

Updates to the Alberta Drug Benefit List

Effective June 1, 2020



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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

| <u>Trade Name / Strength / Form</u> | <u>Generic Description</u> | <u>DIN</u> | <u>MFR</u> |
|--------------------------------------|----------------------------|-------------|------------|
| MAVENCLAD 10 MG TABLET | CLADRIBINE | 00002470179 | SRO |
| RADICAVA 0.3 MG / ML INJECTION | EDARAVONE | 00002475472 | MIT |
| SUBLOCADE 100 MG / SYRINGE INJECTION | BUPRENORPHINE | 00002483084 | IUK |
| SUBLOCADE 300 MG / SYRINGE INJECTION | BUPRENORPHINE | 00002483092 | IUK |
| TRUXIMA (10 ML) 10 MG / ML INJECTION | RITUXIMAB | 00002478382 | CTC |
| TRUXIMA (50 ML) 10 MG / ML INJECTION | RITUXIMAB | 00002478390 | CTC |

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

| <u>Trade Name / Strength / Form</u> | <u>Generic Description</u> | <u>DIN</u> | <u>MFR</u> |
|-------------------------------------|----------------------------|-------------|------------|
| ASPEN-DIENOGEST 2 MG TABLET | DIENOGEST | 00002493055 | APC |
| XARELTO 2.5 MG TABLET | RIVAROXABAN | 00002480808 | BAI |

Drug Product(s) with Changes to Criteria for Coverage

| <u>Trade Name / Strength / Form</u> | <u>Generic Description</u> | <u>DIN</u> | <u>MFR</u> |
|---|----------------------------|-------------|------------|
| APO-FINGOLIMOD 0.5 MG CAPSULE | FINGOLIMOD HYDROCHLORIDE | 00002469936 | APX |
| AUBAGIO 14 MG TABLET | TERIFLUNOMIDE | 00002416328 | GZM |
| AVONEX PS/PEN (30 MCG / 0.5 ML) 6 MIU / SYRINGE INJECTION | INTERFERON BETA-1A | 00002269201 | BIO |
| BETASERON (0.3 MG) 9.6 MIU / VIAL INJECTION | INTERFERON BETA-1B | 00002169649 | BAI |
| COPAXONE 20 MG / SYRINGE INJECTION | GLATIRAMER ACETATE | 00002245619 | TMP |
| ENBREL 25 MG / VIAL INJECTION | ETANERCEPT | 00002242903 | AMG |
| ENBREL 50 MG / SYRINGE INJECTION | ETANERCEPT | 00002274728 | AMG |
| EXTAVIA (0.3 MG) 9.6 MIU / VIAL INJECTION | INTERFERON BETA-1B | 00002337819 | NOV |
| GILENYA 0.5 MG CAPSULE | FINGOLIMOD HYDROCHLORIDE | 00002365480 | NOV |
| GLATECT 20 MG / SYRINGE INJECTION | GLATIRAMER ACETATE | 00002460661 | PMS |
| HUMIRA (40 MG / 0.8 ML) 40 MG / SYRINGE INJECTION | ADALIMUMAB | 00002258595 | ABV |
| JAMP FINGOLIMOD 0.5 MG CAPSULE | FINGOLIMOD HYDROCHLORIDE | 00002487772 | JPC |
| LEMTRADA 12 MG / VIAL INJECTION | ALEMTUZUMAB | 00002418320 | GZM |

Drug Product(s) with Changes to Criteria for Coverage

| <u>Trade Name / Strength / Form</u> | <u>Generic Description</u> | <u>DIN</u> | <u>MFR</u> |
|---|---|-------------|------------|
| MAR-FINGOLIMOD 0.5 MG CAPSULE | FINGOLIMOD HYDROCHLORIDE | 00002474743 | MAR |
| MYLAN-FINGOLIMOD 0.5 MG CAPSULE | FINGOLIMOD HYDROCHLORIDE | 00002469715 | MYP |
| OCREVUS 30 MG / ML INJECTION | OCRELIZUMAB | 00002467224 | HLR |
| PLEGRIDY 125 MCG / SYRINGE INJECTION | PEGINTERFERON BETA-1A | 00002444399 | BIO |
| PLEGRIDY 63 MCG / SYRINGE / 94 MCG / SYRINGE INJECTION | PEGINTERFERON BETA-1A/ PEGINTERFERON BETA-1A | 00002444402 | BIO |
| PMS-FINGOLIMOD 0.5 MG CAPSULE | FINGOLIMOD HYDROCHLORIDE | 00002469782 | PMS |
| REBIF (0.5 ML SYRINGE) 22 MCG / SYRINGE INJECTION | INTERFERON BETA-1A | 00002237319 | SRO |
| REBIF (0.5 ML SYRINGE) 44 MCG / SYRINGE INJECTION | INTERFERON BETA-1A | 00002237320 | SRO |
| REBIF (1.5 ML CARTRIDGE) 44 MCG / ML INJECTION CARTRIDGE | INTERFERON BETA-1A | 00002318253 | SRO |
| REBIF (1.5 ML CARTRIDGE) 88 MCG / ML INJECTION CARTRIDGE | INTERFERON BETA-1A | 00002318261 | SRO |
| RITUXAN 10 MG / ML INJECTION | RITUXIMAB | 00002241927 | HLR |
| SANDOZ FINGOLIMOD 0.5 MG CAPSULE | FINGOLIMOD HYDROCHLORIDE | 00002482606 | SDZ |
| STELARA (0.5 ML VIAL OR SYRINGE) 45 MG INJECTION VIAL OR SYRINGE | USTEKINUMAB | 00002320673 | JAI |
| STELARA (1.0 ML SYRINGE) 90 MG / SYRINGE INJECTION | USTEKINUMAB | 00002320681 | JAI |
| TARO-FINGOLIMOD 0.5 MG CAPSULE | FINGOLIMOD HYDROCHLORIDE | 00002469618 | TAR |
| TECFIDERA 120 MG DELAYED-RELEASE CAPSULE | DIMETHYL FUMARATE | 00002404508 | BIO |
| TEVA-FINGOLIMOD 0.5 MG CAPSULE | FINGOLIMOD HYDROCHLORIDE | 00002469561 | TEV |
| TYSABRI 20 MG / ML INJECTION | NATALIZUMAB | 00002286386 | BIO |

Restricted Benefit(s)

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

| <u>Trade Name / Strength / Form</u> | <u>Generic Description</u> | <u>DIN</u> | <u>MFR</u> |
|-------------------------------------|----------------------------|-------------|------------|
| FLEXERIL 10 MG TABLET | CYCLOBENZAPRINE HCL | 00002495422 | ORI |

Added Product(s)

| <u>Trade Name / Strength / Form</u> | <u>Generic Description</u> | <u>DIN</u> | <u>MFR</u> |
|---|----------------------------|-------------|------------|
| AURO-AZITHROMYCIN 20 MG / ML ORAL SUSPENSION | AZITHROMYCIN | 00002482363 | AUR |

Added Product(s), continued

| <u>Trade Name / Strength / Form</u> | <u>Generic Description</u> | <u>DIN</u> | <u>MFR</u> |
|--|----------------------------|-------------|------------|
| AURO-AZITHROMYCIN 40 MG / ML ORAL SUSPENSION | AZITHROMYCIN | 00002482371 | AUR |
| MINT-TELMISARTAN 40 MG TABLET | TELMISARTAN | 00002486369 | MPI |
| MINT-TELMISARTAN 80 MG TABLET | TELMISARTAN | 00002486377 | MPI |
| PMS-ATORVASTATIN 10 MG TABLET | ATORVASTATIN CALCIUM | 00002477149 | PMS |
| PMS-ATORVASTATIN 20 MG TABLET | ATORVASTATIN CALCIUM | 00002477157 | PMS |
| PMS-ATORVASTATIN 40 MG TABLET | ATORVASTATIN CALCIUM | 00002477165 | PMS |
| PMS-ATORVASTATIN 80 MG TABLET | ATORVASTATIN CALCIUM | 00002477173 | PMS |
| PROPAFENONE 150 MG TABLET | PROPAFENONE HCL | 00002343053 | SNS |
| PROPAFENONE 300 MG TABLET | PROPAFENONE HCL | 00002343061 | SNS |

New Established Interchangeable (IC) Grouping(s)

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

| <u>Generic Description</u> | <u>Strength / Form</u> | <u>New LCA Price</u> |
|----------------------------|------------------------|----------------------|
| DIENOGEST | 2 MG TABLET | 1.5346 |

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 July 1, 2020.

Please review the online [Interactive Drug Benefit List](#) for further information.

| <u>Generic Description</u> | <u>Strength / Form</u> | <u>New LCA Price</u> |
|----------------------------|------------------------|----------------------|
| INDAPAMIDE HEMIHYDRATE | 2.5 MG TABLET | 0.2364 |

Product(s) with a Price Change

The following product(s) had a Price Change. The previous higher price will be recognized until June 30, 2020. For products within an established IC Grouping, the LCA price may apply.

| <u>Trade Name / Strength / Form</u> | <u>Generic Description</u> | <u>DIN</u> | <u>MFR</u> |
|-------------------------------------|----------------------------|-------------|------------|
| APO-INDAPAMIDE 2.5 MG TABLET | INDAPAMIDE HEMIHYDRATE | 00002223678 | APX |
| JAMP-INDAPAMIDE 2.5 MG TABLET | INDAPAMIDE HEMIHYDRATE | 00002373912 | JPC |
| MYLAN-INDAPAMIDE 2.5 MG TABLET | INDAPAMIDE HEMIHYDRATE | 00002153483 | MYP |

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 June 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 July 1, 2020 claims will no longer pay for these product(s).

| <u>Trade Name / Strength / Form</u> | <u>Generic Description</u> | <u>DIN</u> | <u>MFR</u> |
|---|-----------------------------------|-------------------|-------------------|
| ACT DILTIAZEM T 120 MG EXTENDED- RELEASE CAPSULE | DILTIAZEM HCL | 00002370441 | APH |
| ACT DILTIAZEM T 180 MG EXTENDED- RELEASE CAPSULE | DILTIAZEM HCL | 00002370492 | APH |
| ACT DILTIAZEM T 240 MG EXTENDED- RELEASE CAPSULE | DILTIAZEM HCL | 00002370506 | APH |
| ACT DILTIAZEM T 300 MG EXTENDED- RELEASE CAPSULE | DILTIAZEM HCL | 00002370514 | APH |
| ACT DILTIAZEM T 360 MG EXTENDED- RELEASE CAPSULE | DILTIAZEM HCL | 00002370522 | APH |
| ACT RANITIDINE 150 MG TABLET | RANITIDINE HCL | 00002248570 | APH |
| ACT RANITIDINE 300 MG TABLET | RANITIDINE HCL | 00002248571 | APH |
| TEVA-ARIPIPIRAZOLE 2 MG TABLET | ARIPIPIRAZOLE | 00002464144 | TEV |
| TEVA-AMLODIPINE 5 MG TABLET | AMLODIPINE BESYLATE | 00002250497 | TEV |
| TEVA-AMLODIPINE 10 MG TABLET | AMLODIPINE BESYLATE | 00002250500 | TEV |

PART 2

Drug Additions

ALBERTA DRUG BENEFIT LIST UPDATE

ATORVASTATIN CALCIUM

10 MG (BASE) ORAL TABLET

| | | | | |
|-------------|---------------------|-----|----|--------|
| 00002457741 | ACH-ATORVASTATIN | AHI | \$ | 0.1743 |
| 00002295261 | APO-ATORVASTATIN | APX | \$ | 0.1743 |
| 00002411350 | ATORVASTATIN-10 | SIV | \$ | 0.1743 |
| 00002407256 | AURO-ATORVASTATIN | AUR | \$ | 0.1743 |
| 00002391058 | JAMP-ATORVASTATIN | JPC | \$ | 0.1743 |
| 00002454017 | MAR-ATORVASTATIN | MAR | \$ | 0.1743 |
| 00002479508 | MINT-ATORVASTATIN | MPI | \$ | 0.1743 |
| 00002392933 | MYLAN-ATORVASTATIN | MYP | \$ | 0.1743 |
| 00002399377 | PMS-ATORVASTATIN | PMS | \$ | 0.1743 |
| 00002477149 | PMS-ATORVASTATIN | PMS | \$ | 0.1743 |
| 00002313707 | RAN-ATORVASTATIN | RAN | \$ | 0.1743 |
| 00002417936 | REDDY-ATORVASTATIN | DRL | \$ | 0.1743 |
| 00002324946 | SANDOZ ATORVASTATIN | SDZ | \$ | 0.1743 |
| 00002310899 | TEVA-ATORVASTATIN | TEV | \$ | 0.1743 |
| 00002230711 | LIPITOR | PFI | \$ | 1.8223 |

20 MG (BASE) ORAL TABLET

| | | | | |
|-------------|---------------------|-----|----|--------|
| 00002457768 | ACH-ATORVASTATIN | AHI | \$ | 0.2179 |
| 00002295288 | APO-ATORVASTATIN | APX | \$ | 0.2179 |
| 00002411369 | ATORVASTATIN-20 | SIV | \$ | 0.2179 |
| 00002407264 | AURO-ATORVASTATIN | AUR | \$ | 0.2179 |
| 00002391066 | JAMP-ATORVASTATIN | JPC | \$ | 0.2179 |
| 00002454025 | MAR-ATORVASTATIN | MAR | \$ | 0.2179 |
| 00002479516 | MINT-ATORVASTATIN | MPI | \$ | 0.2179 |
| 00002392941 | MYLAN-ATORVASTATIN | MYP | \$ | 0.2179 |
| 00002399385 | PMS-ATORVASTATIN | PMS | \$ | 0.2179 |
| 00002477157 | PMS-ATORVASTATIN | PMS | \$ | 0.2179 |
| 00002313715 | RAN-ATORVASTATIN | RAN | \$ | 0.2179 |
| 00002417944 | REDDY-ATORVASTATIN | DRL | \$ | 0.2179 |
| 00002324954 | SANDOZ ATORVASTATIN | SDZ | \$ | 0.2179 |
| 00002310902 | TEVA-ATORVASTATIN | TEV | \$ | 0.2179 |
| 00002230713 | LIPITOR | PFI | \$ | 2.2779 |

40 MG (BASE) ORAL TABLET

| | | | | |
|-------------|---------------------|-----|----|--------|
| 00002457776 | ACH-ATORVASTATIN | AHI | \$ | 0.2342 |
| 00002295296 | APO-ATORVASTATIN | APX | \$ | 0.2342 |
| 00002411377 | ATORVASTATIN-40 | SIV | \$ | 0.2342 |
| 00002407272 | AURO-ATORVASTATIN | AUR | \$ | 0.2342 |
| 00002391074 | JAMP-ATORVASTATIN | JPC | \$ | 0.2342 |
| 00002454033 | MAR-ATORVASTATIN | MAR | \$ | 0.2342 |
| 00002479524 | MINT-ATORVASTATIN | MPI | \$ | 0.2342 |
| 00002392968 | MYLAN-ATORVASTATIN | MYP | \$ | 0.2342 |
| 00002399393 | PMS-ATORVASTATIN | PMS | \$ | 0.2342 |
| 00002477165 | PMS-ATORVASTATIN | PMS | \$ | 0.2342 |
| 00002313723 | RAN-ATORVASTATIN | RAN | \$ | 0.2342 |
| 00002417952 | REDDY-ATORVASTATIN | DRL | \$ | 0.2342 |
| 00002324962 | SANDOZ ATORVASTATIN | SDZ | \$ | 0.2342 |
| 00002310910 | TEVA-ATORVASTATIN | TEV | \$ | 0.2342 |
| 00002230714 | LIPITOR | PFI | \$ | 2.4483 |

ALBERTA DRUG BENEFIT LIST UPDATE

ATORVASTATIN CALCIUM

| 80 MG (BASE) | ORAL TABLET | | | |
|--------------|---------------------|-----|----|--------|
| 00002457784 | ACH-ATORVASTATIN | AHI | \$ | 0.2342 |
| 00002295318 | APO-ATORVASTATIN | APX | \$ | 0.2342 |
| 00002411385 | ATORVASTATIN-80 | SIV | \$ | 0.2342 |
| 00002407280 | AURO-ATORVASTATIN | AUR | \$ | 0.2342 |
| 00002391082 | JAMP-ATORVASTATIN | JPC | \$ | 0.2342 |
| 00002454041 | MAR-ATORVASTATIN | MAR | \$ | 0.2342 |
| 00002392976 | MYLAN-ATORVASTATIN | MYP | \$ | 0.2342 |
| 00002399407 | PMS-ATORVASTATIN | PMS | \$ | 0.2342 |
| 00002477173 | PMS-ATORVASTATIN | PMS | \$ | 0.2342 |
| 00002313758 | RAN-ATORVASTATIN | RAN | \$ | 0.2342 |
| 00002417960 | REDDY-ATORVASTATIN | DRL | \$ | 0.2342 |
| 00002324970 | SANDOZ ATORVASTATIN | SDZ | \$ | 0.2342 |
| 00002310929 | TEVA-ATORVASTATIN | TEV | \$ | 0.2342 |
| 00002243097 | LIPITOR | PFI | \$ | 2.4483 |

AZITHROMYCIN

| 20 MG / ML | ORAL SUSPENSION | | | |
|-------------|---------------------|-----|----|--------|
| 00002482363 | AURO-AZITHROMYCIN | AUR | \$ | 0.3726 |
| 00002332388 | SANDOZ AZITHROMYCIN | SDZ | \$ | 0.3726 |
| 00002223716 | ZITHROMAX | PFI | \$ | 1.1310 |
| 40 MG / ML | ORAL SUSPENSION | | | |
| 00002482371 | AURO-AZITHROMYCIN | AUR | \$ | 0.5280 |
| 00002332396 | SANDOZ AZITHROMYCIN | SDZ | \$ | 0.5280 |
| 00002223724 | ZITHROMAX | PFI | \$ | 1.6026 |

CYCLOBENZAPRINE HCL

RESTRICTED BENEFIT - Coverage is limited to 126 tablets per plan participant per year as an adjunct to rest and physical therapy for the treatment of acute muscle spasm.

| 10 MG | ORAL TABLET | | | |
|-------------|----------------------|-----|----|--------|
| 00002177145 | APO-CYCLOBENZAPRINE | APX | \$ | 0.1022 |
| 00002348853 | AURO-CYCLOBENZAPRINE | AUR | \$ | 0.1022 |
| 00002287064 | CYCLOBENZAPRINE | SNS | \$ | 0.1022 |
| 00002424584 | CYCLOBENZAPRINE | SIV | \$ | 0.1022 |
| 00002495422 | FLEXERIL | ORI | \$ | 0.1022 |
| 00002357127 | JAMP-CYCLOBENZAPRINE | JPC | \$ | 0.1022 |
| 00002212048 | PMS-CYCLOBENZAPRINE | PMS | \$ | 0.1022 |
| 00002080052 | TEVA-CYCLOBENZAPRINE | TEV | \$ | 0.1022 |

INDAPAMIDE HEMIHYDRATE

| 2.5 MG (BASE) | ORAL TABLET | | | |
|---------------|------------------|-----|----|--------|
| 00002223678 | APO-INDAPAMIDE | APX | \$ | 0.2364 |
| 00002373912 | JAMP-INDAPAMIDE | JPC | \$ | 0.2364 |
| 00002153483 | MYLAN-INDAPAMIDE | MYP | \$ | 0.2364 |
| 00000564966 | LOZIDE | SEV | \$ | 0.5116 |

ALBERTA DRUG BENEFIT LIST UPDATE

PROPAFENONE HCL

150 MG ORAL TABLET

| | | | | |
|-------------|-------------------|-----|----|--------|
| 00002243324 | APO-PROPAFENONE | APX | \$ | 0.2965 |
| 00002457172 | MYLAN-PROPAFENONE | MYP | \$ | 0.2965 |
| 00002343053 | PROPAFENONE | SNS | \$ | 0.2965 |
| 00000603708 | RYTHMOL | BGP | \$ | 1.2546 |

300 MG ORAL TABLET

| | | | | |
|-------------|-------------------|-----|----|--------|
| 00002243325 | APO-PROPAFENONE | APX | \$ | 0.5227 |
| 00002457164 | MYLAN-PROPAFENONE | MYP | \$ | 0.5227 |
| 00002343061 | PROPAFENONE | SNS | \$ | 0.5227 |
| 00000603716 | RYTHMOL | BGP | \$ | 2.2114 |

TELMISARTAN

40 MG ORAL TABLET

| | | | | |
|-------------|--------------------|-----|----|--------|
| 00002453568 | AURO-TELMISARTAN | AUR | \$ | 0.2161 |
| 00002486369 | MINT-TELMISARTAN | MPI | \$ | 0.2161 |
| 00002375958 | SANDOZ TELMISARTAN | SDZ | \$ | 0.2161 |
| 00002388944 | TELMISARTAN | SNS | \$ | 0.2161 |
| 00002390345 | TELMISARTAN | SIV | \$ | 0.2161 |
| 00002407485 | TELMISARTAN | AHI | \$ | 0.2161 |
| 00002320177 | TEVA-TELMISARTAN | TEV | \$ | 0.2161 |
| 00002240769 | MICARDIS | BOE | \$ | 1.2474 |

80 MG ORAL TABLET

| | | | | |
|-------------|--------------------|-----|----|--------|
| 00002453576 | AURO-TELMISARTAN | AUR | \$ | 0.2161 |
| 00002486377 | MINT-TELMISARTAN | MPI | \$ | 0.2161 |
| 00002375966 | SANDOZ TELMISARTAN | SDZ | \$ | 0.2161 |
| 00002388952 | TELMISARTAN | SNS | \$ | 0.2161 |
| 00002390353 | TELMISARTAN | SIV | \$ | 0.2161 |
| 00002407493 | TELMISARTAN | AHI | \$ | 0.2161 |
| 00002320185 | TEVA-TELMISARTAN | TEV | \$ | 0.2161 |
| 00002240770 | MICARDIS | BOE | \$ | 1.2474 |

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

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

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

Hidradenitis Suppurativa

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

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

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

ADALIMUMAB

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.
- 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.

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ADALIMUMAB

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 40mg/day, tapering by 5 mg each week to 20 mg then tapering by 2.5mg 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 1mg/kg/day for a minimum of 3 months; OR
- Methotrexate: minimum of 15mg/week for a minimum of 3 months.

OR

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

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

Coverage Criteria for Moderately to Severely Active Crohn's Disease

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

Induction Dosing for New Patients:

- Coverage for Induction dosing may only be approved for New Patients (those who have never been treated with adalimumab by any health care provider).
- 'Induction Dosing' means a maximum of one 160 mg dose of adalimumab per New Patient at Week 0 followed by an 80 mg dose at Week 2.
- New Patients are eligible to receive Induction Dosing only once, after which time the Maintenance Dosing for New Patients and Continued Coverage for Maintenance Dosing criteria will apply.
- As an interim measure, 40mg 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:

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- 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 Disease.

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 Disease; OR
- For Existing Patients: The Specialist must confirm that the patient has maintained the Existing Patient's Baseline Score."

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

Plaque Psoriasis

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

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

'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").

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- 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."

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

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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 (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:

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

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CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

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

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

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

- Initial coverage may be approved for 40 mg administered every other week for 8 weeks.
- Patients will be limited to receiving a one-month supply of Humira 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 with this biologic agent 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 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; and
- 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:

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

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

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

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

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

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

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

For continued coverage beyond 5 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

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completed using the Abatacept/Adalimumab/Anakinra/Certolizumab/Etanercept/Golimumab/Infliximab/Sarilumab/Tocilizumab/Tofacitinib for Rheumatoid Arthritis Special Authorization Request Form (ABC 60027).

Ulcerative Colitis

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

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

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

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

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

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

For coverage, this drug must be prescribed by a Specialist in Gastroenterology 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

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initiation of adalimumab therapy."

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

40 MG / SYR INJECTION SYRINGE

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

ALEMTUZUMAB

Relapsing Remitting Multiple Sclerosis (RRMS):

"Special authorization coverage may be provided for the treatment of highly active 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 TWO of the following disease modifying therapies (DMTs):

- dimethyl fumarate
- fingolimod
- glatiramer acetate
- interferon beta
- natalizumab
- ocrelizumab
- peginterferon beta
- teriflunomide

Definition of 'intolerant'

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

Definition of 'refractory'

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

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

*A relapse is defined as the appearance of new symptoms or worsening of old symptoms, lasting at least 48 hours in the absence of fever, not associated with withdrawal from steroids. Onset of clinical relapses must be separated by a period of at least one month. At least one new T2 lesion or definite gadolinium-enhancing T1 MRI lesion (not questionable faint enhancement) obtained at least 90 days after initiation of the DMT and at least 90 days before or after a relapse may substitute for one clinical relapse.

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

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

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

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

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

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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 For Multiple Sclerosis Special Authorization Request Form (ABC 60079).

12 MG / VIAL INJECTION

00002418320 LEMTRADA GZM \$ 13031.1100

BUPRENORPHINE

"For the management of moderate to severe opioid use disorder in patients clinically stabilized on 8 mg to 24 mg per day of sublingual (SL) buprenorphine for a minimum of 7 days and to be used in combination with counseling and psychosocial support.

The patient should be under the care of a health care provider with experience in the diagnosis and management of opioid use disorder and who has been certified to administer subcutaneous buprenorphine extended release injection.

Buprenorphine extended release injection must be administered subcutaneously in the abdominal region by a healthcare provider.

Patients will be limited to receiving one syringe per prescription at their pharmacy.

Special authorization may be granted for six months."

This product is eligible for auto-renewal.

100 MG / SYR INJECTION SYRINGE

00002483084 SUBLOCADE IUUK \$ 550.0000

300 MG / SYR INJECTION SYRINGE

00002483092 SUBLOCADE IUUK \$ 550.0000

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CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

CLADRIBINE

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:

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

Definition of 'intolerant'

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

Definition of 'refractory'

-Development of neutralizing antibodies to interferon beta.

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

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

*A relapse is defined as the appearance of new symptoms or worsening of old symptoms, lasting at least 48 hours in the absence of fever, not associated with withdrawal from steroids. Onset of clinical relapses must be separated by a period of at least one month. At least one new T2 lesion or 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

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CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

CLADRIBINE

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 cladribine.

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

Following assessment of the request, cladribine may be approved for coverage at a cumulative dose of 3.5 mg/kg over 2 years, administered as 1 treatment course of 1.75 mg/kg per year. Each treatment course consists of 2 treatment weeks, with each treatment week consisting of 4 or 5 days on which a patient receives 10 mg or 20 mg (one or two tablets) as a single daily dose, depending on body weight.

- The Initial Treatment Course is administered in one treatment week at the beginning of the first month and one treatment week at the beginning of the second month of the same year.

-The Second Treatment Course is administered in the subsequent year in two treatment weeks one month apart, in the same manner as the initial treatment course.

Patients will be limited to receiving one treatment week of cladribine per prescription at their pharmacy.
Coverage is limited to two treatment courses.

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

10 MG ORAL TABLET

| | | | | |
|-------------|-----------|-----|----|-----------|
| 00002470179 | MAVENCLAD | SRO | \$ | 3212.0000 |
|-------------|-----------|-----|----|-----------|

DIENOGEST

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

"Special authorization may be granted for 6 months."

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

2 MG ORAL TABLET

| | | | | |
|-------------|-----------------|-----|----|--------|
| 00002493055 | ASPEN-DIENOGEST | APC | \$ | 1.5346 |
| 00002374900 | VISANNE | BAI | \$ | 2.0461 |

DIMETHYL FUMARATE

Relapsing Remitting Multiple Sclerosis (RRMS):

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

Coverage

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

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

Initial Coverage

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

*A relapse is defined as the appearance of new symptoms or worsening of old symptoms, lasting at least 48 hours in the absence of fever, not associated with withdrawal from steroids. Onset of clinical relapses must be separated by a period of at least one month. At least one new T2 lesion or definite gadolinium-enhancing T1 MRI lesion (not questionable faint enhancement) obtained at least 90 days after initiation of the DMT and at least 90 days before or after a relapse may substitute for one clinical relapse.

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

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

Continued Coverage

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

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

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

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

Restarting After an Interruption in Therapy Greater Than 12 Months

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DIMETHYL FUMARATE

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

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

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

120 MG ORAL DELAYED-RELEASE CAPSULE

00002404508 TECFIDERA BIO \$ 17.3422

EDARAVONE

For patients who have a probable or definite diagnosis of amyotrophic lateral sclerosis (ALS), as defined by World Federation of Neurology (WFN) criteria, and who meet ALL of the following:

- scores of at least two points on each item of the ALS Functional Rating Scale - Revised (ALSFRRS-R), AND
- a forced vital capacity (FVC) greater than or equal to 80% of predicted, AND
- ALS symptoms for two years or less, AND
- not currently requiring permanent non-invasive or invasive ventilation.

For coverage, this drug must be prescribed by a Specialist in Neurology.

Initial coverage may be approved for a first treatment cycle of 60mg IV daily for 14 days, followed by a 14-day drug-free period, and 5 subsequent cycles of 60mg IV daily for 10 days out of 14-day periods, followed by 14-day drug-free periods.

Special authorization may be granted for 6 months.

Patients will be limited to receiving a 28-day supply of edaravone per prescription at their pharmacy.

Coverage cannot be renewed once the patient:

- becomes non-ambulatory (ALSFRRS-R score less than or equal to 1 for item 8) AND is unable to cut food and feed themselves without assistance, irrespective of whether a gastrostomy is in place (ALSFRRS-R score less than 1 for item 5a or 5b);

OR

- requires permanent non-invasive or invasive ventilation.

Continued coverage may be considered for treatment cycles of 60mg IV daily for 10 days out of 14-day periods, followed by 14-day drug-free periods, for a period of 6 months.

All requests (including renewal requests) for edaravone must be completed using the Edaravone Special Authorization Request Form (ABC 60080).

0.3 MG / ML INJECTION

00002475472 RADICAVA MIT \$ 4.6000

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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
AND

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

- who are refractory or intolerant to treatment with 2 or more NSAIDs each taken for a minimum of 4 weeks at maximum tolerated or recommended doses.

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

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

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

- Initial coverage may be approved for 50 mg per week for 12 weeks.

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

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

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

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

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

1) The patient must be assessed at week 12 by an RA Specialist after the initial twelve weeks of therapy to determine response.

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

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

ETANERCEPT

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

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

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

Plaque Psoriasis

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

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

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

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

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

at least THREE of the following:

- Cosentyx (secukinumab)
 - Humira (adalimumab)
 - 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.

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CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

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

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

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

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

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

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

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

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

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

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

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

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

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

Psoriatic Arthritis

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ETANERCEPT

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- 1) The patient has been assessed by an RA Specialist to determine response;
- 2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy

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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").

- 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

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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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ETANERCEPT

50 MG / SYR INJECTION SYRINGE

00002274728 ENBREL AMG \$ 401.5400

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.

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

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

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

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

Plaque Psoriasis

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

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

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

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

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

at least THREE of the following:

- Cosentyx (secukinumab)
 - Humira (adalimumab)
 - 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.

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

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

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

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

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

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

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

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

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

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

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

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

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

Psoriatic Arthritis

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- 1) The patient has been assessed by an RA Specialist to determine response;
- 2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy

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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").

- 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

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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:

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

Definition of 'intolerant'

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

Definition of 'refractory'

-Development of neutralizing antibodies to interferon beta.

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

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

* A relapse is defined as the appearance of new symptoms or worsening of old symptoms, lasting at least 48 hours in the absence of fever, not associated with withdrawal from steroids. Onset of clinical relapses must be separated by a period of at least one month. At least one new T2 lesion or 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

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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 new T2 lesion 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 Cladribine/Fingolimod/Natalizumab For Multiple Sclerosis Special Authorization Request Form (ABC 60000).

0.5 MG (BASE) ORAL CAPSULE

| | | | | |
|--------------------|------------------------|------------|-----------|----------------|
| 00002469936 | APO-FINGOLIMOD | APX | \$ | 21.7381 |
| 00002487772 | JAMP FINGOLIMOD | JPC | \$ | 21.7381 |

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

FINGOLIMOD HYDROCHLORIDE

| | | | | |
|-------------|-------------------|-----|----|---------|
| 00002474743 | MAR-FINGOLIMOD | MAR | \$ | 21.7381 |
| 00002469715 | MYLAN-FINGOLIMOD | MYP | \$ | 21.7381 |
| 00002469782 | PMS-FINGOLIMOD | PMS | \$ | 21.7381 |
| 00002482606 | SANDOZ FINGOLIMOD | SDZ | \$ | 21.7381 |
| 00002469618 | TARO-FINGOLIMOD | TAR | \$ | 21.7381 |
| 00002469561 | TEVA-FINGOLIMOD | TEV | \$ | 21.7381 |
| 00002365480 | GILENYA | NOV | \$ | 86.9525 |

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

GLATIRAMER ACETATE

20 MG / SYR INJECTION SYRINGE

00002460661 GLATECT PMS \$ 32.4000

Relapsing Remitting Multiple Sclerosis (RRMS):

Effective July 1, 2018, all new Special Authorization requests for the treatment of Relapsing Remitting Multiple Sclerosis (RRMS) for glatiramer-naïve patients will be assessed for coverage with Glatect. Copaxone will not be approved for new glatiramer acetate starts for patients with the indication stated above; however, coverage for Copaxone will continue for patients who are currently well maintained on Copaxone as per maintenance coverage criteria. Additionally, patients will not be permitted to switch from Glatect to Copaxone.

"Special authorization coverage may be provided for the reduction of the frequency and severity of clinical relapses and reduction of the number and volume of active brain lesions, identified on MRI scans, in ambulatory patients with relapsing remitting multiple sclerosis.

Coverage

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

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

Initial Coverage

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

*A relapse is defined as the appearance of new symptoms or worsening of old symptoms, lasting at least 48 hours in the absence of fever, not associated with withdrawal from steroids. Onset of clinical relapses must be separated by a period of at least one month. At least one new T2 lesion or definite gadolinium-enhancing T1 MRI lesion (not questionable faint enhancement) obtained at least 90 days after initiation of the DMT and at least 90 days before or after a relapse may substitute for one clinical relapse.

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

Coverage may be approved for up to 12 months. Patients will be limited to receiving a one-month supply of glatiramer acetate per prescription at their pharmacy for the first 12 months of coverage.

Continued Coverage

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

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

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

Continued coverage may be approved for up to 12 months. Patients may receive up to 100 days' supply of glatiramer acetate per prescription at their pharmacy.

Restarting After an Interruption in Therapy Greater Than 12 Months

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

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

GLATIRAMER ACETATE

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

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

00002245619 COPAXONE TMP \$ 48.8051

Relapsing Remitting Multiple Sclerosis (RRMS):

Effective July 1, 2018, all new Special Authorization requests for the treatment of Relapsing Remitting Multiple Sclerosis (RRMS) for glatiramer-naive patients will be assessed for coverage with Glatect. Copaxone will not be approved for new glatiramer acetate starts for patients with the indication stated above; however, coverage for Copaxone will continue for patients who are currently well maintained on Copaxone as per maintenance coverage criteria. Additionally, patients will not be permitted to switch from Glatect to Copaxone.

"Special authorization coverage may be provided for the reduction of the frequency and severity of clinical relapses and reduction of the number and volume of active brain lesions, identified on MRI scans, in ambulatory patients with relapsing remitting multiple sclerosis.

Coverage

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

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

Initial Coverage

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

*A relapse is defined as the appearance of new symptoms or worsening of old symptoms, lasting at least 48 hours in the absence of fever, not associated with withdrawal from steroids. Onset of clinical relapses must be separated by a period of at least one month. At least one new T2 lesion or definite gadolinium-enhancing T1 MRI lesion (not questionable faint enhancement) obtained at least 90 days after initiation of the DMT and at least 90 days before or after a relapse may substitute for one clinical relapse.

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

Coverage may be approved for up to 12 months. Patients will be limited to receiving a one-month supply of glatiramer acetate per prescription at their pharmacy for the first 12 months of coverage.

Continued Coverage

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

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

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

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

GLATIRAMER ACETATE

Continued coverage may be approved for up to 12 months. Patients may receive up to 100 days' supply of glatiramer acetate per prescription at their pharmacy.

Restarting After an Interruption in Therapy Greater Than 12 Months

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

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

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

INTERFERON BETA-1A

Relapsing Remitting Multiple Sclerosis (RRMS):

"Special authorization coverage may be provided for the reduction of the frequency and severity of clinical relapses and reduction of the number and volume of active brain lesions, identified on MRI scans, in ambulatory patients with relapsing remitting multiple sclerosis.

Coverage

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

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

Initial Coverage

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

*A relapse is defined as the appearance of new symptoms or worsening of old symptoms, lasting at least 48 hours in the absence of fever, not associated with withdrawal from steroids. Onset of clinical relapses must be separated by a period of at least one month. At least one new T2 lesion or definite gadolinium-enhancing T1 MRI lesion (not questionable faint enhancement) obtained at least 90 days after initiation of the DMT and at least 90 days before or after a relapse may substitute for one clinical relapse.

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

Coverage may be approved for up to 12 months. Patients will be limited to receiving a one-month supply of interferon beta-1a per prescription at their pharmacy for the first 12 months of coverage.

Continued Coverage

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

- 1) The patient must be assessed by a registered MS Neurologist;
- 2) The registered MS Neurologist must confirm a diagnosis of RRMS;
- 3) The registered MS Neurologist must provide a current updated EDSS score. The patient must not have an EDSS score of 7.0 or above sustained for one year or more. Coverage of this drug may be considered in a patient with a sustained EDSS score of 7.0 or above in exceptional circumstances. For MS DMT coverage to be considered, details of the exceptional circumstance must be provided in a letter from the registered MS Neurologist and accompany the Special Authorization Request Form.

Continued coverage may be approved for up to 12 months. Patients may receive up to 100 days' supply of interferon beta-1a per prescription at their pharmacy.

Restarting After an Interruption in Therapy Greater Than 12 Months

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

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

INTERFERON BETA-1A

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

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

| | | | |
|--|-------------------------------|-----|-------------|
| 44 MCG / ML INJECTION CARTRIDGE | | | |
| 00002318253 | REBIF (1.5 ML CARTRIDGE) | SRO | \$ 267.0400 |
| 88 MCG / ML INJECTION CARTRIDGE | | | |
| 00002318261 | REBIF (1.5 ML CARTRIDGE) | SRO | \$ 325.0900 |
| 6 MIU / SYR INJECTION SYRINGE | | | |
| 00002269201 | AVONEX PS/PEN (30 MCG/0.5 ML) | BIO | \$ 419.8047 |
| 22 MCG / SYR INJECTION SYRINGE | | | |
| 00002237319 | REBIF (0.5 ML SYRINGE) | SRO | \$ 133.5200 |
| 44 MCG / SYR INJECTION SYRINGE | | | |
| 00002237320 | REBIF (0.5 ML SYRINGE) | SRO | \$ 162.5470 |

INTERFERON BETA-1B

Relapsing Remitting Multiple Sclerosis (RRMS):

"Special authorization coverage may be provided for the reduction of the frequency and severity of clinical relapses and reduction of the number and volume of active brain lesions, identified on MRI scans, in ambulatory patients with relapsing remitting multiple sclerosis.

Coverage

For coverage, this drug must be prescribed by a registered MS Neurologist. A current assessment must be completed by a registered MS Neurologist at every request. To register to become an MS Neurologist please complete the Registration for MS Neurologist Status Form (ABC 60002).

Initial Coverage

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

*A relapse is defined as the appearance of new symptoms or worsening of old symptoms, lasting at least 48 hours in the absence of fever, not associated with withdrawal from steroids. Onset of clinical relapses must be separated by a period of at least one month. At least one new T2 lesion or definite gadolinium-enhancing T1 MRI lesion (not questionable faint enhancement) obtained at least 90 days after initiation of the DMT and at least 90 days before or after a relapse may substitute for one clinical relapse.

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

Coverage may be approved for up to 12 months. Patients will be limited to receiving a one-month supply of interferon beta-1b per prescription at their pharmacy for the first 12 months of coverage.

Continued Coverage

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

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

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

Continued coverage may be approved for up to 12 months. Patients may receive up to 100 days' supply of interferon beta-1b per prescription at their pharmacy.

Restarting After an Interruption in Therapy Greater Than 12 Months

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

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

INTERFERON BETA-1B

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

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

Secondary Progressive Multiple Sclerosis with Relapses (SPMS with relapses):

"Special authorization coverage may be provided for the slowing of progression in disability and the reduction of the frequency of clinical relapses in patients with secondary progressive multiple sclerosis with relapses.

Coverage

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

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

Initial Coverage

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

*A relapse is defined as the appearance of new symptoms or worsening of old symptoms (documented by a physician), lasting at least 72 hours in the absence of fever, not associated with withdrawal from steroids, and preceded by stability for at least one month. Onset of clinical relapses must be separated by a period of at least one month. At least one new T2 lesion or definite gadolinium-enhancing T1 MRI lesion (not questionable faint enhancement) obtained at least 90 days after initiation of the DMT and at least 90 days before or after a relapse may substitute for one clinical relapse.

- 3) The patient must be ambulatory to 100m without an aid (The registered MS Neurologist must provide an updated Expanded Disability Status Scale (EDSS) score of less than or equal to 5.5).

Coverage may be approved for up to 12 months. Patients will be limited to receiving a one-month supply of interferon beta-1b per prescription at their pharmacy for the first 12 months of coverage.

Continued Coverage

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

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

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

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

INTERFERON BETA-1B

Continued coverage may be approved for up to 12 months. Patients may receive up to 100 days' supply of interferon beta-1b per prescription at their pharmacy.

Restarting After an Interruption in Therapy Greater Than 12 Months

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

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

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

9.6 MIU / VIAL INJECTION

| | | | | |
|--------------------|---------------------------|------------|-----------|----------------|
| 00002169649 | BETASERON (0.3 MG) | BAI | \$ | 99.3593 |
| 00002337819 | EXTAVIA (0.3 MG) | NOV | \$ | 99.3593 |

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:

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

Definition of 'intolerant'

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

Definition of 'refractory'

-Development of neutralizing antibodies to interferon beta.

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

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

*A relapse is defined as the appearance of new symptoms or worsening of old symptoms, lasting at least 48 hours in the absence of fever, not associated with withdrawal from steroids. Onset of clinical relapses must be separated by a period of at least one month. At least one new T2 lesion or definite gadolinium-enhancing T1 MRI lesion (not questionable faint enhancement) obtained at least 90 days after initiation of the DMT and at least 90 days before or after a relapse may substitute for one clinical relapse.

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

Coverage

For coverage, this drug must be prescribed by a registered MS Neurologist. A current assessment must be completed by a registered MS Neurologist at every request. To register to become an MS Neurologist please complete the Registration for MS Neurologist Status Form (ABC 60002).

Initial Coverage

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

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

NATALIZUMAB

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

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

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

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

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

Continued Coverage

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

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

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

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

5) The registered MS Neurologist must confirm in writing that the patient is a 'responder' who has experienced no more than one inflammatory event in the last year (defined as either a clinical relapse or new T2 lesion 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 Cladribine/Fingolimod/Natalizumab For Multiple Sclerosis Special Authorization Request Form (ABC 60000).

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

NATALIZUMAB

20 MG / ML INJECTION

00002286386 TYSABRI

BIO

\$ 181.4455

OCRELIZUMAB

Relapsing Remitting Multiple Sclerosis (RRMS)

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

Coverage

For coverage, this drug must be prescribed by a registered MS Neurologist. A current assessment must be completed by a registered MS Neurologist at every request. To register to become an MS Neurologist, please complete the Registration for MS Neurologist Status Form (ABC 60002).

Initial Coverage

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

*A relapse is defined as the appearance of new symptoms or worsening of old symptoms, lasting at least 48 hours in the absence of fever, not associated with withdrawal from steroids. Onset of clinical relapses must be separated by a period of at least one month. At least one new T2 lesion or definite gadolinium-enhancing T1 MRI lesion (not questionable faint enhancement) obtained at least 90 days after initiation of the DMT and at least 90 days before or after a relapse may substitute for one clinical relapse.

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

Initial coverage may be approved for an initial dose of ocrelizumab 300 mg given by intravenous (IV) infusion, followed 2 weeks later by a second 300 mg dose. A maintenance dose of ocrelizumab 600 mg at 6 months will also be provided in the initial coverage period. Patients will be limited to receiving one dose of ocrelizumab per prescription at their pharmacy.

Continued Coverage

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

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

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

Continued coverage may be approved for one dose of ocrelizumab 600 mg every 6 months for up to 12 months. Patients may receive one dose of ocrelizumab 600 mg per prescription at their pharmacy.

Restarting After an Interruption in Therapy Greater Than 12 Months

In order to be eligible for coverage, after an interruption in therapy greater than 12 months, the

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

OCRELIZUMAB

patient must meet the following criteria:

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

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

Primary Progressive Multiple Sclerosis (PPMS):

"Special authorization coverage may be provided for the management of adult patients with early primary progressive multiple sclerosis (PPMS), as defined by disease duration and level of disability in conjunction with imaging features characteristic of inflammatory activity.

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

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

Initial Coverage

- 1) The registered MS Neurologist must confirm a diagnosis of PPMS (based on McDonald criteria 2017);
- 2) The patient must have an Expanded Disability Status Scale (EDSS) score between 3.0 and 6.5;
- 3) The patient must have a score of at least 2.0 on the Functional Systems scale for the pyramidal system due to lower extremity findings;
- 4) There are documented imaging features characteristic of inflammatory activity;
- 5) Disease duration must be less than 15 years for those with an EDSS greater than 5.0, or less than 10 years for those with an EDSS of 5.0 or less.

Initial coverage may be approved for an initial dose of ocrelizumab 300 mg given by intravenous (IV) infusion, followed 2 weeks later by a second 300 mg dose. A maintenance dose of ocrelizumab 600 mg at 6 months will also be provided in the initial coverage period. Patients will be limited to receiving one dose of ocrelizumab per prescription at their pharmacy.

Continued Coverage

For continued coverage beyond the initial coverage period, the patient must be assessed between 6 months and 12 months, and every 12 months thereafter, and the request must meet the following criteria:

- 1) The registered MS Neurologist must confirm a diagnosis of PPMS;
- 2) A current updated EDSS score must be provided and the patient must not have an EDSS score of 7.0 or above.

Continued coverage may be approved for one dose of ocrelizumab 600 mg every 6 months for up to 12 months. Patients may receive one dose of ocrelizumab 600 mg per prescription at their pharmacy."

All requests (including renewal requests) for ocrelizumab for PPMS must be completed using the Ocrelizumab for PPMS Special Authorization Request Form (ABC 60067).

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

OCRELIZUMAB

30 MG / ML INJECTION

00002467224 OCREVUS

HLR

\$ 815.0000

PEGINTERFERON BETA-1A

Relapsing Remitting Multiple Sclerosis (RRMS)

"Special authorization coverage may be provided for the reduction of the frequency and severity of clinical relapses and reduction of the number and volume of active brain lesions, identified on MRI scans, in ambulatory patients with relapsing remitting multiple sclerosis.

Coverage

For coverage, this drug must be prescribed by a registered MS Neurologist. A current assessment must be completed by a registered MS Neurologist at every request. To register to become an MS Neurologist please complete the Registration for MS Neurologist Status Form (ABC 60002).

Initial Coverage

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

*A relapse is defined as the appearance of new symptoms or worsening of old symptoms, lasting at least 48 hours in the absence of fever, not associated with withdrawal from steroids. Onset of clinical relapses must be separated by a period of at least one month. At least one new T2 lesion or definite gadolinium-enhancing T1 MRI lesion (not questionable faint enhancement) obtained at least 90 days after initiation of the DMT and at least 90 days before or after a relapse may substitute for one clinical relapse.

- 3) The patient must be ambulatory with or without aid (The registered MS Neurologist must provide a current updated Expanded Disability Status Scale (EDSS) score less than or equal to 6.5). Coverage may be approved for up to 12 months. Patients will be limited to receiving a one-month supply of peg-interferon beta-1a per prescription at their pharmacy for the first 12 months of coverage.

Continued Coverage

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

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

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

Continued coverage may be approved for up to 12 months. Patients may receive up to 100 days' supply of peg-interferon beta-1a per prescription at their pharmacy.

Restarting After an Interruption in Therapy Greater Than 12 Months

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

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

PEGINTERFERON BETA-1A

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

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

125 MCG / SYR INJECTION SYRINGE

| | | | | |
|-------------|----------|-----|----|----------|
| 00002444399 | PLEGRIDY | BIO | \$ | 885.8010 |
|-------------|----------|-----|----|----------|

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

PEGINTERFERON BETA-1A/ PEGINTERFERON BETA-1A

"Special authorization coverage may be provided for the reduction of the frequency and severity of clinical relapses and reduction of the number and volume of active brain lesions, identified on MRI scans, in ambulatory patients with relapsing remitting multiple sclerosis.

Coverage

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

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

Initial Coverage

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

*A relapse is defined as the appearance of new symptoms or worsening of old symptoms, lasting at least 48 hours in the absence of fever, not associated with withdrawal from steroids. Onset of clinical relapses must be separated by a period of at least one month. At least one new T2 lesion or definite gadolinium-enhancing T1 MRI lesion (not questionable faint enhancement) obtained at least 90 days after initiation of the DMT and at least 90 days before or after a relapse may substitute for one clinical relapse.

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

Coverage may be approved for up to 12 months. Patients will be limited to receiving a one-month supply of peg-interferon beta-1a per prescription at their pharmacy for the first 12 months of coverage.

Continued Coverage

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

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

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

Continued coverage may be approved for up to 12 months. Patients may receive up to 100 days' supply of peg-interferon beta-1a per prescription at their pharmacy.

Restarting After an Interruption in Therapy Greater Than 12 Months

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

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

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

PEGINTERFERON BETA-1A/ PEGINTERFERON BETA-1A

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

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

63 MCG / SYR * 94 MCG / SYR INJECTION SYRINGE

00002444402 PLEGRIDY

BIO

\$ 885.8010

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

RITUXIMAB

10 MG / ML INJECTION

☒ 00002478382 TRUXIMA (10 ML) CTC \$ 33.7615

Rheumatoid Arthritis

***Effective June 1, 2020, all new Special Authorization requests for the treatment of Rheumatoid Arthritis for rituximab naive patients will be assessed for coverage with Truxima. Rituxan will not be approved for new rituximab starts for patients with Rheumatoid Arthritis; however, coverage for Rituxan will continue for patients who completed a previous two-dose course of therapy with Rituxan and are considered a 'responder' as defined in criteria.

Additionally, patients will not be permitted to switch between rituximab products, if the patient has been previously trialed on any rituximab 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); AND
- One anti-tumor necrosis factor (anti-TNF) therapy (minimum 12 week trial).

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

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

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

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

For coverage for an additional two-dose course of therapy, the patient must meet the following criteria:

- 1) The patient must be assessed by an RA Specialist after each course of therapy, between 16 and 24 weeks after receiving the initial dose of each course of therapy, to determine response.
- 2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
 - An improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place] following the initial course of rituximab; AND
 - An improvement of 0.22 in HAQ score [reported to two (2) decimal places] following the initial course of rituximab.

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

- 3) The patient must have residual disease or disease activity returning to a level above a DAS28 score of 2.6.

Subsequent courses of therapy cannot be considered prior to 24 weeks elapsing from the initial dose of the previous course of therapy."

All requests (including renewal requests) for rituximab for Rheumatoid Arthritis must be completed using the Rituximab for Rheumatoid Arthritis Special Authorization Request Form (ABC 60046).

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

RITUXIMAB

☒ 00002478390 TRUXIMA (50 ML) CTC \$ 33.7615

Rheumatoid Arthritis

***Effective June 1, 2020, all new Special Authorization requests for the treatment of Rheumatoid Arthritis for rituximab naive patients will be assessed for coverage with Truxima. Rituxan will not be approved for new rituximab starts for patients with Rheumatoid Arthritis; however, coverage for Rituxan will continue for patients who completed a previous two-dose course of therapy with Rituxan and are considered a 'responder' as defined in criteria.

Additionally, patients will not be permitted to switch between rituximab products, if the patient has been previously trialed on any rituximab 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); AND
- One anti-tumor necrosis factor (anti-TNF) therapy (minimum 12 week trial).

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

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

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

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

For coverage for an additional two-dose course of therapy, the patient must meet the following criteria:

- 1) The patient must be assessed by an RA Specialist after each course of therapy, between 16 and 24 weeks after receiving the initial dose of each course of therapy, to determine response.
- 2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
 - An improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place] following the initial course of rituximab; AND
 - An improvement of 0.22 in HAQ score [reported to two (2) decimal places] following the initial course of rituximab.

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

- 3) The patient must have residual disease or disease activity returning to a level above a DAS28 score of 2.6.

Subsequent courses of therapy cannot be considered prior to 24 weeks elapsing from the initial dose of the previous course of therapy."

All requests (including renewal requests) for rituximab for Rheumatoid Arthritis must be completed using the Rituximab for Rheumatoid Arthritis Special Authorization Request Form (ABC 60046).

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

RITUXIMAB

00002241927 RITUXAN HLR \$ 48.2308

Granulomatosis with Polyangiitis (GPA) or Microscopic Polyangiitis (MPA)

"For use in combination with glucocorticoids for the induction of remission of severely active granulomatosis with polyangiitis (GPA, also known as Wegener's granulomatosis) or microscopic polyangiitis (MPA) in adult patients who have:

- Severe active disease that is life- or organ-threatening. The organ(s) and how the organ(s) is (are) threatened must be specified; AND
- A positive serum assay for either proteinase 3-ANCA (anti-neutrophil cytoplasmic antibody) or myeloperoxidase-ANCA. A copy of the lab report must be provided; AND
- Cyclophosphamide cannot be used for ONE of the following reasons:
 - a) The patient has failed a minimum of six intravenous pulses of cyclophosphamide; OR
 - b) The patient has failed three months of oral cyclophosphamide therapy; OR
 - c) The patient has a severe intolerance or an allergy to cyclophosphamide; OR
 - d) Cyclophosphamide is contraindicated; OR
 - e) The patient has received a cumulative lifetime dose of at least 25 grams of cyclophosphamide.

- Coverage may be approved for a maximum of 375 mg per square metre of body surface area weekly for 4 weeks.
- Patients will be limited to receiving two doses of rituximab per prescription at their pharmacy.
- For relapse following a remission, coverage may be provided for patients who experience a flare of severe active disease that is life- or organ-threatening; or, who experience worsening symptoms in 2 or more organs even if not life-threatening. Note: For relapse following a rituximab-induced remission, additional coverage may be approved no sooner than 6 months after previous rituximab treatment."

All requests (including renewal requests) for Rituxan for Granulomatosis with Polyangiitis (GPA) or Microscopic Polyangiitis (MPA) must be completed using the Rituxan for Granulomatosis with Polyangiitis/Microscopic Polyangiitis Special Authorization Request Form (ABC 60018).

Rheumatoid Arthritis

***Effective June 1, 2020, all new Special Authorization requests for the treatment of Rheumatoid Arthritis for rituximab naive patients will be assessed for coverage with Truxima. Rituxan will not be approved for new rituximab starts for patients with Rheumatoid Arthritis; however, coverage for Rituxan will continue for patients who completed a previous two-dose course of therapy with Rituxan and are considered a 'responder' as defined in criteria.

Additionally, patients will not be permitted to switch between rituximab products, if the patient has been previously trialed on any rituximab 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); AND
- One anti-tumor necrosis factor (anti-TNF) therapy (minimum 12 week trial).

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

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

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

- Initial coverage may be approved for a dose of 1000 mg of rituximab administered at 0 and 2 weeks (total of 2 - 1000 mg doses).
- Patients will be limited to receiving one dose of rituximab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another (with the exception of anakinra) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the

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

RITUXIMAB

completion of induction dosing (e.g. initial coverage period).

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

For coverage for an additional two-dose course of therapy, the patient must meet the following criteria:

1) The patient must be assessed by an RA Specialist after each course of therapy, between 16 and 24 weeks after receiving the initial dose of each course of therapy, to determine response.

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

- An improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place] following the initial course of rituximab; AND

- An improvement of 0.22 in HAQ score [reported to two (2) decimal places] following the initial course of rituximab.

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

3) The patient must have residual disease or disease activity returning to a level above a DAS28 score of 2.6.

Subsequent courses of therapy cannot be considered prior to 24 weeks elapsing from the initial dose of the previous course of therapy."

All requests (including renewal requests) for rituximab for Rheumatoid Arthritis must be completed using the Rituximab for Rheumatoid Arthritis Special Authorization Request Form (ABC 60046).

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

RIVAROXABAN

For use in combination with acetylsalicylic acid (ASA; 75 mg to 100 mg) for the prevention of stroke, myocardial infarction, and cardiovascular death, and for the prevention of acute limb ischemia and mortality in patients with concomitant coronary artery disease (CAD) and peripheral artery disease (PAD) as defined below.

Patients with CAD are defined as having one or more of the following:

- 1) myocardial infarction within the last 20 years
- 2) multi-vessel coronary disease (i.e., stenosis of greater than or equal to 50 per cent in two or more coronary arteries, or in one coronary territory if at least one other territory has been revascularized) with symptoms or history of stable or unstable angina
- 3) multi-vessel percutaneous coronary intervention
- 4) multi-vessel coronary artery bypass graft surgery.

For coverage, patients with CAD as defined above must also meet one of the following criteria:

- aged 65 years or older, or
- aged younger than 65 years with documented atherosclerosis or revascularization involving at least two vascular beds (coronary and other vascular) or at least two additional risk factors (current smoker, diabetes mellitus, estimated glomerular filtration rate less than 60 mL/min, heart failure, non-lacunar ischemic stroke 1 month or more ago).

Patients with PAD are defined as having one or more of the following:

- 1) previous aorto-femoral bypass surgery, limb bypass surgery, or percutaneous transluminal angioplasty revascularization of the iliac or infrainguinal arteries
- 2) previous limb or foot amputation for arterial vascular disease
- 3) history of intermittent claudication and one or more of the following:
 - an anklebrachial index less than 0.90
 - significant peripheral stenosis (greater than or equal to 50%) documented by angiography or by duplex ultrasound
- 4) previous carotid revascularization or asymptomatic carotid artery stenosis greater than or equal to 50%, as diagnosed by duplex ultrasound or angiography.

Exclusions from coverage:

- Patients who have CAD or PAD alone, OR;
- Patients with any one of the following characteristics:
 - 1) at high risk of bleeding
 - 2) a history of stroke within one month of treatment initiation or any history of hemorrhagic or lacunar stroke
 - 3) severe heart failure with a known ejection fraction less than 30% or New York Heart Association (NYHA) class III or IV symptoms
 - 4) an estimated glomerular filtration rate less than 15 mL/min
 - 5) require dual antiplatelet therapy, other non-ASA antiplatelet therapy, or oral anticoagulant therapy.

Special authorization may be granted for six months. This product is eligible for auto-renewal.

All requests for rivaroxaban 2.5 mg must be completed using the Rivaroxaban 2.5 mg Special Authorization Request Form (ABC 60081).

2.5 MG ORAL TABLET

00002480808 XARELTO BAI \$ 1.4200

TERIFLUNOMIDE

Relapsing Remitting Multiple Sclerosis (RRMS):

"Special authorization coverage may be provided for the reduction of the frequency and severity of clinical relapses and reduction of the number and volume of active brain lesions, identified on MRI scans, in ambulatory patients with relapsing remitting multiple sclerosis.

Coverage

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

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

Initial Coverage

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

*A relapse is defined as the appearance of new symptoms or worsening of old symptoms, lasting at least 48 hours in the absence of fever, not associated with withdrawal from steroids. Onset of clinical relapses must be separated by a period of at least one month. At least one new T2 lesion or definite gadolinium-enhancing T1 MRI lesion (not questionable faint enhancement) obtained at least 90 days after initiation of the DMT and at least 90 days before or after a relapse may substitute for one clinical relapse.

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

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

Continued Coverage

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

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

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

Continued coverage may be approved for up to 12 months. Patients may receive up to 100 days' supply of teriflunomide per prescription at their pharmacy.

Restarting After an Interruption in Therapy Greater Than 12 Months

In order to be eligible for coverage, after an interruption in therapy greater than 12 months, the

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

TERIFLUNOMIDE

patient must meet the following criteria:

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

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

14 MG ORAL TABLET

00002416328 AUBAGIO

GZM

\$ 57.7432

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)
- Humira (adalimumab)
- 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.

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

USTEKINUMAB

Following this assessment, continued coverage may be considered for 45 mg (90 mg for patients weighing greater than 100 kg) every 12 weeks for a period of 12 months. Ongoing coverage may be considered if the patient is re-assessed by a Dermatology Specialist every 12 months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above."

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

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

45 MG INJECTION VIAL OR SYRINGE

00002320673 STELARA (0.5 ML VIAL OR SYRINGE) JAI \$ 4465.5800

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

90 MG / SYR INJECTION SYRINGE

00002320681 STELARA (1.0 ML SYRINGE) JAI \$ 4465.5800
