Updates to the Alberta Drug Benefit List

Effective August 1, 2018

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)  
(403) 294-4041 (Calgary)  
1-800-361-9632 (Toll Free)  
FAX Number: (780) 498-8406  
1-877-305-9911 (Toll Free)  
Website: [http://www.health.alberta.ca/services/drug-benefit-list.html](http://www.health.alberta.ca/services/drug-benefit-list.html)

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

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>LEMTRADA 12 MG / VIAL INJECTION</td>
<td>ALEMTUZUMAB</td>
<td>00002418320</td>
<td>GZM</td>
</tr>
<tr>
<td>TYSABRI 20 MG / ML INJECTION</td>
<td>NATALIZUMAB</td>
<td>00002286386</td>
<td>BIO</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 August 1, 2018, 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 September 1, 2018 claims will no longer pay for these product(s).

<table>
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<tbody>
<tr>
<td>ACT LOSARTAN 100 MG TABLET</td>
<td>LOSARTAN POTASSIUM</td>
<td>00002354845</td>
<td>APH</td>
</tr>
<tr>
<td>ACT VALSARTAN 160 MG TABLET</td>
<td>VALSARTAN</td>
<td>00002337509</td>
<td>APH</td>
</tr>
<tr>
<td>ACT VENLAFAXINE XR 75 MG EXTENDED-RELEASE CAPSULE</td>
<td>VENLAFAXINE HCL</td>
<td>00002304325</td>
<td>APH</td>
</tr>
<tr>
<td>ACTOS 30 MG TABLET</td>
<td>PIOGLITAZONE HCL</td>
<td>00002242573</td>
<td>TAK</td>
</tr>
<tr>
<td>APO-FENTANYL 25 25 MCG / HR TRANSDERMAL PATCH</td>
<td>FENTANYL</td>
<td>00002314630</td>
<td>APX</td>
</tr>
<tr>
<td>APO-IRBESARTAN/HCTZ 300 MG / 12.5 MG TABLET</td>
<td>IRBESARTAN/ HYDROCHLOROTHIAZIDE</td>
<td>00002387654</td>
<td>APX</td>
</tr>
<tr>
<td>MINOCYCLINE 50 MG CAPSULE</td>
<td>MINOCYCLINE HCL</td>
<td>00002287226</td>
<td>SNS</td>
</tr>
<tr>
<td>MODERIBA 600 MG TABLET</td>
<td>RIBAVIRIN</td>
<td>00002436426</td>
<td>ABV</td>
</tr>
<tr>
<td>MYLAN-CYCLOBENZAPRINE 10 MG TABLET</td>
<td>CYCLOBENZAPRINE HCL</td>
<td>00002231353</td>
<td>MYP</td>
</tr>
<tr>
<td>PMS-MINOCYCLINE 50 MG CAPSULE</td>
<td>MINOCYCLINE HCL</td>
<td>00002294419</td>
<td>PMS</td>
</tr>
</tbody>
</table>

Product(s) Removed from ADBL as Price Policy Requirements not Satisified

The Alberta government-sponsored drug programs previously covered the following drug product(s). Effective August 1, 2018, 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 September 1, 2018 claims will no longer pay for these product(s).

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</thead>
<tbody>
<tr>
<td>CUBICIN 500 MG / VIAL INJECTION</td>
<td>DAPTOMYCIN</td>
<td>00002299909</td>
<td>CUB</td>
</tr>
</tbody>
</table>
PART 3

Special Authorization
ALEMTUZUMAB
Relapsing Remitting Multiple Sclerosis (RRMS):

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

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

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

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

1) Been adherent to the MS DMT (greater than 80% of approved doses have been administered);
2) Experienced at least two relapses* of MS confirmed by the presence of neurologic deficits on examination.
   i. The first qualifying clinical relapse must have begun at least one month after treatment initiation.
   ii. Both qualifying relapses must be classified with a relapse severity of moderate, severe or very severe**.

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

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

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

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

Coverage may be considered only if the following criteria are met:
1) The registered MS Neurologist must confirm a diagnosis of RRMS;
2) The patient must have active disease which is defined as at least two relapses* of MS during the previous two years or in the two years prior to starting an MS DMT. In most cases this will be
ALEMTUZUMAB satisfied by the 'refractory' to treatment criterion but if a patient failed an MS DMT more than one year earlier, ongoing active disease must be confirmed.

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

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

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

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

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

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

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

<table>
<thead>
<tr>
<th>12 MG / VIAL INJECTION</th>
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<tr>
<td>00002418320 LEMTRADA GZM</td>
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</table>

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

PRODUCT IS NOT INTERCHANGEABLE

EFFECTIVE AUGUST 1, 2018
NATALIZUMAB
Relapsing Remitting Multiple Sclerosis (RRMS):

Special authorization coverage may be provided for the treatment of relapsing remitting multiple sclerosis (RRMS) to reduce the frequency of clinical relapses, to decrease the number and volume of active brain lesions identified on magnetic resonance imaging (MRI) scans and to delay the progression of physical disability, in adult patients (18 years of age or older) who are refractory or intolerant to at least ONE of the following:
- interferon beta
- glatiramer acetate
- dimethyl fumarate
- teriflunomide
- peginterferon beta.

Definition of 'intolerant'

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

Definition of 'refractory'

- Development of neutralizing antibodies to interferon beta.

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

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

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

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

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

Coverage

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

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

Initial Coverage

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

2) The patient must have active disease which is defined as at least two relapses* of MS during the previous two years or in the two years prior to starting an MS DMT. In most cases this will be satisfied by the 'refractory' to treatment criterion but if a patient failed an MS DMT more than one year earlier, ongoing active disease must be confirmed.

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

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

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

Following assessment of the request, coverage may be approved for up to 13 doses of 300 mg (i.e., one dose administered every 4 weeks for a period up to 12 months). Patients will be limited to receiving one dose (4 weeks supply) of natalizumab per prescription at their pharmacy.

Continued Coverage

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

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

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

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

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

4) At the first renewal there must be evidence that neutralizing antibodies to natalizumab are absent.

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

Following assessment of the request, continued coverage may be approved for maintenance therapy of 300 mg every 4 weeks for a period up to 12 months. Patients will be limited to receiving one dose of natalizumab per prescription at their pharmacy.

Restarting After an Interruption in Therapy Greater Than 12 Months

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

1) At least one relapse* per 12 month period; or

2) At least two relapses* during the previous 24 month period.

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

| 20 mg/mL Injection | 00002286386 TYSABRI BIO | $172.8052 |

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**UNIT OF ISSUE - REFER TO PRICE POLICY**  
**EFFECTIVE AUGUST 1, 2018**