Updates to the Alberta Drug Benefit List

Effective October 1, 2020

Alberta Government

Inquiries should be directed to:

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Edmonton AB T5J 3C5

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Website: https://www.alberta.ca/drug-benefit-list-and-drug-review-process.aspx

Administered by Alberta Blue Cross
on behalf of Alberta Health.

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

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

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

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

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.

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

Trade Name / Strength / Form	Generic Description	DIN	MFR
ODAN ITRACONAZOLE 10 MG / ML ORAL SOLUTION	ITRACONAZOLE	00002495988	ODN

Drug Product(s) with Changes to Criteria for Coverage

Trade Name / Strength / Form	Generic Description	DIN	MFR
ACTEMRA (0.9 ML SYRINGE) 162 MG / SYRINGE INJECTION	TOCILIZUMAB	00002424770	HLR

Added Product(s)

Trade Name / Strength / Form	Generic Description	DIN	MFR
AG-ALENDRONATE 70 MG TABLET	ALENDRONATE SODIUM	00002485184	AGP
AG-FLUOXETINE 10 MG CAPSULE	FLUOXETINE HCL	00002485052	AGP
AG-FLUOXETINE 20 MG CAPSULE	FLUOXETINE HCL	00002485060	AGP
AG-METOPROLOL-L 100 MG TABLET	METOPROLOL TARTRATE	00002481324	AGP
AG-METOPROLOL-L 50 MG TABLET	METOPROLOL TARTRATE	00002481316	AGP
AG-SIMVASTATIN 5 MG TABLET	SIMVASTATIN	00002480050	AGP
AG-SIMVASTATIN 10 MG TABLET	SIMVASTATIN	00002480069	AGP
AG-SIMVASTATIN 20 MG TABLET	SIMVASTATIN	00002480077	AGP
AG-SIMVASTATIN 40 MG TABLET	SIMVASTATIN	00002480085	AGP
AG-SIMVASTATIN 80 MG TABLET	SIMVASTATIN	00002480093	AGP
LATANOPROST AND TIMOLOL 0.005% / 0.5% OPHTHALMIC SOLUTION	LATANOPROST/ TIMOLOL MALEATE	00002489368	TGT

Least Cost Alternative (LCA) Price Change(s)

The following established IC Grouping(s) are affected and a revised LCA price has been established. Groupings affected by a price decrease, will be effective November 1, 2020. Please review the online ***Interactive Drug Benefit List*** *for further information.*

Generic Description	Strength / Form	New LCA Price
ENTECAVIR	0.5 MG TABLET	4.4000

Least Cost Alternative (LCA) Price Change(s), continued

Generic Description	Strength / Form	New LCA Price
ITRACONAZOLE	10 MG / ML ORAL SOLUTION	0.4111
LEFLUNOMIDE	10 MG TABLET	2.0000
LEFLUNOMIDE	20 MG TABLET	2.0000

Product(s) with a Price Change

The following product(s) had a Price Change. The previous higher price will be recognized until October 31, 2020. For products within an established IC Grouping, the LCA price may apply.

Trade Name / Strength / Form	Generic Description	DIN	MFR
ACCEL-ENTECAVIR 0.5 MG TABLET	ENTECAVIR	00002479907	ACP
ACCEL-LEFLUNOMIDE 10 MG TABLET	LEFLUNOMIDE	00002478862	ACP
ACCEL-LEFLUNOMIDE 20 MG TABLET	LEFLUNOMIDE	00002478870	ACP
HYDROMORPHONE HP 50 MG / ML INJECTION	HYDROMORPHONE HCL	00002146126	SDZ
JAMP ITRACONAZOLE 10 MG / ML ORAL SOLUTION	ITRACONAZOLE	00002484315	JPC

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, 2020, the listed product(s) will no longer be a benefit and where applicable, will not be considered for coverage by Special Authorization. A transition period will be applied and as of November 1, 2020 claims will no longer pay for these product(s).

Trade Name / Strength / Form	Generic Description	DIN	MFR
MAR-OLANZAPINE ODT 5 MG ORAL DISINTEGRATING TABLET	OLANZAPINE	00002389088	MAR
MICRONOR (28 DAY) 0.35 MG TABLET	NORETHINDRONE	00000037605	JAI
RHINOCORT TURBUHALER 100 MCG / DOSE NASAL METERED DOSE AEROSOL	BUDESONIDE	00002035324	AZC

PART 2

Drug Additions

ALENDRONATE SODIUM

70 MG ORAL TABLET

00002485184	**AG-ALENDRONATE**	**AGP**	$	**2.1014**
00002299712	**ALENDRONATE**	**SIV**	$	**2.1014**
00002352966	**ALENDRONATE**	**SNS**	$	**2.1014**
00002381494	**ALENDRONATE SODIUM**	**AHI**	$	**2.1014**
00002248730	**APO-ALENDRONATE**	**APX**	$	**2.1014**
00002388553	**AURO-ALENDRONATE**	**AUR**	$	**2.1014**
00002385031	**JAMP-ALENDRONATE**	**JPC**	$	**2.1014**
00002394871	**MINT-ALENDRONATE**	**MPI**	$	**2.1014**
00002284006	**PMS-ALENDRONATE-FC**	**PMS**	$	**2.1014**
00002288109	**SANDOZ ALENDRONATE**	**SDZ**	$	**2.1014**
00002261715	**TEVA-ALENDRONATE**	**TEV**	$	**2.1014**
00002245329	FOSAMAX	MFC	$	11.0114

ENTECAVIR

RESTRICTED BENEFIT - This product is a benefit for the treatment of chronic hepatitis B when prescribed by a Specialist in Internal Medicine or a designated prescriber.

0.5 MG ORAL TABLET

00002479907	**ACCEL-ENTECAVIR**	**ACP**	$	**4.4000**
00002396955	APO-ENTECAVIR	APX	$	5.5000
00002448777	AURO-ENTECAVIR	AUR	$	5.5000
00002467232	JAMP-ENTECAVIR	JPC	$	5.5000
00002485907	MINT-ENTECAVIR	MPI	$	5.5000
00002430576	PMS-ENTECAVIR	PMS	$	5.5000
00002282224	BARACLUDE	BMS	$	22.6601

FLUOXETINE HCL

10 MG (BASE) ORAL CAPSULE

00002485052	**AG-FLUOXETINE**	**AGP**	$	**0.3404**
00002216353	**APO-FLUOXETINE**	**APX**	$	**0.3404**
00002385627	**AURO-FLUOXETINE**	**AUR**	$	**0.3404**
00002286068	**FLUOXETINE**	**SNS**	$	**0.3404**
00002374447	**FLUOXETINE**	**SIV**	$	**0.3404**
00002393441	**FLUOXETINE BP**	**AHI**	$	**0.3404**
00002401894	**JAMP-FLUOXETINE**	**JPC**	$	**0.3404**
00002177579	**PMS-FLUOXETINE**	**PMS**	$	**0.3404**
00002479486	**SANDOZ FLUOXETINE**	**SDZ**	$	**0.3404**
00002216582	**TEVA-FLUOXETINE**	**TEV**	$	**0.3404**
00002018985	PROZAC	LIL	$	1.9522

20 MG (BASE) ORAL CAPSULE

00002485060	**AG-FLUOXETINE**	**AGP**	$	**0.3311**
00002216361	**APO-FLUOXETINE**	**APX**	$	**0.3311**
00002385635	**AURO-FLUOXETINE**	**AUR**	$	**0.3311**
00002448432	**BIO-FLUOXETINE**	**BMD**	$	**0.3311**
00002286076	**FLUOXETINE**	**SNS**	$	**0.3311**
00002374455	**FLUOXETINE**	**SIV**	$	**0.3311**
00002383241	**FLUOXETINE BP**	**AHI**	$	**0.3311**
00002386402	**JAMP-FLUOXETINE**	**JPC**	$	**0.3311**
00002177587	**PMS-FLUOXETINE**	**PMS**	$	**0.3311**
00002479494	**SANDOZ FLUOXETINE**	**SDZ**	$	**0.3311**
00002216590	**TEVA-FLUOXETINE**	**TEV**	$	**0.3311**
00000636622	PROZAC	LIL	$	1.9522

HYDROMORPHONE HCL

50 MG / ML INJECTION

00002146126	HYDROMORPHONE HP 50	SDZ	$	6.9525

ITRACONAZOLE

10 MG / ML ORAL SOLUTION

00002484315	**JAMP ITRACONAZOLE**	**JPC**	$	**0.4111**
00002495988	**ODAN ITRACONAZOLE**	**ODN**	$	**0.4111**
00002231347	SPORANOX	JAI	$	0.8632

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

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

LATANOPROST/ TIMOLOL MALEATE

0.005 % * 0.5 % (BASE) OPHTHALMIC SOLUTION

00002436256	**ACT LATANOPROST/TIMOLOL**	**APH**	$	**4.4268**
00002373068	**GD-LATANOPROST/TIMOLOL**	**UJC**	$	**4.4268**
00002453770	**JAMP-LATANOPROST/TIMOLOL**	**JPC**	$	**4.4268**
00002489368	**LATANOPROST AND TIMOLOL**	**TGT**	$	**4.4268**
00002454505	**MED-LATANOPROST-TIMOLOL**	**GMP**	$	**4.4268**
00002246619	XALACOM	UJC	$	13.7543

LEFLUNOMIDE

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

10 MG ORAL TABLET

00002478862	**ACCEL-LEFLUNOMIDE**	**ACP**	$	**2.0000**
00002256495	APO-LEFLUNOMIDE	APX	$	2.6433
00002351668	LEFLUNOMIDE	SNS	$	2.6433
00002283964	SANDOZ LEFLUNOMIDE	SDZ	$	2.6433
00002261251	TEVA-LEFLUNOMIDE	TEV	$	2.6433
00002241888	ARAVA	SAV	$	11.0677

20 MG ORAL TABLET

00002478870	**ACCEL-LEFLUNOMIDE**	**ACP**	$	**2.0000**
00002256509	APO-LEFLUNOMIDE	APX	$	2.6433
00002351676	LEFLUNOMIDE	SNS	$	2.6433
00002283972	SANDOZ LEFLUNOMIDE	SDZ	$	2.6433
00002261278	TEVA-LEFLUNOMIDE	TEV	$	2.6433
00002241889	ARAVA	SAV	$	11.0680

METOPROLOL TARTRATE

50 MG ORAL TABLET

00002481316	**AG-METOPROLOL-L**	**AGP**	$	**0.0624**
00000618632	**APO-METOPROLOL**	**APX**	$	**0.0624**
00000749354	**APO-METOPROLOL (TYPE L)**	**APX**	$	**0.0624**
00002356821	**JAMP-METOPROLOL-L**	**JPC**	$	**0.0624**
00002350394	**METOPROLOL**	**SNS**	$	**0.0624**
00002442124	**METOPROLOL-L**	**SIV**	$	**0.0624**
00002230803	**PMS-METOPROLOL-L**	**PMS**	$	**0.0624**
00000842648	**TEVA-METOPROL**	**TEV**	$	**0.0624**
00000648035	**TEVA-METOPROL (FC)**	**TEV**	$	**0.0624**

100 MG ORAL TABLET

00002481324	**AG-METOPROLOL-L**	**AGP**	$	**0.1250**
00000618640	**APO-METOPROLOL**	**APX**	$	**0.1250**
00000751170	**APO-METOPROLOL (TYPE L)**	**APX**	$	**0.1250**
00002356848	**JAMP-METOPROLOL-L**	**JPC**	$	**0.1250**
00002350408	**METOPROLOL**	**SNS**	$	**0.1250**
00002442132	**METOPROLOL-L**	**SIV**	$	**0.1250**
00002230804	**PMS-METOPROLOL-L**	**PMS**	$	**0.1250**
00000842656	**TEVA-METOPROL**	**TEV**	$	**0.1250**
00000648043	**TEVA-METOPROL (FC)**	**TEV**	$	**0.1250**

SIMVASTATIN

5 MG ORAL TABLET

00002480050	**AG-SIMVASTATIN**	**AGP**	$	**0.1023**
00002247011	**APO-SIMVASTATIN**	**APX**	$	**0.1023**
00002405148	**AURO-SIMVASTATIN**	**AUR**	$	**0.1023**
00002375591	**JAMP-SIMVASTATIN**	**JPC**	$	**0.1023**
00002372932	**MINT-SIMVASTATIN**	**MPI**	$	**0.1023**
00002469979	**PHARMA-SIMVASTATIN**	**PMS**	$	**0.1023**
00002329131	**RAN-SIMVASTATIN**	**RAN**	$	**0.1023**
00002386291	**SIMVASTATIN**	**SIV**	$	**0.1023**
00002250144	**TEVA-SIMVASTATIN**	**TEV**	$	**0.1023**

10 MG ORAL TABLET

00002480069	AG-SIMVASTATIN	AGP	***$ 0.1354***	$	0.2023
00002247012	APO-SIMVASTATIN	APX	***$ 0.1354***	$	0.2023
00002405156	AURO-SIMVASTATIN	AUR	***$ 0.1354***	$	0.2023
00002375605	JAMP-SIMVASTATIN	JPC	***$ 0.1354***	$	0.2023
00002375044	MAR-SIMVASTATIN	MAR	***$ 0.1354***	$	0.2023
00002372940	MINT-SIMVASTATIN	MPI	***$ 0.1354***	$	0.2023
00002469987	PHARMA-SIMVASTATIN	PMS	***$ 0.1354***	$	0.2023
00002329158	RAN-SIMVASTATIN	RAN	***$ 0.1354***	$	0.2023
00002386305	SIMVASTATIN	SIV	***$ 0.1354***	$	0.2023
00002250152	TEVA-SIMVASTATIN	TEV	***$ 0.1354***	$	0.2023
00000884332	ZOCOR	MFC	***$ 0.1354***	$	2.2268

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

20 MG ORAL TABLET

00002480077	AG-SIMVASTATIN	AGP	***$ 0.1354***	$	0.2501
00002247013	APO-SIMVASTATIN	APX	***$ 0.1354***	$	0.2501
00002405164	AURO-SIMVASTATIN	AUR	***$ 0.1354***	$	0.2501
00002375613	JAMP-SIMVASTATIN	JPC	***$ 0.1354***	$	0.2501
00002375052	MAR-SIMVASTATIN	MAR	***$ 0.1354***	$	0.2501
00002372959	MINT-SIMVASTATIN	MPI	***$ 0.1354***	$	0.2501
00002469995	PHARMA-SIMVASTATIN	PMS	***$ 0.1354***	$	0.2501
00002329166	RAN-SIMVASTATIN	RAN	***$ 0.1354***	$	0.2501
00002386313	SIMVASTATIN	SIV	***$ 0.1354***	$	0.2501
00002250160	TEVA-SIMVASTATIN	TEV	***$ 0.1354***	$	0.2501
00000884340	ZOCOR	MFC	***$ 0.1354***	$	2.7521

MAC pricing will be applied based on the LCA Price for Rosuvastatin Calcium 1 x 10

SIMVASTATIN

mg tablet or the LCA Price of Atorvastatin 1 x 20 mg tablet whichever is lower.

40 MG ORAL TABLET

00002480085	AG-SIMVASTATIN	AGP	***$ 0.1354***	$	0.2501
00002247014	APO-SIMVASTATIN	APX	***$ 0.1354***	$	0.2501
00002405172	AURO-SIMVASTATIN	AUR	***$ 0.1354***	$	0.2501
00002375621	JAMP-SIMVASTATIN	JPC	***$ 0.1354***	$	0.2501
00002375060	MAR-SIMVASTATIN	MAR	***$ 0.1354***	$	0.2501
00002372967	MINT-SIMVASTATIN	MPI	***$ 0.1354***	$	0.2501
00002470004	PHARMA-SIMVASTATIN	PMS	***$ 0.1354***	$	0.2501
00002329174	RAN-SIMVASTATIN	RAN	***$ 0.1354***	$	0.2501
00002386321	SIMVASTATIN	SIV	***$ 0.1354***	$	0.2501
00002250179	TEVA-SIMVASTATIN	TEV	***$ 0.1354***	$	0.2501
00000884359	ZOCOR	MFC	***$ 0.1354***	$	2.7521

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

80 MG ORAL TABLET

00002480093	AG-SIMVASTATIN	AGP	***$ 0.1354***	$	0.2501
00002247015	APO-SIMVASTATIN	APX	***$ 0.1354***	$	0.2501
00002405180	AURO-SIMVASTATIN	AUR	***$ 0.1354***	$	0.2501
00002375648	JAMP-SIMVASTATIN	JPC	***$ 0.1354***	$	0.2501
00002372975	MINT-SIMVASTATIN	MPI	***$ 0.1354***	$	0.2501
00002470012	PHARMA-SIMVASTATIN	PMS	***$ 0.1354***	$	0.2501
00002329182	RAN-SIMVASTATIN	RAN	***$ 0.1354***	$	0.2501
00002386348	SIMVASTATIN	SIV	***$ 0.1354***	$	0.2501
00002250187	TEVA-SIMVASTATIN	TEV	***$ 0.1354***	$	0.2501

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

PART 3

Special Authorization

INDACATEROL MALEATE/ GLYCOPYRRONIUM BROMIDE

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

CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD)

FIRST-LINE DRUG PRODUCT(S): LONG-ACTING BRONCHODILATOR (I.E., LONG-ACTING BETA-2 AGONIST [LABA] OR LONG-ACTING MUSCARINIC ANTAGONIST [LAMA])

"For the long-term maintenance treatment of airflow obstruction in patients with moderate to severe (i.e., FEV1 < 80% predicted) chronic obstructive pulmonary disease (COPD), who have an inadequate response to a long-acting bronchodilator (long-acting beta-2 agonist [LABA] or long-acting muscarinic antagonist [LAMA])."

"For the long-term maintenance treatment of airflow obstruction in patients with severe (i.e., FEV1 < 50% predicted) chronic obstructive pulmonary disease (COPD)."

"Special authorization may be granted for 24 months."

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

UP - First-line therapy ineffective

All requests for indacaterol maleate + glycopyrronium bromide must be completed using the Long-Acting Fixed-Dose Combination Products for Asthma/COPD Special Authorization Request Form (ABC 60025).

110 MCG (BASE) * 50 MCG (BASE) INHALATION CAPSULE				
00002418282	ULTIBRO BREEZHALER	NOV	$	2.5830

ITRACONAZOLE

(Refer to Section 1 - Restricted Benefits of the Alberta Drug Benefit List for coverage of the product when prescribed by a Specialist in Infectious Diseases or a designated prescriber.)

"For the treatment of oral and/or esophageal candidiasis in immunocompromised patients who are intolerant to fluconazole, or who have failed fluconazole as evidenced by significant clinical deterioration due to the fungal infection during a course of therapy or no resolution after a full course of therapy."*

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

10 MG / ML ORAL SOLUTION				
00002484315	**JAMP ITRACONAZOLE**	**JPC**	$	**0.4111**
00002495988	**ODAN ITRACONAZOLE**	**ODN**	$	**0.4111**
00002231347	SPORANOX	JAI	$	0.8632

TOCILIZUMAB

162 MG / SYR INJECTION SYRINGE

☒ 00002424770	ACTEMRA (0.9 ML SYRINGE)	HLR	$	358.9050

Giant Cell Arteritis

"Special authorization coverage may be provided for use in combination with glucocorticoids for the treatment of giant cell arteritis (GCA) in adult patients.

For coverage, this drug must be initiated in consultation with a Specialist in Internal Medicine, Rheumatology or Neurology.

Initial coverage may be approved for 12 weeks as follows:
-Coverage may be approved for one 162 mg subcutaneous dose of tocilizumab administered every week.
-As an interim measure, coverage will be provided for additional doses up to week 16, to allow time to determine whether the patient meets criteria for continued coverage below.
-Patients will be limited to receiving a one-month supply of subcutaneous tocilizumab per prescription at their pharmacy.
-Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond the initial 12 weeks, the patient must meet the following criteria:
1) The patient must be assessed after 12 weeks, but no longer than 16 weeks after treatment to determine response; AND
2) The patient must be a `responder' that meets the following criteria:
-Patient has achieved remission which is defined as the absence of flare* AND normalization of C-reactive protein (CRP) to <1 mg/dL (<10 mg/L).
*Flare is defined as the recurrence of signs or symptoms of GCA and/or erythrocyte sedimentation rate (ESR) greater or equal to 30 mm/hr attributable to GCA.

Following this assessment, continued coverage may be approved for one 162 mg subcutaneous dose administered every week for a period of 36 weeks.

Duration of therapy with tocilizumab will be limited to 52 weeks per treatment course. Re-treatment may be considered for patients who experience a disease flare after treatment discontinuation."

All requests (including renewal requests) for tocilizumab for Giant Cell Arteritis must be completed using the Tocilizumab for Giant Cell Arteritis Special Authorization Request Form (ABC 60066).

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 2 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).

- Initial coverage may be approved for 12 weeks as follows:
- Tocilizumab intravenous infusion: 10 mg/kg/dose for patients less than 30 kg, or 8 mg/kg/dose for patients 30 kg or greater every 4 weeks.
- Tocilizumab subcutaneous injection: one 162 mg dose of tocilizumab administered every 3 weeks for patients less than 30 kg, or administered every other week for patients 30 kg or greater.
- Patients will be limited to receiving up to a one-month supply of tocilizumab 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.

TOCILIZUMAB

- Patients will not be permitted to switch from abatacept to other biologic agents except under exceptional circumstances.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

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

Following this assessment, continued coverage may be approved for a period of 12 months. Coverage for tocilizumab will be provided for one intravenous dose of 8 mg/kg to 10 mg/kg every 4 weeks, or one 162 mg subcutaneous dose administered every two to three weeks (based on weight). 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 tocilizumab for Polyarticular Juvenile Idiopathic Arthritis must be completed using the Adalimumab/Etanercept/Tocilizumab for Polyarticular Juvenile Idiopathic Arthritis Special Authorization Request Form (ABC 60011).

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 16 weeks as follows:

TOCILIZUMAB

- Tocilizumab intravenous infusion: one dose of 4 mg/kg or 8 mg/kg (up to a maximum of 800 mg per dose) of tocilizumab administered at 0, 4, 8, 12 and 16 weeks (total of 5 doses). Patients will be limited to receiving one dose of intravenous tocilizumab per prescription at their pharmacy.
-Tocilizumab subcutaneous injection: for patients weighing less than 100 kg, initial coverage may be approved for one 162 mg dose of tocilizumab administered every other week, up to weekly based on clinical response. For patients weighing 100 kg or more, initial coverage may be approved for one 162 mg dose of tocilizumab administered every week. Patients will be limited to receiving a one-month supply of subcutaneous tocilizumab 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 the initial 16 weeks, the patient must meet the following criteria:
1) The patient must be assessed by an RA Specialist after 16 weeks, but no longer than 20 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 a period of 12 months. Coverage for tocilizumab will be provided for one intravenous dose of 4 mg/kg to 8 mg/kg (up to a maximum of 800 mg per dose) every 4 weeks, or one 162 mg subcutaneous dose administered every one to two weeks (based on weight and clinical response). 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 tocilizumab for Rheumatoid Arthritis must be completed using the Abatacept/Adalimumab/Anakinra/Certolizumab/Etanercept/Golimumab/Infliximab/Sarilumab/Tocilizumab/Tofacitinib for Rheumatoid Arthritis Special Authorization Request Form (ABC 60027).

Systemic Juvenile Idiopathic Arthritis

"Special authorization coverage may be provided for the treatment of active systemic juvenile idiopathic arthritis (sJIA) in patients 2 years of age and older when all of the following conditions are met:
- the patient has a diagnosis of systemic JIA with fever (greater than 38 degrees Celsius) for at least two weeks and at least one of the following: rash of systemic JIA; serositis; lymphadenopathy; hepatomegaly; splenomegaly; AND
- the physician has ruled out other potential etiologies; AND
- the patient is refractory to one or more non-steroidal anti-inflammatory drugs (NSAIDs) and one or more systemic corticosteroids.

"Refractory" is defined as one or more of the following: lack of effect, 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

TOCILIZUMAB

Clinic in Edmonton or Calgary (Pediatric RA Specialist).

- Initial coverage may be approved for 12 weeks as follows:
- Tocilizumab intravenous infusion: 12 mg/kg/dose for patients weighing less than 30 kg, or 8 mg/kg/dose for patients weighing greater than or equal to 30 kg (up to a maximum of 800 mg per dose), administered every two weeks, OR
- Tocilizumab subcutaneous injection: one 162 mg dose of tocilizumab administered once every 2 weeks for patients less than 30 kg, or administered once every week for patients 30 kg or greater.
- Patients will be limited to receiving one month of tocilizumab per prescription at their pharmacy.

For continued coverage beyond 12 weeks, the patient must meet the following criteria:
1) The patient must be assessed by a Pediatric RA Specialist after 12 weeks, but no longer than 16 weeks after, treatment with this biologic agent to determine response.
2) The Pediatric RA Specialist must confirm in writing that the patient is a responder as demonstrated by JIA ACR30 response and/or absence of fever and/or reduction in inflammatory markers [e.g., C-reactive protein (CRP) concentration of less than 15 mg/L or reduction in erythrocyte sedimentation rate (ESR)].
Following this assessment, continued coverage may be approved for a period of 12 months.
Coverage for tocilizumab will be provided for:
- One intravenous dose of 12 mg/kg for patients weighing less than 30 kg or 8 mg/kg for patients weighing greater than or equal to 30 kg (up to a maximum of 800 mg per dose), administered every two weeks, OR
- One 162 mg subcutaneous dose administered every one to two weeks (based on weight).
After twelve months, in order to be considered for continued coverage, the patient must meet the following criteria:
1) The patient has been re-assessed every 12 months by a Pediatric RA Specialist to determine response, AND
2) The Pediatric RA Specialist must confirm in writing that the patient has maintained a response to therapy."

All requests (including renewal requests) for tocilizumab for Systemic Juvenile Idiopathic Arthritis must be completed using the Tocilizumab for Systemic Juvenile Idiopathic Arthritis Special Authorization Request Form (ABC 60048).