Updates to the Alberta Human Services Drug Benefit Supplement

Effective May 1, 2015

Alberta Human Services

Inquiries should be directed to:

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Edmonton AB T5J 3C5

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Website: http://www.employment.alberta.ca/FCH/2086.html

Administered by Alberta Blue Cross
on behalf of Alberta Health.

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

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

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

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

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Special Authorization

The following drug product(s) may be considered for coverage by special authorization for Alberta Human Services.

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

Trade Name / Strength / Form	Generic Description	DIN	MFR
APO-FLUTAMIDE 250 MG TABLET	FLUTAMIDE	00002238560	APX
CELECOXIB 100 MG CAPSULE	CELECOXIB	00002436299	SNS
CELECOXIB 200 MG CAPSULE	CELECOXIB	00002436302	SNS
DUTASTERIDE 0.5 MG CAPSULE	DUTASTERIDE	00002429012	SIV
MAR-EZETIMIBE 10 MG TABLET	EZETIMIBE	00002422662	MAR
PMS-EZETIMIBE 10 MG TABLET	EZETIMIBE	00002416409	PMS

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
NAT-ZOLMITRIPTAN 2.5 MG TABLET	ZOLMITRIPTAN	00002421534	NTP

Drug Product(s) with Changes to Criteria for Coverage

Trade Name / Strength / Form	Generic Description	DIN	MFR
ACTEMRA (4 ML) 80 MG / VIAL INJECTION	TOCILIZUMAB	00002350092	HLR
ACTEMRA (10 ML) 200 MG / VIAL INJECTION	TOCILIZUMAB	00002350106	HLR
INVEGA SUSTENNA (0.5 ML SYR) 50 MG / SYR INJECTION SYRINGE	PALIPERIDONE PALMITATE	00002354217	JAI
INVEGA SUSTENNA (0.75 ML SYR) 75 MG / SYR INJECTION SYRINGE	PALIPERIDONE PALMITATE	00002354225	JAI
INVEGA SUSTENNA (1 ML SYR) 100 MG / SYR INJECTION SYRINGE	PALIPERIDONE PALMITATE	00002354233	JAI
INVEGA SUSTENNA (1.5 ML SYR) 150 MG / SYR INJECTION SYRINGE	PALIPERIDONE PALMITATE	00002354241	JAI
RISPERDAL CONSTA 25 MG / VIAL INJECTION	RISPERIDONE	00002255707	JAI
RISPERDAL CONSTA 37.5 MG / VIAL INJECTION	RISPERIDONE	00002255723	JAI
RISPERDAL CONSTA 50 MG / VIAL INJECTION	RISPERIDONE	00002255758	JAI

Added Product(s)

Trade Name / Strength / Form	Generic Description	DIN	MFR
JAMP-FLUCONAZOLE 150 MG CAPSULE	FLUCONAZOLE	00002432471	JPC

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 June 1, 2015.

Please review the online Alberta Drug Benefit List at https://www.ab.bluecross.ca/dbl/idbl_main1.html for further information.

Generic Description	Strength / Form	New LCA Price
ZOLMITRIPTAN	2.5 MG TABLET	3.5375

Product(s) With A Price Change

The following product(s) had a Price Decrease. The previous higher price will be recognized until May 31, 2015. For products within an established IC Grouping, the LCA price may apply.

Trade Name / Strength / Form	Generic Description	DIN	MFR
APO-ZOLMITRIPTAN 2.5 MG TABLET	ZOLMITRIPTAN	00002380951	APX
CELECOXIB 100 MG CAPSULE	CELECOXIB	00002429675	SIV
CELECOXIB 200 MG CAPSULE	CELECOXIB	00002429683	SIV
JAMP-CELECOXIB 100 MG CAPSULE	CELECOXIB	00002424533	JPC
JAMP-CELECOXIB 200 MG CAPSULE	CELECOXIB	00002424541	JPC
MAR-ZOLMITRIPTAN 2.5 MG TABLET	ZOLMITRIPTAN	00002399458	MAR
MINT-ZOLMITRIPTAN 2.5 MG TABLET	ZOLMITRIPTAN	00002419521	MPI
MYLAN-CELECOXIB 100 MG CAPSULE	CELECOXIB	00002423278	MYP
MYLAN-CELECOXIB 200 MG CAPSULE	CELECOXIB	00002399881	MYP
MYLAN-ZOLMITRIPTAN 2.5 MG TABLET	ZOLMITRIPTAN	00002369036	MYP
PMS-ZOLMITRIPTAN 2.5 MG TABLET	ZOLMITRIPTAN	00002324229	PMS
SANDOZ ZOLMITRIPTAN 2.5 MG TABLET	ZOLMITRIPTAN	00002362988	SDZ
TEVA-ZOLMITRIPTAN 2.5 MG TABLET	ZOLMITRIPTAN	00002313960	TEV

Discontinued Listing(s)

Notification of discontinuation has been received from the manufacturers. The Alberta government-sponsored drug programs previously covered the following drug product(s). Effective May 1, 2015, 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 May 31, 2015 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 April 30, 2015, claims will no longer pay for these products.

Trade Name / Strength / Form	Generic Description	DIN	MFR
AZITHROMYCIN 600 MG TABLET	AZITHROMYCIN	00002330911	SNS
INFANTOL 320 UNIT / ML / 80 UNIT / ML / 16 MG / ML / 0.25 MG / ML / 0.4 MG / ML / 2 MG / ML / 0.24 MG / ML ORAL LIQUID	VITAMIN A/ VITAMIN D/ ASCORBIC ACID/ THIAMINE/ RIBOFLAVIN (VITAMIN B2)/ NIACINAMIDE/ PYRIDOXINE	00000558079	CHD

Product(s) Removed from the HSDBS as Price Policy Requirements Not Satisfied

The Alberta government-sponsored drug programs previously covered the following drug product(s). Effective May 1, 2015, 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 May 31, 2015 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 April 30, 2015, claims will no longer pay for these products.

Trade Name / Strength / Form	Generic Description	DIN	MFR
JAMP-ZOLMITRIPTAN 2.5 MG TABLET	ZOLMITRIPTAN	00002421623	JPC

PART 2

Drug Additions

FLUCONAZOLE

150 MG ORAL CAPSULE

	00002241895	**APO-FLUCONAZOLE-150**	**APX**	$	**3.9400**
☒	00002432471	JAMP-FLUCONAZOLE	JPC	$	3.9400
	00002282348	**PMS-FLUCONAZOLE**	**PMS**	$	**3.9400**

PART 3

Special Authorization

CELECOXIB

"1) For patients who are at high risk of upper gastrointestinal (GI) complications due to a proven history of prior complicated GI events (e.g. GI perforation, obstruction or major bleeding) or

2) For patients who have a documented history of ulcers proven radiographically and/or endoscopically.

Special authorization for both criteria may be granted for 6 months."

All requests for celecoxib must be completed using the Celecoxib Special Authorization Request Form (ABC 31140).

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

100 MG ORAL CAPSULE

00002418932	**APO-CELECOXIB**	**APX**	$	**0.1748**
00002429675	**CELECOXIB**	**SIV**	$	**0.1748**
00002424533	**JAMP-CELECOXIB**	**JPC**	$	**0.1748**
00002423278	**MYLAN-CELECOXIB**	**MYP**	$	**0.1748**
00002355442	**PMS-CELECOXIB**	**PMS**	$	**0.1748**
00002436299	CELECOXIB	SNS	$	0.1776
00002420155	CO CELECOXIB	APH	$	0.1776
00002291975	GD-CELECOXIB	GMD	$	0.1776
00002420058	MAR-CELECOXIB	MAR	$	0.1776
00002412497	MINT-CELECOXIB	MPI	$	0.1776
00002412373	RAN-CELECOXIB	RAN	$	0.1776
00002321246	SANDOZ CELECOXIB	SDZ	$	0.1776
00002288915	TEVA-CELECOXIB	TEV	$	0.1776
00002239941	CELEBREX	PFI	$	0.6992

200 MG ORAL CAPSULE

00002418940	**APO-CELECOXIB**	**APX**	$	**0.3497**
00002429683	**CELECOXIB**	**SIV**	$	**0.3497**
00002424541	**JAMP-CELECOXIB**	**JPC**	$	**0.3497**
00002399881	**MYLAN-CELECOXIB**	**MYP**	$	**0.3497**
00002355450	**PMS-CELECOXIB**	**PMS**	$	**0.3497**
00002436302	CELECOXIB	SNS	$	0.3553
00002420163	CO CELECOXIB	APH	$	0.3553
00002291983	GD-CELECOXIB	GMD	$	0.3553
00002420066	MAR-CELECOXIB	MAR	$	0.3553
00002412500	MINT-CELECOXIB	MPI	$	0.3553
00002412381	RAN-CELECOXIB	RAN	$	0.3553
00002321254	SANDOZ CELECOXIB	SDZ	$	0.3553
00002288923	TEVA-CELECOXIB	TEV	$	0.3553
00002239942	CELEBREX	PFI	$	1.3988

DUTASTERIDE

"For the treatment of benign prostatic hyperplasia in patients who are poor surgical risks or who have enlarged prostates and have moderate to severe symptoms suggestive of obstruction.

Special authorization may be granted for 6 months"

Information is required regarding the medical condition(s) or circumstances by which this patient would be deemed a poor surgical risk.

All requests (including renewal requests) for dutasteride must be completed using the Dutasteride/Finasteride Special Authorization Request Form (ABC 31257).

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

0.5 MG ORAL CAPSULE

00002412691	**ACT DUTASTERIDE**	**APH**	$	**0.4205**
00002404206	**APO-DUTASTERIDE**	**APX**	$	**0.4205**
00002429012	**DUTASTERIDE**	**SIV**	$	**0.4205**
00002416298	**MED-DUTASTERIDE**	**GMP**	$	**0.4205**
00002428873	**MINT-DUTASTERIDE**	**MPI**	$	**0.4205**
00002393220	**PMS-DUTASTERIDE**	**PMS**	$	**0.4205**
00002424444	**SANDOZ DUTASTERIDE**	**SDZ**	$	**0.4205**
00002408287	**TEVA-DUTASTERIDE**	**TEV**	$	**0.4205**
00002247813	AVODART	GSK	$	1.6819

EZETIMIBE

"For the treatment of hypercholesterolemia in patients who are intolerant to statins or in whom a statin is contraindicated and who are at high cardiovascular risk*; or

For the treatment of hypercholesterolemia when used in combination with a statin in patients failing to achieve target LDL with a statin at maximum tolerable dose or maximum recommended dose as per respective product monograph and who are at high cardiovascular risk*:

* High cardiovascular risk is defined as possessing one of the following:
1) Pre-existing cardiovascular disease and/or cerebrovascular disease, or
2) Diabetes, or
3) Familial hypercholesterolemia, or
4) Greater than or equal to 20% risk as defined by the Framingham Risk Assessment Tool, or
5) Three or more of the following risk factors:
- Family history of premature cardiovascular disease
- Smoking
- Hypertension
- Obesity
- Glucose intolerance
- Renal disease.

Special authorization for these criteria may be granted for 6 months."

All requests for ezetimibe must be completed using the Ezetimibe Special Authorization Request Form (ABC 30925).

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

10 MG ORAL TABLET

00002425610	**ACH-EZETIMIBE**	**AHI**	$	**0.4549**
00002427826	**APO-EZETIMIBE**	**APX**	$	**0.4549**
00002429659	**EZETIMIBE**	**SIV**	$	**0.4549**
00002378035	**MYLAN-EZETIMIBE**	**MYP**	$	**0.4549**
00002416409	**PMS-EZETIMIBE**	**PMS**	$	**0.4549**
00002414716	ACT EZETIMIBE	APH	$	0.4612
00002431300	EZETIMIBE	SNS	$	0.4612
00002422662	MAR-EZETIMIBE	MAR	$	0.4612
00002419548	RAN-EZETIMIBE	RAN	$	0.4612
00002416778	SANDOZ EZETIMIBE	SDZ	$	0.4612
00002354101	TEVA-EZETIMIBE	TEV	$	0.4612
00002247521	EZETROL	MFC	$	1.8360

FLUTAMIDE

"When prescribed for non-cancer, non-cosmetic indications.

Special authorization may be granted for 6 months."

Information is required regarding the patient's diagnosis/indication for use of this medication.

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

250 MG ORAL TABLET

00002238560	APO-FLUTAMIDE	APX	$	1.8255

PALIPERIDONE PALMITATE

"For the management of the manifestations of schizophrenia in patients who demonstrate a pattern of significant non-compliance that compromises therapeutic success and who possess clinical evidence of previous successful treatment with risperidone or paliperidone therapy;

AND who meet at least one of the following criteria:

- Experiences extra-pyramidal symptoms with either an oral or depot first generation antipsychotic agent that precludes the use of a first generation antipsychotic depot product; OR

- Is refractory to trials of at least two other antipsychotic therapies (Note: one trial must include a first generation antipsychotic agent)

Special Authorization may be granted for six months."

All requests (including renewal requests) for paliperidone prolonged release injection must be completed using the Paliperidone/Risperidone Prolonged Release Injection Special Authorization Request Form (ABC 60024).

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

50 MG / SYR (BASE) INJECTION SYRINGE			
00002354217	INVEGA SUSTENNA (0.5 ML SYR)	JAI	$ 311.4300
75 MG / SYR (BASE) INJECTION SYRINGE			
00002354225	INVEGA SUSTENNA (0.75 ML SYR)	JAI	$ 467.1800
100 MG / SYR (BASE) INJECTION SYRINGE			
00002354233	INVEGA SUSTENNA (1 ML SYR)	JAI	$ 467.1800
150 MG / SYR (BASE) INJECTION SYRINGE			
00002354241	INVEGA SUSTENNA (1.5 ML SYR)	JAI	$ 622.8900

RISPERIDONE

"For the management of the manifestations of schizophrenia and related psychotic disorders in patients who demonstrate a pattern of significant non-compliance that compromises therapeutic success and who possess clinical evidence of previous successful treatment with risperidone or paliperidone therapy;

AND who meet at least one of the following criteria:

- Experiences extra-pyramidal symptoms with either an oral or depot first generation antipsychotic agent that precludes the use of a first generation antipsychotic depot product; OR
- Is refractory to trials of at least two other antipsychotic therapies (Note: one trial must include a first generation antipsychotic agent)

Special Authorization may be granted for six months."

All requests (including renewal requests) for risperidone prolonged release injection must be completed using the Paliperidone/Risperidone Prolonged Release Injection Special Authorization Request Form (ABC 60024).

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

25 MG / VIAL INJECTION			
00002255707	RISPERDAL CONSTA	JAI	$ 162.5300
37.5 MG / VIAL INJECTION			
00002255723	RISPERDAL CONSTA	JAI	$ 243.7900

RISPERIDONE

50 MG / VIAL INJECTION

00002255758	RISPERDAL CONSTA	JAI	$ 325.0500

TOCILIZUMAB

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 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 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 5 doses, 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].

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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 dose of 4 mg/kg to 8 mg/kg (up to a maximum of 800 mg per dose) every 4 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 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/Etanercept/Golimumab/Infliximab/ Tocilizumab for Rheumatoid Arthritis Special Authorization Request Form (ABC 30902).

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 Clinic in Edmonton or Calgary (Pediatric RA Specialist).

- Coverage may be approved for one dose of 12 mg/kg for patient weight less than 30 kg or 8 mg/kg for patient weight greater than or equal to 30 kg to a maximum of 800 mg, administered every two weeks for 12 weeks.
- 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 one dose of 12 mg/kg for patient weight less than 30 kg or 8 mg/kg for patient weight greater than or equal to 30 kg to a maximum of 800 mg, administered every two weeks, for a maximum

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of twelve months. 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 31419).

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).

- Coverage may be approved for 10 mg/kg/dose for patients less than 30 kg, or 8 mg/kg/dose for patients 30 kg or greater every 4 weeks.
- Patients will be limited to receiving 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.
- 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),

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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 10 mg/kg/dose for patients less than 30 kg, or 8 mg/kg/dose for patients 30 kg or greater every 4 weeks, 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 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).

80 MG / VIAL INJECTION

00002350092	ACTEMRA (4 ML)	HLR	$ 180.8128

TOCILIZUMAB

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 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 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 5 doses, 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].

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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 dose of 4 mg/kg to 8 mg/kg (up to a maximum of 800 mg per dose) every 4 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 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/Etanercept/Golimumab/Infliximab/ Tocilizumab for Rheumatoid Arthritis Special Authorization Request Form (ABC 30902).

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 Clinic in Edmonton or Calgary (Pediatric RA Specialist).

- Coverage may be approved for one dose of 12 mg/kg for patient weight less than 30 kg or 8 mg/kg for patient weight greater than or equal to 30 kg to a maximum of 800 mg, administered every two weeks for 12 weeks.
- 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 one dose of 12 mg/kg for patient weight less than 30 kg or 8 mg/kg for patient weight greater than or equal to 30 kg to a maximum of 800 mg, administered every two weeks, for a maximum

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of twelve months. 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 31419).

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).

- Coverage may be approved for 10 mg/kg/dose for patients less than 30 kg, or 8 mg/kg/dose for patients 30 kg or greater every 4 weeks.
- Patients will be limited to receiving 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.
- 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),

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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 10 mg/kg/dose for patients less than 30 kg, or 8 mg/kg/dose for patients 30 kg or greater every 4 weeks, 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 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).

200 MG / VIAL INJECTION

00002350106	ACTEMRA (10 ML)	HLR	$	452.0320

ZOLMITRIPTAN

"For the treatment of acute migraine attacks in patients where other standard therapy has failed. Special authorization may be granted for 24 months."

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 TABLET

00002380951	**APO-ZOLMITRIPTAN**	**APX**	$	**3.5375**
00002399458	**MAR-ZOLMITRIPTAN**	**MAR**	$	**3.5375**
00002419521	**MINT-ZOLMITRIPTAN**	**MPI**	$	**3.5375**
00002369036	**MYLAN-ZOLMITRIPTAN**	**MYP**	$	**3.5375**
00002421534	**NAT-ZOLMITRIPTAN**	**NTP**	$	**3.5375**
00002324229	**PMS-ZOLMITRIPTAN**	**PMS**	$	**3.5375**
00002362988	**SANDOZ ZOLMITRIPTAN**	**SDZ**	$	**3.5375**
00002313960	**TEVA-ZOLMITRIPTAN**	**TEV**	$	**3.5375**
00002238660	ZOMIG	AZC	$	14.1533