

Updates to the Alberta Drug Benefit List

Effective November 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.

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

| <u>Trade Name / Strength / Form</u> | <u>Generic Description</u> | <u>DIN</u> | <u>MFR</u> |
|-------------------------------------|----------------------------|-------------|------------|
| ACH-PIOGLITAZONE 15 MG TABLET | PIOGLITAZONE HCL | 00002391600 | AHI |
| ACH-PIOGLITAZONE 30 MG TABLET | PIOGLITAZONE HCL | 00002339587 | AHI |
| ACH-PIOGLITAZONE 45 MG TABLET | PIOGLITAZONE HCL | 00002339595 | AHI |
| JAMP-PIOGLITAZONE 15 MG TABLET | PIOGLITAZONE HCL | 00002397307 | JPC |
| JAMP-PIOGLITAZONE 30 MG TABLET | PIOGLITAZONE HCL | 00002365529 | JPC |
| JAMP-PIOGLITAZONE 45 MG TABLET | PIOGLITAZONE HCL | 00002365537 | JPC |

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> |
|--|----------------------------|-------------|------------|
| ENBREL 25 MG / VIAL INJECTION | ETANERCEPT | 00002242903 | AMG |
| ENBREL 50 MG / SYRINGE INJECTION | ETANERCEPT | 00002274728 | AMG |
| ERELZI 25 MG / 0.5 ML INJECTION SYRINGE | ETANERCEPT | 00002462877 | SDZ |
| ERELZI 50 MG / ML INJECTION SYRINGE | ETANERCEPT | 00002462869 | SDZ |
| ERELZI 50 MG / ML SENSOREADY AUTO INJECTOR SYRINGE | ETANERCEPT | 00002462850 | SDZ |
| STELARA (0.5 ML VIAL OR SYRINGE) 45 MG VIAL OR SYRINGE INJECTION | USTEKINUMAB | 00002320673 | JAI |
| STELARA (1.0 ML SYRINGE) 90 MG / SYRINGE INJECTION | USTEKINUMAB | 00002320681 | JAI |

Optional Special Authorization

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

Please refer to [Section 3A](#) of the online Alberta Drug Benefit List for further information regarding the Optional Special Authorization of Select Drug Products criteria and related forms.

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

| <u>Trade Name / Strength / Form</u> | <u>Generic Description</u> | <u>DIN</u> | <u>MFR</u> |
|-------------------------------------|----------------------------|-------------|------------|
| AG-MOXIFLOXACIN 400 MG TABLET | MOXIFLOXACIN HCL | 00002478137 | AGP |

Added Product(s)

| <u>Trade Name / Strength / Form</u> | <u>Generic Description</u> | <u>DIN</u> | <u>MFR</u> |
|--|----------------------------|-------------|------------|
| ACARBOSE 50 MG TABLET | ACARBOSE | 00002493780 | STR |
| ACARBOSE 100 MG TABLET | ACARBOSE | 00002493799 | STR |
| AG-ATENOLOL 50 MG TABLET | ATENOLOL | 00002369184 | AGP |
| AG-ATENOLOL 100 MG TABLET | ATENOLOL | 00002369192 | AGP |
| AG-ATORVASTATIN 10 MG TABLET | ATORVASTATIN CALCIUM | 00002478145 | AGP |
| AG-ATORVASTATIN 20 MG TABLET | ATORVASTATIN CALCIUM | 00002478153 | AGP |
| AG-ATORVASTATIN 40 MG TABLET | ATORVASTATIN CALCIUM | 00002478161 | AGP |
| AG-ATORVASTATIN 80 MG TABLET | ATORVASTATIN CALCIUM | 00002478188 | AGP |
| AG-PAROXETINE 20 MG TABLET | PAROXETINE HCL | 00002475545 | AGP |
| AG-PAROXETINE 30 MG TABLET | PAROXETINE HCL | 00002475553 | AGP |
| AG-PRAVASTATIN 10 MG TABLET | PRAVASTATIN SODIUM | 00002476142 | AGP |
| AG-PRAVASTATIN 20 MG TABLET | PRAVASTATIN SODIUM | 00002476150 | AGP |
| AG-PRAVASTATIN 40 MG TABLET | PRAVASTATIN SODIUM | 00002476169 | AGP |
| AG-PREGABALIN 25 MG CAPSULE | PREGABALIN | 00002480727 | AGP |
| AG-PREGABALIN 50 MG CAPSULE | PREGABALIN | 00002480735 | AGP |
| AG-PREGABALIN 75 MG CAPSULE | PREGABALIN | 00002480743 | AGP |
| AG-PREGABALIN 150 MG CAPSULE | PREGABALIN | 00002480751 | AGP |
| AG-QUETIAPINE 25 MG TABLET | QUETIAPINE FUMARATE | 00002475979 | AGP |
| AG-RAMIPRIL 2.5 MG CAPSULE | RAMIPRIL | 00002477572 | AGP |
| AG-RAMIPRIL 5 MG CAPSULE | RAMIPRIL | 00002477580 | AGP |
| AG-RAMIPRIL 10 MG CAPSULE | RAMIPRIL | 00002477599 | AGP |
| AG-SERTRALINE 25 MG CAPSULE | SERTRALINE HCL | 00002477882 | AGP |
| AG-SERTRALINE 50 MG CAPSULE | SERTRALINE HCL | 00002477890 | AGP |
| AG-SERTRALINE 100 MG CAPSULE | SERTRALINE HCL | 00002477904 | AGP |
| CALCITRIOL 0.25 MCG CAPSULE | CALCITRIOL | 00002495899 | STR |
| CALCITRIOL 0.5 MCG CAPSULE | CALCITRIOL | 00002495902 | STR |
| FRAGMIN 16500 IU/0.66 ML INJECTION SYRINGE | DALTEPARIN SODIUM | 00002494582 | PFI |
| JAMP METHIMAZOLE 5 MG TABLET | THIAMAZOLE | 00002490625 | JPC |
| NRA-AMLODIPINE 2.5 MG TABLET | AMLODIPINE BESYLATE | 00002476452 | NRA |
| NRA-AMLODIPINE 5 MG TABLET | AMLODIPINE BESYLATE | 00002476460 | NRA |
| NRA-AMLODIPINE 10 MG TABLET | AMLODIPINE BESYLATE | 00002476479 | NRA |
| RIVA-PYRIDOSTIGMINE 60 MG TABLET | PYRIDOSTIGMINE BROMIDE | 00002495643 | RIV |

Added Product(s), continued

| <u>Trade Name / Strength / Form</u> | <u>Generic Description</u> | <u>DIN</u> | <u>MFR</u> |
|-------------------------------------|--|-------------|------------|
| TRI-JORDYNA (21 DAY) TABLET | NORGESTIMATE/ ETHINYL ESTRADIOL/ NORGESTIMATE/ ETHINYL ESTRADIOL/ NORGESTIMATE/ ETHINYL ESTRADIOL | 00002486296 | GLM |
| VALSARTAN 80 MG TABLET | VALSARTAN | 00002366959 | SNS |
| VALSARTAN 160 MG TABLET | VALSARTAN | 00002366967 | SNS |
| VALSARTAN 320 MG TABLET | VALSARTAN | 00002366975 | SNS |
| ZAMINE 21 TABLET | DROSPIRENONE/ ETHINYL ESTRADIOL | 00002410788 | APX |
| ZAMINE 28 TABLET | DROSPIRENONE/ ETHINYL ESTRADIOL | 00002410796 | APX |

New Established Interchangeable (IC) Grouping(s)

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

| <u>Generic Description</u> | <u>Strength / Form</u> | <u>New LCA Price</u> |
|---|---|----------------------|
| DROSPIRENONE/ ETHINYL ESTRADIOL | (21 DAY) 3 MG / 0.03 MG TABLET | 0.4442 |
| DROSPIRENONE/ ETHINYL ESTRADIOL | (28 DAY) 3 MG / 0.03 MG TABLET | 0.3332 |
| NORGESTIMATE/ ETHINYL ESTRADIOL/ NORGESTIMATE/ ETHINYL ESTRADIOL/ NORGESTIMATE/ ETHINYL ESTRADIOL | (21 DAY) 0.18 MG / 0.035 MG / 0.215 MG / 0.035 MG / 0.25 MG / 0.035 MG TABLET | 1.0279 |
| PIOGLITAZONE HCL | 45 MG TABLET | 1.3113 |
| PYRIDOSTIGMINE BROMIDE | 60 MG TABLET | 0.4009 |

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 decrease, will be effective December 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> |
|-----------------------------------|------------------------|----------------------|
| ACARBOSE | 50 MG TABLET | 0.1348 |
| ACARBOSE | 100 MG TABLET | 0.1866 |
| CALCITRIOL | 0.25 MCG CAPSULE | 0.2341 |
| CALCITRIOL | 0.5 MCG CAPSULE | 0.7446 |
| METHIMAZOLE | 5 MG TABLET | 0.1531 |
| METHOTREXATE SODIUM (UNPRESERVED) | 25 MG / ML INJECTION | 3.5101 |

Product(s) with a Price Change

The following product(s) had a Price Change. The previous higher price will be recognized until November 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> |
|---|----------------------------|-------------|------------|
| CALCITRIOL-ODAN 0.25 MCG CAPSULE | CALCITRIOL | 00002431637 | ODN |
| CALCITRIOL-ODAN 0.5 MCG CAPSULE | CALCITRIOL | 00002431645 | ODN |
| MAR-ACARBOSE 100 MG TABLET | ACARBOSE | 00002494086 | MAR |
| MAR-ACARBOSE 50 MG TABLET | ACARBOSE | 00002494078 | MAR |
| MAR-METHIMAZOLE 5 MG TABLET | THIAMAZOLE | 00002480107 | MAR |
| METHOTREXATE SODIUM (UNPRESERVED) 25 MG / ML INJECTION | METHOTREXATE SODIUM | 00002099705 | TEV |
| METOJECT SUBCUTANEOUS 15 MG / SYRINGE INJECTION | METHOTREXATE SODIUM | 00002454858 | MDX |
| METOJECT SUBCUTANEOUS 17.5 MG / SYRINGE INJECTION | METHOTREXATE SODIUM | 00002454769 | MDX |
| METOJECT SUBCUTANEOUS 20 MG / SYRINGE INJECTION | METHOTREXATE SODIUM | 00002454866 | MDX |
| METOJECT SUBCUTANEOUS 22.5 MG / SYRINGE INJECTION | METHOTREXATE SODIUM | 00002454777 | MDX |
| METOJECT SUBCUTANEOUS 25 MG / SYRINGE INJECTION | METHOTREXATE SODIUM | 00002454874 | MDX |
| RUXIENCE 10 MG / ML INJECTION | RITUXIMAB | 00002495724 | PFI |
| SALAGEN 5 MG TABLET | PILOCARPINE HCL | 00002216345 | AMD |
| TARO-CALCITRIOL 0.25 MCG CAPSULE | CALCITRIOL | 00002485710 | TAR |
| TARO-CALCITRIOL 0.5 MCG CAPSULE | CALCITRIOL | 00002485729 | TAR |
| ZIEXTENZO (0.6 ML SYRINGE) 6 MG / SYRINGE INJECTION | PEGFILGRASTIM | 00002497395 | SDZ |

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 November 1, 2020, the listed product(s) will no longer be a benefit and where applicable, will not be considered for coverage by Special Authorization. A transition period will be applied and as of December 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> |
|---|--|-------------|------------|
| ANUGESIC-HC RECTAL SUPPOSITORY | HYDROCORTISONE ACETATE/ PRAMOXINE HCL/ ZINC SULFATE | 00000476242 | MCL |
| DDAVP 10 MCG / DOSE NASAL METERED DOSE SPRAY | DESMOPRESSIN ACETATE | 00000836362 | FEI |
| FIBRISTAL 5 MG TABLET | ULIPRISTAL ACETATE | 00002408163 | ALL |

Discontinued Listing(s), continued

| <u>Trade Name / Strength / Form</u> | <u>Generic Description</u> | <u>DIN</u> | <u>MFR</u> |
|--|----------------------------|-------------|------------|
| JAMP-ALPRAZOLAM 0.25 MG TABLET | ALPRAZOLAM | 00002400111 | JPC |
| JAMP-ALPRAZOLAM 0.5 MG TABLET | ALPRAZOLAM | 00002400138 | JPC |
| LIORESAL 10 MG TABLET | BACLOFEN | 00000455881 | NOV |
| LIORESAL D.S. 20 MG TABLET | BACLOFEN | 00000636576 | NOV |
| LOZIDE 2.5 MG TABLET | INDAPAMIDE HEMIHYDRATE | 00000564966 | SEV |
| OCTOSTIM 150 MCG / DOSE NASAL METERED DOSE SPRAY | DESMOPRESSIN ACETATE | 00002237860 | FEI |
| ORCIPRENALINE 2 MG / ML ORAL SYRUP | ORCIPRENALINE SULFATE | 00002236783 | AAP |
| PRINIVIL 10 MG TABLET | LISINOPRIL | 00000839396 | MFC |
| VOLTAREN 50 MG ENTERIC-COATED TABLET | DICLOFENAC SODIUM | 00000514012 | NOV |

PART 2

Drug Additions

ALBERTA DRUG BENEFIT LIST UPDATE

ACARBOSE

50 MG ORAL TABLET

| | | | | |
|-------------|--------------|-----|----|--------|
| 00002493780 | ACARBOSE | STR | \$ | 0.1348 |
| 00002494078 | MAR-ACARBOSE | MAR | \$ | 0.1348 |
| 00002190885 | GLUCOBAY | BAI | \$ | 0.2695 |

100 MG ORAL TABLET

| | | | | |
|-------------|--------------|-----|----|--------|
| 00002493799 | ACARBOSE | STR | \$ | 0.1866 |
| 00002494086 | MAR-ACARBOSE | MAR | \$ | 0.1866 |
| 00002190893 | GLUCOBAY | BAI | \$ | 0.3733 |

AMLODIPINE BESYLATE

2.5 MG (BASE) ORAL TABLET

| | | | | |
|-------------|---------------------|-----|----|--------|
| 00002385783 | AMLODIPINE | SIV | \$ | 0.0767 |
| 00002419556 | AMLODIPINE BESYLATE | AHI | \$ | 0.0767 |
| 00002371707 | MAR-AMLODIPINE | MAR | \$ | 0.0767 |
| 00002476452 | NRA-AMLODIPINE | NRA | \$ | 0.0767 |
| 00002469022 | PHARMA-AMLODIPINE | PMS | \$ | 0.0767 |
| 00002295148 | PMS-AMLODIPINE | PMS | \$ | 0.0767 |
| 00002330474 | SANDOZ AMLODIPINE | SDZ | \$ | 0.0767 |

5 MG (BASE) ORAL TABLET

| | | | | |
|-------------|---------------------|-----|----|--------|
| 00002297485 | ACT AMLODIPINE | APH | \$ | 0.1343 |
| 00002331284 | AMLODIPINE | SNS | \$ | 0.1343 |
| 00002385791 | AMLODIPINE | SIV | \$ | 0.1343 |
| 00002429217 | AMLODIPINE | JPC | \$ | 0.1343 |
| 00002419564 | AMLODIPINE BESYLATE | AHI | \$ | 0.1343 |
| 00002273373 | APO-AMLODIPINE | APX | \$ | 0.1343 |
| 00002397072 | AURO-AMLODIPINE | AUR | \$ | 0.1343 |
| 00002371715 | MAR-AMLODIPINE | MAR | \$ | 0.1343 |
| 00002362651 | MINT-AMLODIPINE | MPI | \$ | 0.1343 |
| 00002272113 | MYLAN-AMLODIPINE | MYP | \$ | 0.1343 |
| 00002476460 | NRA-AMLODIPINE | NRA | \$ | 0.1343 |
| 00002469030 | PHARMA-AMLODIPINE | PMS | \$ | 0.1343 |
| 00002321858 | RAN-AMLODIPINE | RAN | \$ | 0.1343 |
| 00002284383 | SANDOZ AMLODIPINE | SDZ | \$ | 0.1343 |
| 00002357712 | SEPTA-AMLODIPINE | SEP | \$ | 0.1343 |
| 00000878928 | NORVASC | UJC | \$ | 1.4064 |

10 MG (BASE) ORAL TABLET

| | | | | |
|-------------|---------------------|-----|----|--------|
| 00002297493 | ACT AMLODIPINE | APH | \$ | 0.1993 |
| 00002331292 | AMLODIPINE | SNS | \$ | 0.1993 |
| 00002385805 | AMLODIPINE | SIV | \$ | 0.1993 |
| 00002429225 | AMLODIPINE | JPC | \$ | 0.1993 |
| 00002419572 | AMLODIPINE BESYLATE | AHI | \$ | 0.1993 |
| 00002273381 | APO-AMLODIPINE | APX | \$ | 0.1993 |
| 00002397080 | AURO-AMLODIPINE | AUR | \$ | 0.1993 |
| 00002371723 | MAR-AMLODIPINE | MAR | \$ | 0.1993 |
| 00002362678 | MINT-AMLODIPINE | MPI | \$ | 0.1993 |
| 00002272121 | MYLAN-AMLODIPINE | MYP | \$ | 0.1993 |
| 00002476479 | NRA-AMLODIPINE | NRA | \$ | 0.1993 |
| 00002469049 | PHARMA-AMLODIPINE | PMS | \$ | 0.1993 |
| 00002321866 | RAN-AMLODIPINE | RAN | \$ | 0.1993 |
| 00002284391 | SANDOZ AMLODIPINE | SDZ | \$ | 0.1993 |
| 00002357720 | SEPTA-AMLODIPINE | SEP | \$ | 0.1993 |
| 00000878936 | NORVASC | UJC | \$ | 2.0528 |

ALBERTA DRUG BENEFIT LIST UPDATE

ATENOLOL

50 MG ORAL TABLET

| | | | | |
|-------------|---------------|-----|----|--------|
| 00002369184 | AG-ATENOLOL | AGP | \$ | 0.1107 |
| 00000773689 | APO-ATENOL | APX | \$ | 0.1107 |
| 00002238316 | ATENOLOL | SIV | \$ | 0.1107 |
| 00002466465 | ATENOLOL | SNS | \$ | 0.1107 |
| 00002367564 | JAMP-ATENOLOL | JPC | \$ | 0.1107 |
| 00002371987 | MAR-ATENOLOL | MAR | \$ | 0.1107 |
| 00002368021 | MINT-ATENOL | MPI | \$ | 0.1107 |
| 00002237600 | PMS-ATENOLOL | PMS | \$ | 0.1107 |
| 00002267985 | RAN-ATENOLOL | RAN | \$ | 0.1107 |
| 00002171791 | TEVA-ATENOLOL | TEV | \$ | 0.1107 |
| 00002039532 | TENORMIN | AZC | \$ | 0.6086 |

100 MG ORAL TABLET

| | | | | |
|-------------|---------------|-----|----|--------|
| 00002369192 | AG-ATENOLOL | AGP | \$ | 0.1821 |
| 00000773697 | APO-ATENOL | APX | \$ | 0.1821 |
| 00002238318 | ATENOLOL | SIV | \$ | 0.1821 |
| 00002466473 | ATENOLOL | SNS | \$ | 0.1821 |
| 00002367572 | JAMP-ATENOLOL | JPC | \$ | 0.1821 |
| 00002371995 | MAR-ATENOLOL | MAR | \$ | 0.1821 |
| 00002368048 | MINT-ATENOL | MPI | \$ | 0.1821 |
| 00002237601 | PMS-ATENOLOL | PMS | \$ | 0.1821 |
| 00002267993 | RAN-ATENOLOL | RAN | \$ | 0.1821 |
| 00002171805 | TEVA-ATENOLOL | TEV | \$ | 0.1821 |
| 00002039540 | TENORMIN | AZC | \$ | 1.0006 |

ATORVASTATIN CALCIUM

10 MG (BASE) ORAL TABLET

| | | | | |
|-------------|---------------------|-----|----|--------|
| 00002457741 | ACH-ATORVASTATIN | AHI | \$ | 0.1743 |
| 00002478145 | AG-ATORVASTATIN | AGP | \$ | 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 | UJC | \$ | 1.8223 |

20 MG (BASE) ORAL TABLET

| | | | | |
|-------------|---------------------|-----|----|--------|
| 00002457768 | ACH-ATORVASTATIN | AHI | \$ | 0.2179 |
| 00002478153 | AG-ATORVASTATIN | AGP | \$ | 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 | UJC | \$ | 2.2779 |

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

ALBERTA DRUG BENEFIT LIST UPDATE

ATORVASTATIN CALCIUM

40 MG (BASE) ORAL TABLET

| | | | | |
|-------------|---------------------|-----|----|--------|
| 00002457776 | ACH-ATORVASTATIN | AHI | \$ | 0.2342 |
| 00002478161 | AG-ATORVASTATIN | AGP | \$ | 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 | UJC | \$ | 2.4483 |

80 MG (BASE) ORAL TABLET

| | | | | |
|-------------|---------------------|-----|----|--------|
| 00002457784 | ACH-ATORVASTATIN | AHI | \$ | 0.2342 |
| 00002478188 | AG-ATORVASTATIN | AGP | \$ | 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 | UJC | \$ | 2.4483 |

CALCITRIOL

0.25 MCG ORAL CAPSULE

| | | | | |
|-------------|-----------------|-----|----|--------|
| 00002495899 | CALCITRIOL | STR | \$ | 0.2341 |
| 00002431637 | CALCITRIOL-ODAN | ODN | \$ | 0.2341 |
| 00002485710 | TARO-CALCITRIOL | TAR | \$ | 0.2341 |
| 00000481823 | ROCALTROL | HLR | \$ | 0.7071 |

0.5 MCG ORAL CAPSULE

| | | | | |
|-------------|-----------------|-----|----|--------|
| 00002495902 | CALCITRIOL | STR | \$ | 0.3723 |
| 00002431645 | CALCITRIOL-ODAN | ODN | \$ | 0.3723 |
| 00002485729 | TARO-CALCITRIOL | TAR | \$ | 0.3723 |
| 00000481815 | ROCALTROL | HLR | \$ | 1.1246 |

DALTEPARIN SODIUM

16,500 IU / SYR INJECTION SYRINGE

| | | | | |
|-------------|---------|-----|----|---------|
| 00002494582 | FRAGMIN | PFI | \$ | 36.0740 |
|-------------|---------|-----|----|---------|

DROSPIRENONE/ ETHINYL ESTRADIOL

3 MG * 0.03 MG ORAL TABLET

| | | | | |
|-------------|-----------|-----|----|--------|
| 00002410788 | ZAMINE 21 | APX | \$ | 0.4442 |
| 00002261723 | YASMIN 21 | BAI | \$ | 0.5924 |

3 MG * 0.03 MG ORAL TABLET

| | | | | |
|-------------|-----------|-----|----|--------|
| 00002410796 | ZAMINE 28 | APX | \$ | 0.3332 |
| 00002261731 | YASMIN 28 | BAI | \$ | 0.4443 |

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

ALBERTA DRUG BENEFIT LIST UPDATE

METHOTREXATE SODIUM

| | | | | |
|----------------------|--------------------------------|-----|----|---------|
| 25 MG / ML (BASE) | INJECTION | | | |
| 00002099705 | METHOTREXATE SOD.(UNPRESERVED) | TEV | \$ | 3.5101 |
| 00002182955 | METHOTREXATE SOD.(UNPRESERVED) | PFI | \$ | 5.6250 |
| 15 MG / SYR (BASE) | INJECTION SYRINGE | | | |
| 00002454858 | METOJECT SUBCUTANEOUS | MDX | \$ | 24.5700 |
| 17.5 MG / SYR (BASE) | INJECTION SYRINGE | | | |
| 00002454769 | METOJECT SUBCUTANEOUS | MDX | \$ | 24.0000 |
| 20 MG / SYR (BASE) | INJECTION SYRINGE | | | |
| 00002454866 | METOJECT SUBCUTANEOUS | MDX | \$ | 26.2500 |
| 22.5 MG / SYR (BASE) | INJECTION SYRINGE | | | |
| 00002454777 | METOJECT SUBCUTANEOUS | MDX | \$ | 26.2500 |
| 25 MG / SYR (BASE) | INJECTION SYRINGE | | | |
| 00002454874 | METOJECT SUBCUTANEOUS | MDX | \$ | 29.2500 |

**NORGESTIMATE/ ETHINYL ESTRADIOL/ NORGESTIMATE/
ETHINYL ESTRADIOL/ NORGESTIMATE/ ETHINYL ESTRADIOL**

| | | | | |
|---|----------------------|-----|----|--------|
| 0.18 MG * 0.035 MG * 0.215 MG * 0.035 MG * 0.25 MG * 0.035 MG | ORAL TABLET | | | |
| 00002486296 | TRI-JORDYNA (21 DAY) | GLM | \$ | 1.0279 |
| 00002028700 | TRI-CYCLEN (21 DAY) | JAI | \$ | 1.2715 |

PAROXETINE HCL

| | | | | |
|--------------|-----------------|-----|----|--------|
| 20 MG (BASE) | ORAL TABLET | | | |
| 00002475545 | AG-PAROXETINE | AGP | \$ | 0.3250 |
| 00002240908 | APO-PAROXETINE | APX | \$ | 0.3250 |
| 00002383284 | AURO-PAROXETINE | AUR | \$ | 0.3250 |
| 00002368870 | JAMP-PAROXETINE | JPC | \$ | 0.3250 |
| 00002411954 | MAR-PAROXETINE | MAR | \$ | 0.3250 |
| 00002421380 | MINT-PAROXETINE | MPI | \$ | 0.3250 |
| 00002282852 | PAROXETINE | SNS | \$ | 0.3250 |
| 00002388235 | PAROXETINE | SIV | \$ | 0.3250 |
| 00002247751 | PMS-PAROXETINE | PMS | \$ | 0.3250 |
| 00002248557 | TEVA-PAROXETINE | TEV | \$ | 0.3250 |
| 00001940481 | PAXIL | GSK | \$ | 1.8959 |
| 30 MG (BASE) | ORAL TABLET | | | |
| 00002475553 | AG-PAROXETINE | AGP | \$ | 0.3453 |
| 00002240909 | APO-PAROXETINE | APX | \$ | 0.3453 |
| 00002383292 | AURO-PAROXETINE | AUR | \$ | 0.3453 |
| 00002368889 | JAMP-PAROXETINE | JPC | \$ | 0.3453 |
| 00002411962 | MAR-PAROXETINE | MAR | \$ | 0.3453 |
| 00002421399 | MINT-PAROXETINE | MPI | \$ | 0.3453 |
| 00002282860 | PAROXETINE | SNS | \$ | 0.3453 |
| 00002388243 | PAROXETINE | SIV | \$ | 0.3453 |
| 00002247752 | PMS-PAROXETINE | PMS | \$ | 0.3453 |
| 00001940473 | PAXIL | GSK | \$ | 2.0140 |

PILOCARPINE HCL

| | | | | |
|-------------|-------------------|-----|----|--------|
| 5 MG | ORAL TABLET | | | |
| 00002496119 | ACCEL-PILOCARPINE | ACP | \$ | 1.2445 |
| 00002216345 | SALAGEN | AMD | \$ | 1.2445 |

ALBERTA DRUG BENEFIT LIST UPDATE

PRAVASTATIN SODIUM

10 MG ORAL TABLET

| | | | | | |
|-------------|--------------------|-----|-----------|----|--------|
| 00002440644 | ACH-PRAVASTATIN | AHI | \$ 0.1354 | \$ | 0.2916 |
| 00002476142 | AG-PRAVASTATIN | AGP | \$ 0.1354 | \$ | 0.2916 |
| 00002243506 | APO-PRAVASTATIN | APX | \$ 0.1354 | \$ | 0.2916 |
| 00002458977 | AURO-PRAVASTATIN | AUR | \$ 0.1354 | \$ | 0.2916 |
| 00002330954 | JAMP-PRAVASTATIN | JPC | \$ 0.1354 | \$ | 0.2916 |
| 00002432048 | MAR-PRAVASTATIN | MAR | \$ 0.1354 | \$ | 0.2916 |
| 00002317451 | MINT-PRAVASTATIN | MPI | \$ 0.1354 | \$ | 0.2916 |
| 00002247655 | PMS-PRAVASTATIN | PMS | \$ 0.1354 | \$ | 0.2916 |
| 00002356546 | PRAVASTATIN | SNS | \$ 0.1354 | \$ | 0.2916 |
| 00002389703 | PRAVASTATIN | SIV | \$ 0.1354 | \$ | 0.2916 |
| 00002284421 | RAN-PRAVASTATIN | RAN | \$ 0.1354 | \$ | 0.2916 |
| 00002468700 | SANDOZ PRAVASTATIN | SDZ | \$ 0.1354 | \$ | 0.2916 |
| 00002247008 | TEVA-PRAVASTATIN | TEV | \$ 0.1354 | \$ | 0.2916 |

MAC pricing will be applied based on the LCA Price for Rosuvastatin Calcium 1 x 10 mg tablet or the LCA Price of Atorvastatin 1 x 20 mg tablet whichever is lower.

20 MG ORAL TABLET

| | | | | | |
|-------------|--------------------|-----|-----------|----|--------|
| 00002440652 | ACH-PRAVASTATIN | AHI | \$ 0.1354 | \$ | 0.3440 |
| 00002476150 | AG-PRAVASTATIN | AGP | \$ 0.1354 | \$ | 0.3440 |
| 00002243507 | APO-PRAVASTATIN | APX | \$ 0.1354 | \$ | 0.3440 |
| 00002458985 | AURO-PRAVASTATIN | AUR | \$ 0.1354 | \$ | 0.3440 |
| 00002330962 | JAMP-PRAVASTATIN | JPC | \$ 0.1354 | \$ | 0.3440 |
| 00002432056 | MAR-PRAVASTATIN | MAR | \$ 0.1354 | \$ | 0.3440 |
| 00002317478 | MINT-PRAVASTATIN | MPI | \$ 0.1354 | \$ | 0.3440 |
| 00002247656 | PMS-PRAVASTATIN | PMS | \$ 0.1354 | \$ | 0.3440 |
| 00002356554 | PRAVASTATIN | SNS | \$ 0.1354 | \$ | 0.3440 |
| 00002389738 | PRAVASTATIN | SIV | \$ 0.1354 | \$ | 0.3440 |
| 00002284448 | RAN-PRAVASTATIN | RAN | \$ 0.1354 | \$ | 0.3440 |
| 00002468719 | SANDOZ PRAVASTATIN | SDZ | \$ 0.1354 | \$ | 0.3440 |
| 00002247009 | TEVA-PRAVASTATIN | TEV | \$ 0.1354 | \$ | 0.3440 |
| 00000893757 | PRAVACHOL | BMS | \$ 0.1354 | \$ | 1.1243 |

MAC pricing will be applied based on the LCA Price for Rosuvastatin Calcium 1 x 10 mg tablet or the LCA Price of Atorvastatin 1 x 20 mg tablet whichever is lower.

40 MG ORAL TABLET

| | | | | | |
|-------------|--------------------|-----|-----------|----|--------|
| 00002440660 | ACH-PRAVASTATIN | AHI | \$ 0.1354 | \$ | 0.4143 |
| 00002476169 | AG-PRAVASTATIN | AGP | \$ 0.1354 | \$ | 0.4143 |
| 00002243508 | APO-PRAVASTATIN | APX | \$ 0.1354 | \$ | 0.4143 |
| 00002458993 | AURO-PRAVASTATIN | AUR | \$ 0.1354 | \$ | 0.4143 |
| 00002330970 | JAMP-PRAVASTATIN | JPC | \$ 0.1354 | \$ | 0.4143 |
| 00002432064 | MAR-PRAVASTATIN | MAR | \$ 0.1354 | \$ | 0.4143 |
| 00002317486 | MINT-PRAVASTATIN | MPI | \$ 0.1354 | \$ | 0.4143 |
| 00002247657 | PMS-PRAVASTATIN | PMS | \$ 0.1354 | \$ | 0.4143 |
| 00002356562 | PRAVASTATIN | SNS | \$ 0.1354 | \$ | 0.4143 |
| 00002389746 | PRAVASTATIN | SIV | \$ 0.1354 | \$ | 0.4143 |
| 00002284456 | RAN-PRAVASTATIN | RAN | \$ 0.1354 | \$ | 0.4143 |
| 00002468727 | SANDOZ PRAVASTATIN | SDZ | \$ 0.1354 | \$ | 0.4143 |
| 00002247010 | TEVA-PRAVASTATIN | TEV | \$ 0.1354 | \$ | 0.4143 |
| 00002222051 | PRAVACHOL | BMS | \$ 0.1354 | \$ | 1.3543 |

MAC pricing will be applied based on the LCA Price for Rosuvastatin Calcium 1 x 10 mg tablet or the LCA Price of Atorvastatin 1 x 20 mg tablet whichever is lower.

ALBERTA DRUG BENEFIT LIST UPDATE

PREGABALIN

25 MG ORAL CAPSULE

| | | | | |
|-------------|-------------------|-----|----|--------|
| 00002480727 | AG-PREGABALIN | AGP | \$ | 0.1481 |
| 00002394235 | APO-PREGABALIN | APX | \$ | 0.1481 |
| 00002433869 | AURO-PREGABALIN | AUR | \$ | 0.1481 |
| 00002435977 | JAMP-PREGABALIN | JPC | \$ | 0.1481 |
| 00002423804 | MINT-PREGABALIN | MPI | \$ | 0.1481 |
| 00002494841 | NAT-PREGABALIN | NTP | \$ | 0.1481 |
| 00002359596 | PMS-PREGABALIN | PMS | \$ | 0.1481 |
| 00002403692 | PREGABALIN | SIV | \$ | 0.1481 |
| 00002405539 | PREGABALIN | SNS | \$ | 0.1481 |
| 00002392801 | RAN-PREGABALIN | RAN | \$ | 0.1481 |
| 00002390817 | SANDOZ PREGABALIN | SDZ | \$ | 0.1481 |
| 00002361159 | TEVA-PREGABALIN | TEV | \$ | 0.1481 |

50 MG ORAL CAPSULE

| | | | | |
|-------------|-------------------|-----|----|--------|
| 00002480735 | AG-PREGABALIN | AGP | \$ | 0.2324 |
| 00002394243 | APO-PREGABALIN | APX | \$ | 0.2324 |
| 00002433877 | AURO-PREGABALIN | AUR | \$ | 0.2324 |
| 00002435985 | JAMP-PREGABALIN | JPC | \$ | 0.2324 |
| 00002423812 | MINT-PREGABALIN | MPI | \$ | 0.2324 |
| 00002494868 | NAT-PREGABALIN | NTP | \$ | 0.2324 |
| 00002359618 | PMS-PREGABALIN | PMS | \$ | 0.2324 |
| 00002403706 | PREGABALIN | SIV | \$ | 0.2324 |
| 00002405547 | PREGABALIN | SNS | \$ | 0.2324 |
| 00002392828 | RAN-PREGABALIN | RAN | \$ | 0.2324 |
| 00002390825 | SANDOZ PREGABALIN | SDZ | \$ | 0.2324 |
| 00002361175 | TEVA-PREGABALIN | TEV | \$ | 0.2324 |

75 MG ORAL CAPSULE

| | | | | |
|-------------|-------------------|-----|----|--------|
| 00002480743 | AG-PREGABALIN | AGP | \$ | 0.3007 |
| 00002394251 | APO-PREGABALIN | APX | \$ | 0.3007 |
| 00002433885 | AURO-PREGABALIN | AUR | \$ | 0.3007 |
| 00002435993 | JAMP-PREGABALIN | JPC | \$ | 0.3007 |
| 00002424185 | MINT-PREGABALIN | MPI | \$ | 0.3007 |
| 00002494876 | NAT-PREGABALIN | NTP | \$ | 0.3007 |
| 00002359626 | PMS-PREGABALIN | PMS | \$ | 0.3007 |
| 00002403714 | PREGABALIN | SIV | \$ | 0.3007 |
| 00002405555 | PREGABALIN | SNS | \$ | 0.3007 |
| 00002392836 | RAN-PREGABALIN | RAN | \$ | 0.3007 |
| 00002390833 | SANDOZ PREGABALIN | SDZ | \$ | 0.3007 |
| 00002361183 | TEVA-PREGABALIN | TEV | \$ | 0.3007 |

150 MG ORAL CAPSULE

| | | | | |
|-------------|-------------------|-----|----|--------|
| 00002480751 | AG-PREGABALIN | AGP | \$ | 0.4145 |
| 00002394278 | APO-PREGABALIN | APX | \$ | 0.4145 |
| 00002433907 | AURO-PREGABALIN | AUR | \$ | 0.4145 |
| 00002436000 | JAMP-PREGABALIN | JPC | \$ | 0.4145 |
| 00002424207 | MINT-PREGABALIN | MPI | \$ | 0.4145 |
| 00002494884 | NAT-PREGABALIN | NTP | \$ | 0.4145 |
| 00002359634 | PMS-PREGABALIN | PMS | \$ | 0.4145 |
| 00002403722 | PREGABALIN | SIV | \$ | 0.4145 |
| 00002405563 | PREGABALIN | SNS | \$ | 0.4145 |
| 00002392844 | RAN-PREGABALIN | RAN | \$ | 0.4145 |
| 00002390841 | SANDOZ PREGABALIN | SDZ | \$ | 0.4145 |
| 00002361205 | TEVA-PREGABALIN | TEV | \$ | 0.4145 |

PYRIDOSTIGMINE BROMIDE

60 MG ORAL TABLET

| | | | | |
|-------------|---------------------|-----|----|--------|
| 00002495643 | RIVA-PYRIDOSTIGMINE | RIV | \$ | 0.4009 |
| 00000869961 | MESTINON | VCL | \$ | 0.4986 |

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

ALBERTA DRUG BENEFIT LIST UPDATE

QUETIAPINE FUMARATE

25 MG (BASE) ORAL TABLET

| | | | | |
|-------------|-----------------|-----|----|--------|
| 00002316080 | ACT QUETIAPINE | APH | \$ | 0.0494 |
| 00002475979 | AG-QUETIAPINE | AGP | \$ | 0.0494 |
| 00002313901 | APO-QUETIAPINE | APX | \$ | 0.0494 |
| 00002390205 | AURO-QUETIAPINE | AUR | \$ | 0.0494 |
| 00002447193 | BIO-QUETIAPINE | BMD | \$ | 0.0494 |
| 00002330415 | JAMP-QUETIAPINE | JPC | \$ | 0.0494 |
| 00002399822 | MAR-QUETIAPINE | MAR | \$ | 0.0494 |
| 00002438003 | MINT-QUETIAPINE | MPI | \$ | 0.0494 |
| 00002439158 | NAT-QUETIAPINE | NTP | \$ | 0.0494 |
| 00002296551 | PMS-QUETIAPINE | PMS | \$ | 0.0494 |
| 00002317893 | QUETIAPINE | SIV | \$ | 0.0494 |
| 00002353164 | QUETIAPINE | SNS | \$ | 0.0494 |
| 00002387794 | QUETIAPINE | AHI | \$ | 0.0494 |
| 00002397099 | RAN-QUETIAPINE | RAN | \$ | 0.0494 |
| 00002236951 | SEROQUEL | AZC | \$ | 0.5195 |

RAMIPRIL

2.5 MG ORAL CAPSULE/TABLET

| | | | | |
|-------------|---------------------------|-----|----|--------|
| 00002477572 | AG-RAMIPRIL (CAPSULE) | AGP | \$ | 0.0817 |
| 00002251531 | APO-RAMIPRIL (CAPSULE) | APX | \$ | 0.0817 |
| 00002387395 | AURO-RAMIPRIL (CAPSULE) | AUR | \$ | 0.0817 |
| 00002331128 | JAMP-RAMIPRIL (CAPSULE) | JPC | \$ | 0.0817 |
| 00002420465 | MAR-RAMIPRIL (CAPSULE) | MAR | \$ | 0.0817 |
| 00002421305 | MINT-RAMIPRIL (CAPSULE) | MPI | \$ | 0.0817 |
| 00002469065 | PHARMA-RAMIPRIL (CAPSULE) | PMS | \$ | 0.0817 |
| 00002287927 | RAMIPRIL (CAPSULE) | SIV | \$ | 0.0817 |
| 00002374846 | RAMIPRIL (CAPSULE) | SNS | \$ | 0.0817 |
| 00002310511 | RAN-RAMIPRIL (CAPSULE) | RAN | \$ | 0.0817 |
| 00002247945 | TEVA-RAMIPRIL (CAPSULE) | TEV | \$ | 0.0817 |
| 00002221837 | ALTACE (CAPSULE) | VCL | \$ | 0.8726 |

5 MG ORAL CAPSULE/TABLET

| | | | | |
|-------------|---------------------------|-----|----|--------|
| 00002477580 | AG-RAMIPRIL (CAPSULE) | AGP | \$ | 0.0817 |
| 00002251574 | APO-RAMIPRIL (CAPSULE) | APX | \$ | 0.0817 |
| 00002387409 | AURO-RAMIPRIL (CAPSULE) | AUR | \$ | 0.0817 |
| 00002331136 | JAMP-RAMIPRIL (CAPSULE) | JPC | \$ | 0.0817 |
| 00002420473 | MAR-RAMIPRIL (CAPSULE) | MAR | \$ | 0.0817 |
| 00002421313 | MINT-RAMIPRIL (CAPSULE) | MPI | \$ | 0.0817 |
| 00002469073 | PHARMA-RAMIPRIL (CAPSULE) | PMS | \$ | 0.0817 |
| 00002287935 | RAMIPRIL (CAPSULE) | SIV | \$ | 0.0817 |
| 00002374854 | RAMIPRIL (CAPSULE) | SNS | \$ | 0.0817 |
| 00002310538 | RAN-RAMIPRIL (CAPSULE) | RAN | \$ | 0.0817 |
| 00002247946 | TEVA-RAMIPRIL (CAPSULE) | TEV | \$ | 0.0817 |
| 00002221845 | ALTACE (CAPSULE) | VCL | \$ | 0.8954 |

10 MG ORAL CAPSULE/TABLET

| | | | | |
|-------------|---------------------------|-----|----|--------|
| 00002477599 | AG-RAMIPRIL (CAPSULE) | AGP | \$ | 0.1034 |
| 00002251582 | APO-RAMIPRIL (CAPSULE) | APX | \$ | 0.1034 |
| 00002387417 | AURO-RAMIPRIL (CAPSULE) | AUR | \$ | 0.1034 |
| 00002331144 | JAMP-RAMIPRIL (CAPSULE) | JPC | \$ | 0.1034 |
| 00002420481 | MAR-RAMIPRIL (CAPSULE) | MAR | \$ | 0.1034 |
| 00002421321 | MINT-RAMIPRIL (CAPSULE) | MPI | \$ | 0.1034 |
| 00002469081 | PHARMA-RAMIPRIL (CAPSULE) | PMS | \$ | 0.1034 |
| 00002287943 | RAMIPRIL (CAPSULE) | SIV | \$ | 0.1034 |
| 00002374862 | RAMIPRIL (CAPSULE) | SNS | \$ | 0.1034 |
| 00002310546 | RAN-RAMIPRIL (CAPSULE) | RAN | \$ | 0.1034 |
| 00002247947 | TEVA-RAMIPRIL (CAPSULE) | TEV | \$ | 0.1034 |
| 00002221853 | ALTACE (CAPSULE) | VCL | \$ | 1.1501 |

ALBERTA DRUG BENEFIT LIST UPDATE

SERTRALINE HCL

| | | | |
|-----------------------------------|-------------------|-----|-----------|
| 25 MG (BASE) ORAL CAPSULE | | | |
| 00002477882 | AG-SERTRALINE | AGP | \$ 0.1516 |
| 00002238280 | APO-SERTRALINE | APX | \$ 0.1516 |
| 00002390906 | AURO-SERTRALINE | AUR | \$ 0.1516 |
| 00002357143 | JAMP-SERTRALINE | JPC | \$ 0.1516 |
| 00002399415 | MAR-SERTRALINE | MAR | \$ 0.1516 |
| 00002402378 | MINT-SERTRALINE | MPI | \$ 0.1516 |
| 00002244838 | PMS-SERTRALINE | PMS | \$ 0.1516 |
| 00002245159 | SANDOZ SERTRALINE | SDZ | \$ 0.1516 |
| 00002353520 | SERTRALINE | SNS | \$ 0.1516 |
| 00002386070 | SERTRALINE | SIV | \$ 0.1516 |
| 00002469626 | SERTRALINE | JPC | \$ 0.1516 |
| 00002240485 | TEVA-SERTRALINE | TEV | \$ 0.1516 |
| 00002132702 | ZOLOFT | UJC | \$ 0.8762 |
| 50 MG (BASE) ORAL CAPSULE | | | |
| 00002477890 | AG-SERTRALINE | AGP | \$ 0.3032 |
| 00002238281 | APO-SERTRALINE | APX | \$ 0.3032 |
| 00002390914 | AURO-SERTRALINE | AUR | \$ 0.3032 |
| 00002357151 | JAMP-SERTRALINE | JPC | \$ 0.3032 |
| 00002399423 | MAR-SERTRALINE | MAR | \$ 0.3032 |
| 00002402394 | MINT-SERTRALINE | MPI | \$ 0.3032 |
| 00002244839 | PMS-SERTRALINE | PMS | \$ 0.3032 |
| 00002245160 | SANDOZ SERTRALINE | SDZ | \$ 0.3032 |
| 00002353539 | SERTRALINE | SNS | \$ 0.3032 |
| 00002386089 | SERTRALINE | SIV | \$ 0.3032 |
| 00002469634 | SERTRALINE | JPC | \$ 0.3032 |
| 00002240484 | TEVA-SERTRALINE | TEV | \$ 0.3032 |
| 00001962817 | ZOLOFT | UJC | \$ 1.7522 |
| 100 MG (BASE) ORAL CAPSULE | | | |
| 00002477904 | AG-SERTRALINE | AGP | \$ 0.3303 |
| 00002238282 | APO-SERTRALINE | APX | \$ 0.3303 |
| 00002390922 | AURO-SERTRALINE | AUR | \$ 0.3303 |
| 00002357178 | JAMP-SERTRALINE | JPC | \$ 0.3303 |
| 00002399431 | MAR-SERTRALINE | MAR | \$ 0.3303 |
| 00002402408 | MINT-SERTRALINE | MPI | \$ 0.3303 |
| 00002244840 | PMS-SERTRALINE | PMS | \$ 0.3303 |
| 00002245161 | SANDOZ SERTRALINE | SDZ | \$ 0.3303 |
| 00002353547 | SERTRALINE | SNS | \$ 0.3303 |
| 00002386097 | SERTRALINE | SIV | \$ 0.3303 |
| 00002469642 | SERTRALINE | JPC | \$ 0.3303 |
| 00002240481 | TEVA-SERTRALINE | TEV | \$ 0.3303 |
| 00001962779 | ZOLOFT | UJC | \$ 1.8637 |

THIAMAZOLE

| | | | |
|-------------------------|------------------|-----|-----------|
| 5 MG ORAL TABLET | | | |
| 00002490625 | JAMP METHIMAZOLE | JPC | \$ 0.1531 |
| 00002480107 | MAR-METHIMAZOLE | MAR | \$ 0.1531 |
| 00000015741 | TAPAZOLE | PAL | \$ 0.2799 |

ALBERTA DRUG BENEFIT LIST UPDATE

VALSARTAN

80 MG ORAL TABLET

| | | | | |
|-------------|------------------|-----|----|--------|
| 00002414228 | AURO-VALSARTAN | AUR | \$ | 0.2159 |
| 00002363100 | RAN-VALSARTAN | RAN | \$ | 0.2159 |
| 00002356759 | SANDOZ VALSARTAN | SDZ | \$ | 0.2159 |
| 00002356651 | TEVA-VALSARTAN | TEV | \$ | 0.2159 |
| 00002366959 | VALSARTAN | SNS | \$ | 0.2159 |
| 00002244781 | DIOVAN | NOV | \$ | 1.2832 |

160 MG ORAL TABLET

| | | | | |
|-------------|------------------|-----|----|--------|
| 00002414236 | AURO-VALSARTAN | AUR | \$ | 0.2159 |
| 00002363119 | RAN-VALSARTAN | RAN | \$ | 0.2159 |
| 00002356767 | SANDOZ VALSARTAN | SDZ | \$ | 0.2159 |
| 00002356678 | TEVA-VALSARTAN | TEV | \$ | 0.2159 |
| 00002366967 | VALSARTAN | SNS | \$ | 0.2159 |
| 00002244782 | DIOVAN | NOV | \$ | 1.2825 |

320 MG ORAL TABLET

| | | | | |
|-------------|------------------|-----|----|--------|
| 00002414244 | AURO-VALSARTAN | AUR | \$ | 0.2098 |
| 00002356775 | SANDOZ VALSARTAN | SDZ | \$ | 0.2098 |
| 00002356686 | TEVA-VALSARTAN | TEV | \$ | 0.2098 |
| 00002366975 | VALSARTAN | SNS | \$ | 0.2098 |
| 00002289504 | DIOVAN | NOV | \$ | 1.2357 |

PART 3

Special Authorization

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

ETANERCEPT

25 MG / VIAL INJECTION

00002242903 ENBREL

AMG

\$ 200.7100

Ankylosing Spondylitis

***Effective March 1, 2018, all new Special Authorization requests for the treatment of Rheumatoid Arthritis or Ankylosing Spondylitis for etanercept-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. Effective November 1, 2020, all new Special Authorization requests for the treatment of adult Plaque Psoriasis 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 or pediatric Plaque Psoriasis 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 or Plaque Psoriasis 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.***

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

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

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

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

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

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

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

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

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

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

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

ETANERCEPT

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. Effective November 1, 2020, all new Special Authorization requests for the treatment of adult Plaque Psoriasis 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 or pediatric Plaque Psoriasis 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 or Plaque Psoriasis 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.***

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

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

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

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

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

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

- Initial coverage may be approved for up to 100 mg per week for 12 weeks.
- Patients will be limited to receiving a one-month supply of etanercept per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

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

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

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

ETANERCEPT

- 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-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. Effective November 1, 2020, all new Special Authorization requests for the treatment of adult Plaque Psoriasis 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 or pediatric Plaque Psoriasis 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 or Plaque Psoriasis 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.***

"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.

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

ETANERCEPT

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

***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. Effective November 1, 2020, all new Special Authorization requests for the treatment of adult Plaque Psoriasis 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 or pediatric Plaque Psoriasis 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 or Plaque Psoriasis 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.***

"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.

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

ETANERCEPT

'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 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-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. Effective November 1, 2020, all new Special Authorization requests for the treatment of adult Plaque Psoriasis 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 or pediatric Plaque Psoriasis 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 or Plaque Psoriasis 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.***

"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

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

ETANERCEPT

years of age or older) who are refractory or intolerant to:

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

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

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

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

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

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

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

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

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

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

ETANERCEPT

25 MG / SYR INJECTION SYRINGE

00002462877 ERELZI

SDZ

\$ 120.5000

Ankylosing Spondylitis

***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. Effective November 1, 2020, all new Special Authorization requests for the treatment of adult Plaque Psoriasis 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 or pediatric Plaque Psoriasis 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 or Plaque Psoriasis 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.***

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

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

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

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

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

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

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

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

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

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

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

ETANERCEPT

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. Effective November 1, 2020, all new Special Authorization requests for the treatment of adult Plaque Psoriasis 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 or pediatric Plaque Psoriasis 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 or Plaque Psoriasis 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.***

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

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

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

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

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

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

- Initial coverage may be approved for up to 100 mg per week for 12 weeks.
- Patients will be limited to receiving a one-month supply of etanercept per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

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

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

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ETANERCEPT

- 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-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. Effective November 1, 2020, all new Special Authorization requests for the treatment of adult Plaque Psoriasis 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 or pediatric Plaque Psoriasis 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 or Plaque Psoriasis 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.***

"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.

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ETANERCEPT

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

***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. Effective November 1, 2020, all new Special Authorization requests for the treatment of adult Plaque Psoriasis 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 or pediatric Plaque Psoriasis 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 or Plaque Psoriasis 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.***

"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.

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ETANERCEPT

'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 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-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. Effective November 1, 2020, all new Special Authorization requests for the treatment of adult Plaque Psoriasis 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 or pediatric Plaque Psoriasis 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 or Plaque Psoriasis 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.***

"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

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ETANERCEPT

years of age or older) who are refractory or intolerant to:

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

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

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

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

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

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

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

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

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the 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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CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

ETANERCEPT

50 MG / SYR INJECTION SYRINGE

☒ 00002462869 ERELZI SDZ \$ 241.0000

Ankylosing Spondylitis

***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. Effective November 1, 2020, all new Special Authorization requests for the treatment of adult Plaque Psoriasis 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 or pediatric Plaque Psoriasis 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 or Plaque Psoriasis 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.***

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

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

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

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

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

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

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

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

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

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

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ETANERCEPT

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. Effective November 1, 2020, all new Special Authorization requests for the treatment of adult Plaque Psoriasis 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 or pediatric Plaque Psoriasis 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 or Plaque Psoriasis 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.***

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

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

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

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

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

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

- Initial coverage may be approved for up to 100 mg per week for 12 weeks.
- Patients will be limited to receiving a one-month supply of etanercept per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

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

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

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ETANERCEPT

- 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-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. Effective November 1, 2020, all new Special Authorization requests for the treatment of adult Plaque Psoriasis 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 or pediatric Plaque Psoriasis 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 or Plaque Psoriasis 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.***

"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.

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ETANERCEPT

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

***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. Effective November 1, 2020, all new Special Authorization requests for the treatment of adult Plaque Psoriasis 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 or pediatric Plaque Psoriasis 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 or Plaque Psoriasis 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.***

"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.

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'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 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-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. Effective November 1, 2020, all new Special Authorization requests for the treatment of adult Plaque Psoriasis 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 or pediatric Plaque Psoriasis 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 or Plaque Psoriasis 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.***

"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

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years of age or older) who are refractory or intolerant to:

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

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

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

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

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

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

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

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

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the 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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The DBL is not a prescribing or a diagnostic tool. Prescribers should refer to drug monographs and utilize professional judgment.

PRODUCT IS NOT INTERCHANGEABLE

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Ankylosing Spondylitis

***Effective March 1, 2018, all new Special Authorization requests for the treatment of Rheumatoid Arthritis or Ankylosing Spondylitis for etanercept-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. Effective November 1, 2020, all new Special Authorization requests for the treatment of adult Plaque Psoriasis 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 or pediatric Plaque Psoriasis 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 or Plaque Psoriasis 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.***

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

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

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

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

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

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

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

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

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

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

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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. Effective November 1, 2020, all new Special Authorization requests for the treatment of adult Plaque Psoriasis 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 or pediatric Plaque Psoriasis 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 or Plaque Psoriasis 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.***

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

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

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

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

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

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

- Initial coverage may be approved for up to 100 mg per week for 12 weeks.
- Patients will be limited to receiving a one-month supply of etanercept per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

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

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

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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-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. Effective November 1, 2020, all new Special Authorization requests for the treatment of adult Plaque Psoriasis 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 or pediatric Plaque Psoriasis 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 or Plaque Psoriasis 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.***

"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:

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- 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

***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. Effective November 1, 2020, all new Special Authorization requests for the treatment of adult Plaque Psoriasis 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 or pediatric Plaque Psoriasis 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 or Plaque Psoriasis 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.***

"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").

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- Initial coverage may be approved for 50 mg per week for 8 weeks.
- Patients will be limited to receiving a one-month supply of etanercept per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another 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 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-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. Effective November 1, 2020, all new Special Authorization requests for the treatment of adult Plaque Psoriasis 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 or pediatric Plaque Psoriasis 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 or Plaque Psoriasis 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.***

"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

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

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

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

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

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

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

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

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

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

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

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

ETANERCEPT

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. Effective November 1, 2020, all new Special Authorization requests for the treatment of adult Plaque Psoriasis 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 or pediatric Plaque Psoriasis 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 or Plaque Psoriasis 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.***

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

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

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

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

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

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

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

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

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

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

Plaque Psoriasis

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

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. Effective November 1, 2020, all new Special Authorization requests for the treatment of adult Plaque Psoriasis 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 or pediatric Plaque Psoriasis 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 or Plaque Psoriasis 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.***

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

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

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

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

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

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

- Initial coverage may be approved for up to 100 mg per week for 12 weeks.
- Patients will be limited to receiving a one-month supply of etanercept per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

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

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

Following this assessment, continued coverage may be considered for 50 mg per week for a period of 12 months. Ongoing coverage may be considered if the patient is re-assessed by a Dermatology

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

ETANERCEPT

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-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. Effective November 1, 2020, all new Special Authorization requests for the treatment of adult Plaque Psoriasis 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 or pediatric Plaque Psoriasis 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 or Plaque Psoriasis 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.***

"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,

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

ETANERCEPT

- iii. number of active joints (joints with swelling not due to deformity or joints with limitation of motion with pain tenderness or both),
 - iv. number of joints with limitation of motion,
 - v. functional ability based on CHAQ scores,
 - vi. ESR or CRP
- 3) Data from all of the six variables comprising the ACR Pedi 30 and the CHAQ scores must be reported in each request

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

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

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

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

Psoriatic Arthritis

***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. Effective November 1, 2020, all new Special Authorization requests for the treatment of adult Plaque Psoriasis 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 or pediatric Plaque Psoriasis 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 or Plaque Psoriasis 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.***

"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.

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ETANERCEPT

- 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 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-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. Effective November 1, 2020, all new Special Authorization requests for the treatment of adult Plaque Psoriasis 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 or pediatric Plaque Psoriasis 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 or Plaque Psoriasis 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.***

"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

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

ETANERCEPT

- Methotrexate with other disease modifying anti-rheumatic agent(s) (minimum 4-month trial). [e.g., methotrexate with hydroxychloroquine or methotrexate with sulfasalazine]; AND
- Leflunomide (minimum 10 week trial at 20 mg daily).

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

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

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

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

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

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

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

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

PEGFILGRASTIM

Effective June 1, 2019, all Special Authorization requests for pegfilgrastim will be assessed for coverage with Fulphila, Lapelga or Ziextenzo. Neulasta will not be approved for new pegfilgrastim starts or repeat treatments (e.g., new course of chemotherapy).

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

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

Please note: Coverage cannot be considered for palliative patients.

6 MG / SYR INJECTION SYRINGE

| | | | | | |
|-------------------------------------|-------------|----------------------------|-----|----|-----------|
| <input checked="" type="checkbox"/> | 00002484153 | FULPHILA (0.6 ML SYRINGE) | BGP | \$ | 1424.6300 |
| <input checked="" type="checkbox"/> | 00002474565 | LAPELGA (0.6 ML SYRINGE) | APX | \$ | 1424.6300 |
| <input checked="" type="checkbox"/> | 00002497395 | ZIEXTENZO (0.6 ML SYRINGE) | SDZ | \$ | 1424.6300 |
| <input checked="" type="checkbox"/> | 00002249790 | NEULASTA (0.6 ML SYRINGE) | AMG | \$ | 2555.0600 |

PIOGLITAZONE HCL

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

FIRST-LINE DRUG PRODUCT(S): METFORMIN

"For the treatment of Type 2 diabetes in patients who have an inadequate response to a sufficient trial (i.e. a minimum of 6 months) of metformin or who are intolerant to metformin (e.g. dermatologic reactions) or for whom the product is contraindicated."

Special authorization may be granted for 24 months.

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

UP - First-line therapy ineffective

UQ - First-line therapy not tolerated

15 MG (BASE) ORAL TABLET

| | | | | |
|-------------|-------------------|-----|----|--------|
| 00002391600 | ACH-PIOGLITAZONE | AHI | \$ | 0.6225 |
| 00002302861 | ACT PIOGLITAZONE | TEV | \$ | 0.6225 |
| 00002302942 | APO-PIOGLITAZONE | APX | \$ | 0.6225 |
| 00002397307 | JAMP-PIOGLITAZONE | JPC | \$ | 0.6225 |

30 MG (BASE) ORAL TABLET

| | | | | |
|-------------|-------------------|-----|----|--------|
| 00002339587 | ACH-PIOGLITAZONE | AHI | \$ | 0.8721 |
| 00002302888 | ACT PIOGLITAZONE | TEV | \$ | 0.8721 |
| 00002302950 | APO-PIOGLITAZONE | APX | \$ | 0.8721 |
| 00002365529 | JAMP-PIOGLITAZONE | JPC | \$ | 0.8721 |

45 MG (BASE) ORAL TABLET

| | | | | |
|-------------|-------------------|-----|----|--------|
| 00002339595 | ACH-PIOGLITAZONE | AHI | \$ | 1.3113 |
| 00002302977 | APO-PIOGLITAZONE | APX | \$ | 1.3113 |
| 00002365537 | JAMP-PIOGLITAZONE | JPC | \$ | 1.3113 |

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

RITUXIMAB

10 MG / ML INJECTION

00002495724 RUXIENCE PFI \$ 29.7000

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 Riximyo, Ruxience or 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.

"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).

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

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

RITUXIMAB

***Effective September 1, 2020, all new Special Authorization requests for the treatment of Granulomatosis with Polyangiitis or Microscopic Polyangiitis for rituximab naive patients will be assessed for coverage with Ruxience. Rituxan will not be approved for new rituximab starts for patients with Granulomatosis with Polyangiitis or Microscopic Polyangiitis; however, coverage for Rituxan will continue for patients who completed a previous 4 week course of therapy with Rituxan and achieved remission but subsequently relapsed.

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.***

"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 rituximab for Granulomatosis with Polyangiitis (GPA) or Microscopic Polyangiitis (MPA) must be completed using the Rituximab for Granulomatosis with Polyangiitis/Microscopic Polyangiitis Special Authorization Request Form (ABC 60018).

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)
- Erelzi (etanercept)
- 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

PART 3A

Optional Special Authorization

Criteria For Optional Special Authorization Of Select Drug Products

Patient claims for select quinolone prescriptions written by a non-designated prescriber will be subject to a first forgiveness rule, meaning the first claim will be paid. Subsequent claims for the same product (irrespective of strength, route and form) within a 90-day period would require the prescriber to apply for special authorization for coverage on the patient's behalf.

MOXIFLOXACIN HCL

"To be prescribed according to ONE of the following criteria:

For the treatment of

- 1) Community acquired pneumonia after failure of first line therapy, as defined by clinical deterioration after 72 hours of antibiotic therapy or lack of improvement after completion of antibiotic therapy; or
- 2) Community acquired pneumonia in patients with co-morbidities (asthma, lung cancer, COPD, diabetes, alcoholism, chronic renal or liver failure, CHF, chronic corticosteroid use, malnutrition or acute weight loss, hospitalization within previous 3 months, HIV/AIDS, smoking); or
- 3) Acute exacerbation of chronic bronchitis after failure of first and second line therapy, as defined by clinical deterioration after 72 hours of antibiotic therapy or lack of improvement after completion of antibiotic therapy; or
- 4) Acute sinusitis after failure of first line therapy, as defined by clinical deterioration after 72 h of antibiotic therapy or lack of improvement after completion of antibiotic therapy, in patients with beta-lactam (penicillin and cephalosporin) allergy; or
- 5) For use in other current Health Canada approved indications when prescribed by a specialist in Infectious Diseases."

All requests for Moxifloxacin HCl must be completed using the Select Quinolones Special Authorization Request Form (ABC 60042).

| 400 MG (BASE) | ORAL TABLET | | | |
|---------------|---------------------|-----|----|--------|
| 00002478137 | AG-MOXIFLOXACIN | AGP | \$ | 1.5230 |
| 00002404923 | APO-MOXIFLOXACIN | APX | \$ | 1.5230 |
| 00002432242 | AURO-MOXIFLOXACIN | AUR | \$ | 1.5230 |
| 00002443929 | JAMP-MOXIFLOXACIN | JPC | \$ | 1.5230 |
| 00002447061 | JAMP-MOXIFLOXACIN | JPC | \$ | 1.5230 |
| 00002447053 | MAR-MOXIFLOXACIN | MAR | \$ | 1.5230 |
| 00002457814 | MED-MOXIFLOXACIN | GMP | \$ | 1.5230 |
| 00002383381 | SANDOZ MOXIFLOXACIN | SDZ | \$ | 1.5230 |
| 00002375702 | TEVA-MOXIFLOXACIN | TEV | \$ | 1.5230 |