Updates to the Alberta Drug Benefit List

Effective October 1, 2014

Alberta Government

Inquiries should be directed to:

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

Telephone Number: (780) 498-8370 (Edmonton)
(403) 294-4041 (Calgary)
1-800-361-9632 (Toll Free)

FAX Number: (780) 498-8406
1-877-305-9911 (Toll Free)

Website: http://www.health.alberta.ca/services/drug-benefit-list.html

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* Publication 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.

Table of Contents

Special Authorization

The following drug product(s) will be considered for coverage by special authorization for patients covered under Alberta government-sponsored drug programs. Criteria for coverage of Alberta Human Services can be found in the October 1, 2014 Updates To the Alberta Human Services Drug Benefit Supplement.

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

Trade Name / Strength / Form	Generic Description	DIN	MFR
SEPTA DONEPEZIL 5 MG TABLET	DONEPEZIL HCL	00002428482	SEP
SEPTA DONEPEZIL 10 MG TABLET	DONEPEZIL HCL	00002428490	SEP

Additional Brand(s) and/or Strength(s) of Drug Products Available by Restricted Benefit / Special Authorization

Trade Name / Strength / Form	Generic Description	DIN	MFR
SEPTA-ZOLMITRIPTAN-ODT 2.5 MG ORAL DISPERSIBLE TABLET	ZOLMITRIPTAN	00002428474	SEP

Drug Product(s) with Changes to Criteria for Coverage

Trade Name / Strength / Form	Generic Description	DIN	MFR
ACLASTA 0.05 MG / ML INJECTION	ZOLEDRONIC ACID	00002269198	NOV
ENBREL 25 MG / VIAL INJECTION	ETANERCEPT	00002242903	AMG
ENBREL 50 MG / SYR INJECTION SYRINGE	ETANERCEPT	00002274728	AMG
HUMIRA 40 MG / SYR INJECTION SYRINGE	ADALIMUMAB	00002258595	ABV
ORENCIA 250 MG / VIAL (BASE) INJECTION	ABATACEPT	00002282097	BMS
PROLIA 60 MG / SYR INJECTION SYRINGE	DENOSUMAB	00002343541	AMG
REMICADE 100 MG / VIAL INJECTION	INFLIXIMAB	00002244016	JAI
TARO-ZOLEDRONIC ACID 0.05 MG / ML INJECTION	ZOLEDRONIC ACID	00002415100	TAR
ZOLEDRONIC ACID 0.05 MG / ML INJECTION	ZOLEDRONIC ACID	00002422433	DRL
ZOLEDRONIC ACID 0.05 MG / ML INJECTION	ZOLEDRONIC ACID	00002408082	TEV

Restricted Benefit(s)

Drug Product(s) Added as Restricted Benefit(s)

Trade Name / Strength / Form	Generic Description	DIN	MFR
BIPHENTIN 10 MG CONTROLLED-RELEASE CAPSULE	METHYLPHENIDATE HCL	00002277166	PUR
BIPHENTIN 15 MG CONTROLLED-RELEASE CAPSULE	METHYLPHENIDATE HCL	00002277131	PUR
BIPHENTIN 20 MG CONTROLLED-RELEASE CAPSULE	METHYLPHENIDATE HCL	00002277158	PUR
BIPHENTIN 30 MG CONTROLLED-RELEASE CAPSULE	METHYLPHENIDATE HCL	00002277174	PUR
BIPHENTIN 40 MG CONTROLLED-RELEASE CAPSULE	METHYLPHENIDATE HCL	00002277182	PUR
BIPHENTIN 50 MG CONTROLLED-RELEASE CAPSULE	METHYLPHENIDATE HCL	00002277190	PUR
BIPHENTIN 60 MG CONTROLLED-RELEASE CAPSULE	METHYLPHENIDATE HCL	00002277204	PUR
BIPHENTIN 80 MG CONTROLLED-RELEASE CAPSULE	METHYLPHENIDATE HCL	00002277212	PUR

Added Product(s)

Trade Name / Strength / Form	Generic Description	DIN	MFR
APO-TRAVOPROST Z 0.004 % OPHTHALMIC SOLUTION	TRAVOPROST	00002415739	APX
LATUDA 40 MG TABLET	LURASIDONE HCL	00002387751	SUN
LATUDA 80 MG TABLET	LURASIDONE HCL	00002387778	SUN
LATUDA 120 MG TABLET	LURASIDONE HCL	00002387786	SUN
LODALIS 625 MG TABLET	COLESEVELAM HCL	00002373955	VCL
LOSARTAN/HCTZ 50 MG / 12.5 MG TABLET	LOSARTAN POTASSIUM/ HYDROCHLOROTHIAZIDE	00002427648	SNS
LOSARTAN/HCTZ 100 MG / 12.5 MG TABLET	LOSARTAN POTASSIUM/ HYDROCHLOROTHIAZIDE	00002427656	SNS
LOSARTAN/HCTZ 100 MG / 25 MG TABLET	LOSARTAN POTASSIUM/ HYDROCHLOROTHIAZIDE	00002427664	SNS
PMS-AZITHROMYCIN 20 MG / ML ORAL SUSPENSION	AZITHROMYCIN	00002418452	PMS
PMS-AZITHROMYCIN 40 MG / ML ORAL SUSPENSION	AZITHROMYCIN	00002418460	PMS

Added Product(s), continued

Trade Name / Strength / Form	Generic Description	DIN	MFR
SANDOZ TRAVOPROST 0.004 % OPHTHALMIC SOLUTION	TRAVOPROST	00002413167	SDZ
SEPTA-LOSARTAN HCTZ 50 MG / 12.5 MG TABLET	LOSARTAN POTASSIUM/ HYDROCHLOROTHIAZIDE	00002428539	SEP
SEPTA-LOSARTAN HCTZ 100 MG / 25 MG TABLET	LOSARTAN POTASSIUM/ HYDROCHLOROTHIAZIDE	00002428547	SEP
TAMULOSIN CR 0.4 MG EXTENDED-RELEASE TABLET	TRAMSULOSIN HCL	00002427117	SNS
TEVA-TRAVOPROST Z 0.004 % OPHTHALMIC SOLUTION	TRAVOPROST	00002412063	TEV

New Established Interchangeable (IC) Grouping(s)

The following IC Grouping(s) have been established and LCA pricing will be applied effective November 1, 2014.

Generic Description	Strength / Form	New LCA Price
TRAVOPROST	0.004 % OPHTHALMIC SOLUTION	4.0264

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 October 1, 2014, the listed product(s) will no longer be a benefit and will not be considered for coverage by special authorization. A transition period will be applied and, as of October 31, 2014 claims will no longer pay for these products. Please note, for products that were covered by Special Authorization, no transition period will be applied, and as of September 30, 2014, claims will no longer pay for these products.

Trade Name / Strength / Form	Generic Description	DIN	MFR
AURO-LOSARTAN HCT 50 MG / 12.5 MG TABLET	LOSARTAN POTASSIUM/ HYDROCHLOROTHIAZIDE	00002423642	AUR
AURO-LOSARTAN HCT 100 MG / 12.5 MG TABLET	LOSARTAN POTASSIUM/ HYDROCHLOROTHIAZIDE	00002423650	AUR
AURO-LOSARTAN HCT 100 MG / 25 MG TABLET	LOSARTAN POTASSIUM/ HYDROCHLOROTHIAZIDE	00002423669	AUR
MIRTAZAPINE 30 MG TABLET	MIRTAZAPINE	00002252279	MEL
PANTOPRAZOLE 40 MG ENTERIC-COATED TABLET	PANTOPRAZOLE	00002309866	MEL
PAROXETINE 20 MG (BASE) TABLET	PAROXETINE HCL	00002248451	MEL
PAROXETINE 30 MG (BASE) TABLET	PAROXETINE HCL	00002248452	MEL
TEVA-CANDESARTAN/HCTZ 32 MG / 25 MG TABLET	CANDESARTAN CILEXETIL/ HYDROCHLOROTHIAZIDE	00002395576	TEV

Discontinued Listing(s), continued

Trade Name / Strength / Form	Generic Description	DIN	MFR
UREMOL-HC 1 % / 10 % TOPICAL CREAM	HYDROCORTISONE ACETATE/ UREA	00000503134	GSK
UREMOL-HC 1 % / 10 % TOPICAL LOTION	HYDROCORTISONE ACETATE/ UREA	00000560022	GSK

PART 2

Drug Additions

AZITHROMYCIN

20 MG / ML ORAL SUSPENSION

00002274388	**AZITHROMYCIN**	**PMS**	$	**0.3726**
00002274566	**GD-AZITHROMYCIN**	**GMD**	$	**0.3726**
00002418452	**PMS-AZITHROMYCIN**	**PMS**	$	**0.3726**
00002332388	**SANDOZ AZITHROMYCIN**	**SDZ**	$	**0.3726**
00002223716	ZITHROMAX	PFI	$	1.0871

40 MG / ML ORAL SUSPENSION

00002274396	**AZITHROMYCIN**	**PMS**	$	**0.5280**
00002274574	**GD-AZITHROMYCIN**	**GMD**	$	**0.5280**
00002418460	**PMS-AZITHROMYCIN**	**PMS**	$	**0.5280**
00002332396	**SANDOZ AZITHROMYCIN**	**SDZ**	$	**0.5280**
00002223724	ZITHROMAX	PFI	$	1.5404

COLESEVELAM HCL

625 MG ORAL TABLET

00002373955	LODALIS	VCL	$	1.1000

LOSARTAN POTASSIUM/ HYDROCHLOROTHIAZIDE

50 MG * 12.5 MG ORAL TABLET

00002388251	**CO LOSARTAN/HCT**	**APH**	$	**0.3146**
00002408244	**JAMP-LOSARTAN HCTZ**	**JPC**	$	**0.3146**
00002388960	**LOSARTAN/HCT**	**SIV**	$	**0.3146**
00002427648	**LOSARTAN/HCTZ**	**SNS**	$	**0.3146**
00002389657	**MINT-LOSARTAN/HCTZ**	**MPI**	$	**0.3146**
00002378078	**MYLAN-LOSARTAN HCTZ**	**MYP**	$	**0.3146**
00002313375	**SANDOZ LOSARTAN HCT**	**SDZ**	$	**0.3146**
00002428539	**SEPTA-LOSARTAN HCTZ**	**SEP**	$	**0.3146**
00002358263	**TEVA-LOSARTAN/HCTZ**	**TEV**	$	**0.3146**
00002371235	APO-LOSARTAN/HCTZ	APX	$	0.3147
00002392224	PMS-LOSARTAN-HCTZ	PMS	$	0.3147
00002230047	HYZAAR	MFC	$	1.2894

100 MG * 12.5 MG ORAL TABLET

00002371243	**APO-LOSARTAN/HCTZ**	**APX**	$	**0.3082**
00002388278	**CO LOSARTAN/HCT**	**APH**	$	**0.3082**
00002388979	**LOSARTAN/HCT**	**SIV**	$	**0.3082**
00002427656	**LOSARTAN/HCTZ**	**SNS**	$	**0.3082**
00002389665	**MINT-LOSARTAN/HCTZ**	**MPI**	$	**0.3082**
00002378086	**MYLAN-LOSARTAN HCTZ**	**MYP**	$	**0.3082**
00002392232	**PMS-LOSARTAN-HCTZ**	**PMS**	$	**0.3082**
00002362449	**SANDOZ LOSARTAN HCT**	**SDZ**	$	**0.3082**
00002377144	**TEVA-LOSARTAN/HCTZ**	**TEV**	$	**0.3082**
00002297841	HYZAAR	MFC	$	1.2625

100 MG * 25 MG ORAL TABLET

00002388286	**CO LOSARTAN/HCT**	**APH**	$	**0.3146**
00002408252	**JAMP-LOSARTAN HCTZ**	**JPC**	$	**0.3146**
00002388987	**LOSARTAN/HCT**	**SIV**	$	**0.3146**
00002427664	**LOSARTAN/HCTZ**	**SNS**	$	**0.3146**
00002389673	**MINT-LOSARTAN/HCTZ DS**	**MPI**	$	**0.3146**
00002378094	**MYLAN-LOSARTAN HCTZ**	**MYP**	$	**0.3146**
00002313383	**SANDOZ LOSARTAN HCT DS**	**SDZ**	$	**0.3146**
00002428547	**SEPTA-LOSARTAN HCTZ**	**SEP**	$	**0.3146**
00002377152	**TEVA-LOSARTAN/HCTZ**	**TEV**	$	**0.3146**
00002371251	APO-LOSARTAN/HCTZ	APX	$	0.3147
00002392240	PMS-LOSARTAN-HCTZ	PMS	$	0.3147
00002241007	HYZAAR DS	MFC	$	1.2894

LURASIDONE HCL

40 MG ORAL TABLET

00002387751	LATUDA	SUN	$	4.0800

80 MG ORAL TABLET

00002387778	LATUDA	SUN	$	4.0800

120 MG ORAL TABLET

00002387786	LATUDA	SUN	$	4.0800

METHYLPHENIDATE HCL

10 MG ORAL CONTROLLED-RELEASE CAPSULE

00002277166	BIPHENTIN	PUR	$	0.6950

"For the treatment of Attention Deficit Hyperactivity Disorder (ADHD) as a restricted benefit for patients 6 years of age and older."

15 MG ORAL CONTROLLED-RELEASE CAPSULE

00002277131	BIPHENTIN	PUR	$	0.9940

"For the treatment of Attention Deficit Hyperactivity Disorder (ADHD) as a restricted benefit for patients 6 years of age and older."

20 MG ORAL CONTROLLED-RELEASE CAPSULE

00002277158	BIPHENTIN	PUR	$	1.2850

"For the treatment of Attention Deficit Hyperactivity Disorder (ADHD) as a restricted benefit for patients 6 years of age and older."

30 MG ORAL CONTROLLED-RELEASE CAPSULE

00002277174	BIPHENTIN	PUR	$	1.7630

"For the treatment of Attention Deficit Hyperactivity Disorder (ADHD) as a restricted benefit for patients 6 years of age and older."

40 MG ORAL CONTROLLED-RELEASE CAPSULE

00002277182	BIPHENTIN	PUR	$	2.2460

"For the treatment of Attention Deficit Hyperactivity Disorder (ADHD) as a restricted benefit for patients 6 years of age and older."

50 MG ORAL CONTROLLED-RELEASE CAPSULE

00002277190	BIPHENTIN	PUR	$	2.7240

"For the treatment of Attention Deficit Hyperactivity Disorder (ADHD) as a restricted benefit for patients 6 years of age and older."

60 MG ORAL CONTROLLED-RELEASE CAPSULE

00002277204	BIPHENTIN	PUR	$	3.1700

"For the treatment of Attention Deficit Hyperactivity Disorder (ADHD) as a restricted benefit for patients 6 years of age and older."

80 MG ORAL CONTROLLED-RELEASE CAPSULE

00002277212	BIPHENTIN	PUR	$	4.1840

"For the treatment of Attention Deficit Hyperactivity Disorder (ADHD) as a restricted benefit for patients 6 years of age and older."

TAMSULOSIN HCL

0.4 MG ORAL EXTENDED-RELEASE TABLET

00002362406	**APO-TAMSULOSIN CR**	**APX**	$	**0.1500**
00002340208	**SANDOZ TAMSULOSIN CR**	**SDZ**	$	**0.1500**
00002427117	**TAMSULOSIN CR**	**SNS**	$	**0.1500**
00002368242	**TEVA-TAMSULOSIN CR**	**TEV**	$	**0.1500**
00002270102	FLOMAX CR	BOE	$	0.6193

TRAVOPROST

0.004 % OPHTHALMIC SOLUTION

00002415739	**APO-TRAVOPROST Z**	**APX**	$	**4.0264**
00002413167	**SANDOZ TRAVOPROST**	**SDZ**	$	**4.0264**
00002412063	**TEVA-TRAVOPROST Z**	**TEV**	$	**4.0264**
00002318008	TRAVATAN Z	ALC	$	11.3560

ZOLMITRIPTAN

RESTRICTED BENEFIT - This product is a benefit for patients 18 to 64 years of age inclusive for the treatment of acute migraine attacks in patients where other standard therapy has failed. (Refer to Criteria for Special Authorization of Select Drug Products of the List for eligibility in patients 65 years of age and older; and Criteria for Special Authorization of Select Drug Products of the Alberta Human Services Drug Benefit Supplement for eligibility in Alberta Human Services clients.)

2.5 MG ORAL DISPERSIBLE TABLET

00002381575	**APO-ZOLMITRIPTAN RAPID**	**APX**	$	**4.6050**
00002419513	**MINT-ZOLMITRIPTAN ODT**	**MPI**	$	**4.6050**
00002387158	**MYLAN-ZOLMITRIPTAN ODT**	**MYP**	$	**4.6050**
00002324768	**PMS-ZOLMITRIPTAN ODT**	**PMS**	$	**4.6050**
00002362996	**SANDOZ ZOLMITRIPTAN ODT**	**SDZ**	$	**4.6050**
00002428474	**SEPTA-ZOLMITRIPTAN-ODT**	**SEP**	$	**4.6050**
00002342545	**TEVA-ZOLMITRIPTAN OD**	**TEV**	$	**4.6050**
00002243045	ZOMIG RAPIMELT	AZC	$	14.1350

PART 3

Special Authorization

ABATACEPT

Rheumatoid Arthritis:

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

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

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

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

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

Following this assessment, continued coverage may be approved for a period of 12 months. Coverage for abacept will be provided for one intravenous dose of up to 1000

ABATACEPT

mg every 4 weeks, or one weekly 125 mg subcutaneous injection. 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 abatacept for Rheumatoid Arthritis must be completed using the Abatacept/Adalimumab/Anakinra/Etanercept/Golimumab/Infliximab/Tocilizumab for Rheumatoid Arthritis Special Authorization Request Form (ABC 30902).

Polyarticular Juvenile Idiopathic Arthritis:

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

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

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

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

For potential coverage for retreatment with abatacept following a subsequent disease flare, the patient must meet the following criteria:
1) The patient must be assessed by a Pediatric Rheumatology Specialist after the initial

ABATACEPT

16 weeks, but no longer than 20 weeks after, treatment with this biologic agent to determine and document initial treatment response.
2) The Pediatric Rheumatology Specialist must confirm in writing that the patient is a responder that meets the following criteria (ACR Pedi 30):
- 30% improvement from baseline in at least three of the following six response variables, with worsening of 30% or more in no more than one of the six variables. The variables include:
i. global assessment of the severity of the disease by the Pediatric Rheumatology Specialist,
ii. global assessment of overall well-being by the patient or parent,
iii. number of active joints (joints with swelling not due to deformity or joints with limitation of motion with pain tenderness or both),
iv. number of joints with limitation of motion,
v. functional ability based on CHAQ scores,
vi. ESR or CRP
3) Data from all of the six variables comprising the ACR Pedi 30 and the CHAQ scores must be reported.

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

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

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

250 MG / VIAL (BASE)	**INJECTION**		
00002282097	ORENCIA	BMS	$ 467.8233

ADALIMUMAB

Rheumatoid Arthritis:

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

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

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

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

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

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

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

ADALIMUMAB

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

All requests (including renewal requests) for adalimumab for Rheumatoid Arthritis must be completed using the Abatacept/Adalimumab/Anakinra/Etanercept/Golimumab/Infliximab/Tocilizumab for Rheumatoid Arthritis Special Authorization Request Form (ABC 30902).

Psoriatic Arthritis:

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

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

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

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

- Initial coverage may be approved for 40 mg administered every other week for 8 weeks.
- Patients will be limited to receiving a one-month supply of adalimumab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

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

ADALIMUMAB

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

All requests (including renewal requests) for adalimumab for Psoriatic Arthritis must be completed using the Adalimumab/Etanercept/Golimumab/Infliximab for Psoriatic Arthritis Special Authorization Request Form (ABC 30964).

Ankylosing Spondylitis:

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

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

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

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

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

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

ADALIMUMAB

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

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

All requests (including renewal requests) for adalimumab for Ankylosing Spondylitis must be completed using the Adalimumab/Etanercept/Golimumab/Infliximab for Ankylosing Spondylitis Special Authorization Request Form (ABC 31195).

Moderately to Severely Active Crohn's Disease:

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

- Adalimumab must be prescribed by a Specialist in Gastroenterology or a physician appropriately trained by the University of Alberta or the University of Calgary and recognized as a prescriber by Alberta Blue Cross for adalimumab for coverage for the treatment of Moderately to Severely Active Crohn's Disease patients ('Specialist').
- Patients must be 18 years of age or older to be considered for coverage of adalimumab.
- Patients will be limited to receiving a one-month supply of adalimumab per prescription at their pharmacy.
- Patients may be allowed to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy (both primary loss of response and secondary loss of response) or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

Prior to initiation of adalimumab therapy for New Patients:

'New Patients' are patients who have never been treated with adalimumab by any health care provider.

Moderately to Severely Active Crohn's Disease:

Prior to initiation of adalimumab therapy, New Patients must have a current Modified (without the physical exam) Harvey Bradshaw Index score of greater than or equal to 7 (New Patient's Baseline Score), AND be Refractory.

Refractory is defined as one or more of the following:
1) Serious adverse effects or reactions to the treatments specified below; OR
2) Contraindications (as defined in product monographs) to the treatments specified below; OR
3) Previous documented lack of effect at doses and for duration of all treatments specified below:
a) mesalamine: minimum of 3 grams/day for a minimum of 6 weeks; AND refractory to, or dependent on, glucocorticoids: following at least one tapering dosing schedule of 40 mg/day, tapering by 5 mg each week to 20 mg, then tapering by 2.5 mg each week to zero, or similar.

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

AND

ADALIMUMAB

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

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

Coverage Criteria for Moderately to Severely Active Crohn's Disease

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

Induction Dosing for New Patients:

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

Maintenance Dosing:

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

Maintenance Dosing for New Patients after Completion of Induction Dosing:

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

Maintenance Dosing for Existing Patients:

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

Continued Coverage for Maintenance Dosing:

ADALIMUMAB

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

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

All requests (including renewal requests) for adalimumab for Moderately to Severely Active Crohn's Disease must be completed using the Adalimumab for Crohn's/Infliximab for Crohn's/Fistulizing Crohn's Special Authorization Request Form (ABC 31200).

Plaque Psoriasis:

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

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

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

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

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

ADALIMUMAB

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

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

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

All requests (including renewal requests) for adalimumab for Plaque Psoriasis must be completed using the Adalimumab/Etanercept/Infliximab/Ustekinumab for Plaque Psoriasis Special Authorization Request Form (ABC 31192).

Polyarticular Juvenile Idiopathic Arthritis:

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

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

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

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

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

ADALIMUMAB

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

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

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

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

40 MG / SYR	INJECTION	SYRINGE		
00002258595	HUMIRA		ABV	$ 740.3600

DENOSUMAB

Osteoporosis:

"For the treatment of postmenopausal osteoporosis in women who have a high 10-year risk (i.e., greater than 20%) of experiencing a major osteoporotic fracture, as demonstrated by at least two of the following:
- Age greater than or equal to 75 years
- A prior fragility fracture
- A bone mineral density (BMD) T-score of less than or equal to -2.5

AND

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

Special authorization may be granted for 12 months.

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

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

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

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

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

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

60 MG / SYR INJECTION SYRINGE			
00002343541	PROLIA	AMG	$ 347.7600

DONEPEZIL HCL

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

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

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

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

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

All requests (including renewal requests) for donepezil HCl must be completed using the Donepezil/Galantamine/Rivastigmine Special Authorization Request Form (ABC 30776).

5 MG ORAL TABLET

00002362260	**APO-DONEPEZIL**	**APX**	$	**1.1806**
00002400561	**AURO-DONEPEZIL**	**AUR**	$	**1.1806**
00002397595	**CO DONEPEZIL**	**APH**	$	**1.1806**
00002420597	**DONEPEZIL**	**SIV**	$	**1.1806**
00002402645	**DONEPEZIL HYDROCHLORIDE**	**AHI**	$	**1.1806**
00002404419	**JAMP-DONEPEZIL**	**JPC**	$	**1.1806**
00002402092	**MAR-DONEPEZIL**	**MAR**	$	**1.1806**
00002359472	**MYLAN-DONEPEZIL**	**MYP**	$	**1.1806**
00002322331	**PMS-DONEPEZIL**	**PMS**	$	**1.1806**
00002381508	**RAN-DONEPEZIL**	**RAN**	$	**1.1806**
00002328666	**SANDOZ DONEPEZIL**	**SDZ**	$	**1.1806**
00002428482	**SEPTA DONEPEZIL**	**SEP**	$	**1.1806**
00002340607	**TEVA-DONEPEZIL**	**TEV**	$	**1.1806**
00002232043	ARICEPT	PFI	$	4.8620

10 MG ORAL TABLET

00002362279	**APO-DONEPEZIL**	**APX**	$	**1.1806**
00002400588	**AURO-DONEPEZIL**	**AUR**	$	**1.1806**
00002397609	**CO DONEPEZIL**	**APH**	$	**1.1806**
00002420600	**DONEPEZIL**	**SIV**	$	**1.1806**
00002402653	**DONEPEZIL HYDROCHLORIDE**	**AHI**	$	**1.1806**
00002404427	**JAMP-DONEPEZIL**	**JPC**	$	**1.1806**
00002402106	**MAR-DONEPEZIL**	**MAR**	$	**1.1806**
00002359480	**MYLAN-DONEPEZIL**	**MYP**	$	**1.1806**
00002322358	**PMS-DONEPEZIL**	**PMS**	$	**1.1806**
00002381516	**RAN-DONEPEZIL**	**RAN**	$	**1.1806**
00002328682	**SANDOZ DONEPEZIL**	**SDZ**	$	**1.1806**
00002428490	**SEPTA DONEPEZIL**	**SEP**	$	**1.1806**
00002340615	**TEVA-DONEPEZIL**	**TEV**	$	**1.1806**
00002232044	ARICEPT	PFI	$	4.8620

ETANERCEPT

Rheumatoid Arthritis:

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

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

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

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

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

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

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

ETANERCEPT

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/Etanercept/Golimumab/Infliximab/Tocilizumab for Rheumatoid Arthritis Special Authorization Request Form (ABC 30902).

Polyarticular Juvenile Idiopathic Arthritis:

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

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

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

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

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

ETANERCEPT

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 for Polyarticular Juvenile Idiopathic Arthritis Special Authorization Request Form (ABC 60011).

Psoriatic Arthritis:

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

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

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

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

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

For continued coverage beyond 8 weeks, the patient must meet the following criteria:
1) The patient must be assessed by an RA Specialist after 8 weeks, but no longer than 12 weeks after treatment to determine response.

ETANERCEPT

2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
- ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; 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/Etanercept/Golimumab/Infliximab for Psoriatic Arthritis Special Authorization Request Form (ABC 30964).

Ankylosing Spondylitis:

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

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

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

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

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

ETANERCEPT

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/Etanercept/Golimumab/Infliximab for Ankylosing Spondylitis Special Authorization Request Form (ABC 31195).

Plaque Psoriasis:

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

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

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

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

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

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

ETANERCEPT

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

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

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

All requests (including renewal requests) for etanercept for Plaque Psoriasis must be completed using the Adalimumab/Etanercept/Infliximab/Ustekinumab for Plaque Psoriasis Special Authorization Request Form (ABC 31192).

25 MG / VIAL INJECTION			
00002242903	ENBREL	AMG	$ 193.3125
50 MG / SYR INJECTION SYRINGE			
00002274728	ENBREL	AMG	$ 386.7425

Note: 1 x 50 mg syringe is interchangeable with 2 x 25 mg vials

INFLIXIMAB

Rheumatoid Arthritis:

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

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

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

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

- Initial coverage may be approved for three doses as follows: An initial dose of 3 mg/kg, followed by additional 3 mg/kg doses at 2 and 6 weeks after the first infusion.
- Patients will be limited to receiving one dose of infliximab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another (with the exception of anakinra) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients will not be permitted to switch from anakinra to other biologic agents except under exceptional circumstances.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

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

Following this assessment, continued coverage may be approved for one 3 mg/kg dose every 8 weeks for a period of 12 months [Note: For patients who have an incomplete response, consideration may be given to adjusting the dose up to 10 mg/kg and/or treating as often as every 4 weeks]. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by an RA Specialist to determine response;
2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
- confirmation of maintenance of ACR20, OR
- maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.
3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.

INFLIXIMAB

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

All requests (including renewal requests) for infliximab for Rheumatoid Arthritis must be completed using the Abatacept/Adalimumab/Anakinra/Etanercept/Golimumab/Infliximab/Tocilizumab for Rheumatoid Arthritis Special Authorization Request Form (ABC 30902).

Moderately to Severely Active Crohn's Disease and Fistulizing Crohn's Disease:

"Special authorization coverage may be approved for coverage of infliximab for the reduction in signs and symptoms and induction and maintenance of clinical remission of Moderately to Severely Active Crohn's Disease and/or treatment of Fistulizing Crohn's Disease in patients who meet the following criteria:

- Infliximab must be prescribed by a Specialist in Gastroenterology or a physician appropriately trained by the University of Alberta or the University of Calgary and recognized as a prescriber by Alberta Blue Cross for infliximab for coverage for the treatment of Moderately to Severely Active Crohn's Disease and/or Fistulizing Crohn's Disease patients (`Specialist').
- Patients must be 18 years of age or older to be considered for coverage of infliximab.
- Patients will be limited to receiving one dose of infliximab per prescription at their pharmacy.
- Patients may be allowed to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy (both primary loss of response and secondary loss of response) or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

Prior to initiation of infliximab therapy for New Patients:

'New Patients' are patients who have never been treated with infliximab by any health care provider.

Moderately to Severely Active Crohn's Disease:

Prior to initiation of infliximab therapy, New Patients must have a current Modified (without the physical exam) Harvey Bradshaw Index score of greater than or equal to 7 (New Patient's Baseline Score), AND be Refractory.

Refractory is defined as one or more of the following:
1) Serious adverse effects or reactions to the treatments specified below; OR
2) Contraindications (as defined in product monographs) to the treatments specified below; OR
3) Previous documented lack of effect at doses and for duration of all treatments specified below:
a) mesalamine: minimum of 3 grams/day for a minimum of 6 weeks; AND refractory to, or dependent on, glucocorticoids:
following at least one tapering dosing schedule of 40 mg/day, tapering by 5 mg each week to 20 mg, then tapering by 2.5 mg each week to zero, or similar;

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

AND
b) Immunosuppressive therapy as follows:
- Azathioprine: minimum of 2 mg/kg/day for a minimum of 3 months; OR
- 6-mercaptopurine: minimum of 1 mg/kg/day for a minimum of 3 months; OR
- Methotrexate: minimum or 15 mg/week for a minimum of 3 months.

INFLIXIMAB

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

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

Fistulizing Crohn's Disease:

Prior to initiation of infliximab therapy, New Patients must have actively draining perianal or enterocutaneous fistula(s) that have recurred or persisted despite:

a) A course of an appropriate dose of antibiotic therapy (e.g. ciprofloxacin or metronidazole) for a minimum of 3 weeks; AND
b) Immunosuppressive therapy:
- Azathioprine: minimum of 2 mg/kg/day for a minimum of 6 weeks; OR
- 6-mercaptopurine: minimum of 1 mg/kg/day for a minimum of 6 weeks; OR
- Immunosuppressive therapy discontinued at less than 6 weeks due to serious adverse effects or reactions.

[Note: Patients who have used the above treatments in combination for the treatment of Fistulizing Crohn's will not be required to be challenged with individual treatments as monotherapy]

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

Coverage Criteria for Moderately to Severely Active Crohn's Disease AND/OR Fistulizing Crohn's Disease

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

Induction Dosing for New Patients:

- Coverage for Induction Dosing may only be approved for New Patients (those who have never been treated with infliximab by any health care provider).
- 'Induction Dosing' means a maximum of one 5 mg/kg dose of infliximab per New Patient at each 0, 2 and 6 weeks (for a maximum total of three doses).
- New Patients are eligible to receive Induction Dosing only once, after which time the Maintenance Dosing for New Patients and Continued Coverage for Maintenance Dosing criteria will apply.

Maintenance Dosing:

'Maintenance Dosing' means one 5 mg/kg dose of infliximab per patient provided no more often than every 8 weeks for a period of 12 months to:
- New Patients following the completion of Induction Dosing; OR
- Existing Patients, who are patients that are being treated, or have previously been treated, with infliximab.

Maintenance Dosing for New Patients after Completion of Induction Dosing:

- The New Patient must be assessed by a Specialist between weeks 10 and 14 after the initiation of Induction Dosing to determine response by obtaining a Modified Harvey Bradshaw

INFLIXIMAB

Index score for patients with Moderately to Severely Active Crohn's Disease and/or closure of individual fistulas as evidenced by no or minimal fistula drainage despite gentle finger compression of fistulas that were draining at baseline for Fistulizing Crohn's; AND
- The Specialist must confirm the Modified Harvey Bradshaw Index score shows a decrease from the New Patient's Baseline Score of greater than or equal to 3 points for patients with Moderately to Severely Active Crohn's and/or confirm closure of individual fistulas as evidenced by no or minimal fistula drainage despite gentle finger compression of fistulas that were draining at baseline for Fistulizing Crohn's.

Maintenance Dosing for Existing Patients:

- The patient must be assessed by a Specialist at least 4 to 8 weeks after the day the last dose of infliximab was administered to the patient and prior to administration of the next dose to obtain: a Modified Harvey Bradshaw Index Score (Existing Patient's Baseline Score) for Moderately to Severely Active Crohn's and/or closure of individual fistulas as evidenced by no or minimal fistula drainage despite gentle finger compression of fistulas that were draining at baseline for Fistulizing Crohn's; AND

- these measures must be provided to Alberta Blue Cross for assessment for continued coverage for maintenance dosing.

(For existing patients with Moderately to Severely Active Crohn's Disease with an incomplete response or for existing patients with Fistulizing Crohn's who respond then lose their response, the dose may be adjusted to 10 mg/kg by making an additional special authorization request to Alberta Blue Cross for the increased dose.)

Continued Coverage for Maintenance Dosing:

Continued coverage may be considered for one 5 mg/kg dose of infliximab per patient provided no more often than every 8 weeks for a period of 12 months, if the following criteria are met at the end of each 12 month period:

- The New Patient or the Existing Patient must be assessed by a Specialist at least 4 to 6 weeks after the day the last dose of infliximab was administered to the patient and prior to the administration of the next dose to obtain a Modified Harvey Bradshaw Index Score for Moderately to Severely Active Crohn's and/or closure of individual fistulas as evidenced by no or minimal fistula drainage despite gentle finger compression of fistulas that were draining at baseline for Fistulizing Crohn's; AND
- For New Patients: The Specialist must confirm that the patient has maintained a greater than or equal to 3 point decrease from the New Patient's Baseline Score for Moderately to Severely Active Crohn's and/or closure of individual fistulas as evidenced by no or minimal fistula drainage despite gentle finger compression of fistulas that were draining at baseline for Fistulizing Crohn's; OR
- For Existing Patients: The Specialist must confirm that the patient has maintained the Existing Patient's Baseline Score and/or closure of individual fistulas as evidenced by no or minimal fistula drainage despite gentle finger compression of fistulas that were draining at baseline for Fistulizing Crohn's.

(For new and existing patients with Moderately to Severely Active Crohn's Disease with an incomplete response or for new and existing patients with Fistulizing Crohn's who respond then lose their response, the maintenance dose may be adjusted to 10 mg/kg by making an additional special authorization request to Alberta Blue Cross for the increased dose.)"

All requests (including renewal requests) for infliximab for Moderately to Severely Active Crohn's Disease and Fistulizing Crohn's Disease must be completed using the Adalimumab for Crohn's/Infliximab for Crohn's/Fistulizing Crohn's Disease Special Authorization Request Form (ABC 31200).

INFLIXIMAB

Ankylosing Spondylitis:

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

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

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

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

- Initial coverage may be approved for three doses as follows: An initial dose of 5 mg/kg, followed by additional 5 mg/kg doses at 2 and 6 weeks after the first infusion.
- Patients will be limited to receiving one dose of infliximab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

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

Following this assessment, continued coverage may be approved for one 5 mg/kg dose of infliximab every 6 to 8 weeks for a period of 12 months. Ongoing coverage may be considered if the patient is re-assessed by an RA Specialist every 12 months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above."

All requests (including renewal requests) for infliximab for Ankylosing Spondylitis must be completed using the Adalimumab/Etanercept/Golimumab/Infliximab for Ankylosing Spondylitis Special Authorization Request Form (ABC 31195).

Psoriatic Arthritis:

"Special authorization coverage may be provided for use in combination with methotrexate for reducing signs and symptoms and inhibiting the progression of structural damage of active arthritis in adult patients (18 years of age or older) with moderate to severe polyarticular psoriatic arthritis (PsA) or pauciarticular PsA with involvement of knee or hip joint who are refractory or intolerant to:
- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if

INFLIXIMAB

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

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

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

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

- Initial coverage may be approved for three doses as follows: An initial dose of 5 mg/kg, followed by additional 5 mg/kg doses at 2 and 6 weeks after the first infusion.
- Patients will be limited to receiving one dose of infliximab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

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

Following this assessment, continued coverage may be approved for one 5 mg/kg dose every 8 weeks, for a period of 12 months. Ongoing coverage may be considered if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by an RA Specialist to determine response;
2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
- Confirmation of maintenance of ACR20, or
- Maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.
3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above."

All requests (including renewal requests) for infliximab for Psoriatic Arthritis must be completed using the Adalimumab/Etanercept/Golimumab/Infliximab for Psoriatic Arthritis Special Authorization Request Form (ABC 30964).

INFLIXIMAB

Plaque Psoriasis:

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

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

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

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

- Initial coverage may be approved as follows: An initial dose of 5 mg/kg, followed by additional 5 mg/kg doses at 2 and 6 weeks after the first infusion.
- Patients will be limited to receiving one dose of infliximab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

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

Following this assessment, continued coverage may be considered for one 5 mg/kg dose of infliximab every 8 weeks for a period of 12 months. Ongoing coverage may be considered if the patient is re-assessed by a Dermatology Specialist every 12 months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above."

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

All requests (including renewal requests) for infliximab for Plaque Psoriasis must be completed using the Adalimumab/Etanercept/Infliximab/Ustekinumab for Plaque Psoriasis Special

INFLIXIMAB

Authorization Request Form (ABC 31192).

Ulcerative Colitis:

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

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

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

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

Initial coverage may be approved for three doses of 5 mg/kg of infliximab at 0, 2 and 6 weeks.

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

For continued coverage beyond three doses, the patient must meet the following criteria:
1) The patient must be assessed by a Specialist between weeks 10 and 14 after the initiation of therapy to determine response.
2) The Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
- a decrease in the partial Mayo score of greater than or equal to 2 points

Following this assessment, continued coverage may be approved for dose of 5 mg/kg every 8 weeks for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by a Specialist in Gastroenterology to determine response;
2) The Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
- a decrease in the partial Mayo score of greater than or equal to 2 points from the score prior to initiation of infliximab therapy

Note: For patients who showed a response to induction therapy then experienced secondary loss of response while on maintenance dosing with 5 mg/kg, the maintenance dose may be adjusted from 5 mg/kg to 10 mg/kg by making an additional special authorization request to

INFLIXIMAB

Alberta Blue Cross for the increased dose.

All requests (including renewal requests) for infliximab for Ulcerative Colitis must be completed using the Infliximab for Ulcerative Colitis Special Authorization Request Form (ABC 60008).

100 MG / VIAL	INJECTION			
00002244016	REMICADE		JAI	$ 962.6800

ZOLEDRONIC ACID

Osteoporosis:

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

- Age greater than or equal to 75 years
- A prior fragility fracture
- A bone mineral density (BMD) T-score of less than or equal to -2.5

AND

at least one of the following:
1) For whom oral bisphosphonates are contraindicated due to an untreatable abnormality of the esophagus which delays esophageal emptying (e.g., stricture or achalasia);

OR

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

OR

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

Special Authorization may be granted for 12 months.

-Patients will be limited to receiving one dose of zoledronic acid per prescription at their pharmacy.

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

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

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

-This product is eligible for auto-renewal for the treatment of osteoporosis.

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

Paget's Disease:

"For the treatment of Paget's disease. Special Authorization for this criterion may be granted for one dose per 12 month period."

"Coverage cannot be provided for two or more medications used in the treatment of

ZOLEDRONIC ACID

Paget's disease when these medications are intended for use in combination or when therapy with two or more medications overlap."

0.05 MG / ML INJECTION

00002415100	**TARO-ZOLEDRONIC ACID**	**TAR**	$	**3.3540**
00002408082	**ZOLEDRONIC ACID**	**TEV**	$	**3.3540**
00002422433	**ZOLEDRONIC ACID**	**DRL**	$	**3.3540**
00002269198	ACLASTA	NOV	$	6.7683

ZOLMITRIPTAN

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

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

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

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

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

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

2.5 MG ORAL DISPERSIBLE TABLET

00002381575	**APO-ZOLMITRIPTAN RAPID**	**APX**	$	**4.6050**
00002419513	**MINT-ZOLMITRIPTAN ODT**	**MPI**	$	**4.6050**
00002387158	**MYLAN-ZOLMITRIPTAN ODT**	**MYP**	$	**4.6050**
00002324768	**PMS-ZOLMITRIPTAN ODT**	**PMS**	$	**4.6050**
00002362996	**SANDOZ ZOLMITRIPTAN ODT**	**SDZ**	$	**4.6050**
00002428474	**SEPTA-ZOLMITRIPTAN-ODT**	**SEP**	$	**4.6050**
00002342545	**TEVA-ZOLMITRIPTAN OD**	**TEV**	$	**4.6050**
00002243045	ZOMIG RAPIMELT	AZC	$	14.1350