Spondylitis for etanercept-naive patients will be assessed for coverage with Brenzys or Erelzi. Effective June 1, 2019, all new Special Authorization requests for the treatment of Psoriatic Arthritis for etanercept-naive patients will be assessed for coverage with Erelzi. Enbrel will not be approved for new etanercept starts for patients with the indications stated above; however, coverage for Enbrel will continue for patients who are currently well maintained on Enbrel and are considered a ‘responder’ as defined in criteria.

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

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

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

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

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

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

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

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

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

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

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

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

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

Plaque Psoriasis

***Effective March 1, 2018, all new Special Authorization requests for the treatment of Rheumatoid Arthritis or Ankylosing Spondylitis for etanercept-naive patients will be assessed for coverage with Brenzys or Erelzi. Effective June 1, 2019, all new Special Authorization requests for the treatment of Psoriatic Arthritis for etanercept-naive patients will be assessed for coverage with Erelzi. Enbrel will not be approved for new etanercept starts for patients with the indications stated above; however, coverage for Enbrel will continue for patients who are currently well maintained on Enbrel and are considered a ‘responder’ as defined in criteria.

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

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

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

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

at least THREE of the following:

- Cosentyx (secukinumab)
- Inflectra (infliximab)
- Renflexis (infliximab)
- Skyrizi (risankizumab)
- Taltz (ixekizumab);
AND
- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory, OR
- Cyclosporine (6 weeks treatment); AND
- Phototherapy (unless restricted by geographic location)

Patients who have a contraindication to either cyclosporine or methotrexate will be required to
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- 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/IXekizumab/Secukinumab/Ustekinumab for Plaque Psoriasis Special Authorization Request Form (ABC 60030).

Polyarticular Juvenile Idiopathic Arthritis

***Effective March 1, 2018, all new Special Authorization requests for the treatment of Rheumatoid Arthritis or Ankylosing Spondylitis for etanercept-naive patients will be assessed for coverage with Brenzys or Erelzi. Effective June 1, 2019, all new Special Authorization requests for the treatment of Psoriatic Arthritis for etanercept-naive patients will be assessed for coverage with Erelzi. Enbrel will not be approved for new etanercept starts for patients with the indications stated above; however, coverage for Enbrel will continue for patients who are currently well maintained on Enbrel and are considered a 'responder' as defined in criteria.

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

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

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

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

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

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

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

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

Once a child with pJIA has had two disease-free years, it is common clinical practice for drug treatment to be stopped."
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All requests (including renewal requests) for etanercept for Polyarticular Juvenile Idiopathic Arthritis must be completed using the Adalimumab/Etanercept/Tocilizumab for Polyarticular Juvenile Idiopathic Arthritis Special Authorization Request Form (ABC 60011).

Psoriatic Arthritis

***Effective March 1, 2018, all new Special Authorization requests for the treatment of Rheumatoid Arthritis or Ankylosing Spondylitis for etanercept-naive patients will be assessed for coverage with Brenzys or Erelzi. Effective June 1, 2019, all new Special Authorization requests for the treatment of Psoriatic Arthritis for etanercept-naive patients will be assessed for coverage with Erelzi. Enbrel will not be approved for new etanercept starts for patients with the indications stated above; however, coverage for Enbrel will continue for patients who are currently well maintained on Enbrel and are considered a ‘responder’ as defined in criteria.

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

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

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

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

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

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

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

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

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the

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

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correct number of decimal places as indicated above.

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

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

Rheumatoid Arthritis

***Effective March 1, 2018, all new Special Authorization requests for the treatment of Rheumatoid Arthritis or Ankylosing Spondylitis for etanercept-naive patients will be assessed for coverage with Brenzys or Erelzi. Effective June 1, 2019, all new Special Authorization requests for the treatment of Psoriatic Arthritis for etanercept-naive patients will be assessed for coverage with Erelzi. Enbrel will not be approved for new etanercept starts for patients with the indications stated above; however, coverage for Enbrel will continue for patients who are currently well maintained on Enbrel and are considered a ‘responder’ as defined in criteria.

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

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

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

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

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

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

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

- Initial coverage may be approved for 50 mg per week for 8 weeks.

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

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

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

- Patients will not be permitted to switch from anakinra to other biologic agents except under exceptional circumstances.

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

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

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

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

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

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

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

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

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

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

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

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

All requests (including renewal requests) for etanercept for Rheumatoid Arthritis must be completed using the Abatacept/Adalimumab/Anakinra/Certolizumab/Etanercept/Golimumab/Infliximab/Sarilumab/Tocilizumab/Tofacitinib for Rheumatoid Arthritis Special Authorization Request Form (ABC 60027).
FINGOLIMOD HYDROCHLORIDE
Relapsing Remitting Multiple Sclerosis (RRMS):

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

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

Definition of ‘refractory’
- Development of neutralizing antibodies to interferon beta.
- When the above MS DMTs are taken at the recommended doses for a full and adequate course of treatment, within a consecutive 12-month period while the patient was on the MS DMT, the patient has:
  1) Been adherent to the MS DMT (greater than 80% of approved doses have been administered);
  2) Experienced at least two relapses* of MS confirmed by the presence of neurologic deficits on examination.
     i. The first qualifying clinical relapse must have begun at least one month after treatment initiation.
     ii. Both qualifying relapses must be classified with a relapse severity of moderate, severe or very severe**.

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

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

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

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

Initial Coverage
1) The registered MS Neurologist must confirm a diagnosis of RRMS;
2) The patient must have active disease which is defined as at least two relapses* of MS during
FINGOLIMOD HYDROCHLORIDE

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

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

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

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

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

Continued Coverage

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

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

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

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

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

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

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

Restarting After an Interruption in Therapy Greater Than 12 Months

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

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

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

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

"For the treatment of invasive aspergillosis in adult patients who are refractory to or intolerant of voriconazole and caspofungin."

"For the treatment of invasive mucormycosis."

"This medication must be prescribed in consultation with a specialist in Infectious Diseases."

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

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

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

Special authorization may be granted for six months.

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

Each of these products is eligible for auto-renewal.

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

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PERAMPANEL

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

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

Special authorization may be granted for six months.

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

Each of these products are eligible for auto-renewal"

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

- Have a total PASI of 10 or more and a DLQI of more than 10, OR
- Who have significant involvement of the face, palms of the hands, soles of the feet or genital region; AND
- Who are refractory or intolerant to:
  - Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory, OR
  - Cyclosporine (6 weeks treatment); AND
  - Phototherapy (unless restricted by geographic location)

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

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

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

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

Initial coverage may be approved for three doses of 150 mg (two x 75 mg syringes) of risankizumab at weeks 0, 4 and 16.

- Patients will be limited to receiving one 150 mg dose of risankizumab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of the initial coverage period.
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

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

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

2) The Dermatology Specialist must confirm, in writing, that the patient is a ‘responder’ that meets the following criteria:
   - Greater than or equal to 75% reduction in PASI score, OR
   - Greater than or equal to 50% reduction in PASI score AND improvement of greater than or
RISANKIZUMAB

equal to 5 points in the DLQI.

Following this assessment, continued coverage may be considered for one 150 mg dose of risankizumab every 12 weeks for a period of 12 months. Ongoing coverage may be considered if the patient is re-assessed by a Dermatology Specialist every 12 months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above.

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

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

RIVASTIGMINE HYDROGEN TARTRATE

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

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

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

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

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

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

1.5 MG (BASE) ORAL CAPSULE

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RIVASTIGMINE HYDROGEN TARTRATE

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<td>SANDOZ RIVASTIGMINE</td>
<td>SDZ</td>
<td>$ 0.6514</td>
</tr>
<tr>
<td>00002242118</td>
<td>EXELON</td>
<td>NOV</td>
<td>$ 2.7725</td>
</tr>
</tbody>
</table>

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UNIT OF ISSUE - REFER TO PRICE POLICY

EFFECTIVE FEBRUARY 1, 2020
USTEKINUMAB

Plaque Psoriasis

"Special authorization coverage may be provided for the reduction in signs and symptoms of severe, debilitating plaque psoriasis in patients who:
- Have a total PASI of 10 or more and a DLQI of more than 10, OR
- Who have significant involvement of the face, palms of the hands, soles of the feet or genital region; AND
- Who are refractory to or intolerant to:
  at least THREE of the following:
  - Cosentyx (secukinumab)
  - Inflectra (infliximab)
  - Renflexis (infliximab)
  - Skyrizi (risankizumab)
  - Taltz (ixekizumab)
  AND
- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory, OR
- Cyclosporine (6 weeks treatment); AND
- Phototherapy (unless restricted by geographic location)

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

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

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

- Initial coverage may be approved for three doses of 45 mg (90 mg for patients weighing greater than 100 kg) at weeks 0, 4 and 16.
- Patients will be limited to receiving one dose per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage, the patient must meet all of the following criteria:
1) The patient must be assessed by a Dermatology Specialist after the initial 16 weeks of therapy to determine response.
2) The Dermatology Specialist must confirm, in writing, that the patient is a 'responder' that meets the following criteria:
   - Greater than or equal to 75% reduction in PASI score, OR
   - Greater than or equal to 50% reduction in PASI score AND improvement of greater than or equal to 5 points in the DLQI.

Following this assessment, continued coverage may be considered for 45 mg (90 mg for patients weighing greater than 100 kg) every 12 weeks for a period of 12 months. Ongoing coverage may be considered if the patient is re-assessed by a Dermatology Specialist every 12
USTEKINUMAB

months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above."

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

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

<table>
<thead>
<tr>
<th>45 MG</th>
<th>INJECTION</th>
<th>VIAL OR SYRINGE</th>
</tr>
</thead>
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| 00002320673 | STELARA (0.5 ML VIAL OR SYRINGE) | JAI | $4465.5800

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

<table>
<thead>
<tr>
<th>90 MG / SYR</th>
<th>INJECTION</th>
<th>SYRINGE</th>
</tr>
</thead>
</table>
| 00002320681 | STELARA (1.0 ML SYRINGE) | JAI | $4465.5800

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