Updates to the Alberta Drug Benefit List

Effective November 1, 2014

Alberta Government

Inquiries should be directed to:

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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.

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Special Authorization

The following drug product(s) will be considered for coverage by special authorization for patients covered under Alberta government-sponsored drug programs. Criteria for coverage of Alberta Human Services can be found in the November 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
ACT EZETIMIBE 10 MG TABLET	EZETIMIBE	00002414716	APH
MINT-DUTASTERIDE 0.5 MG CAPSULE	DUTASTERIDE	00002428873	MPI
MYLAN-EZETIMIBE 10 MG TABLET	EZETIMIBE	00002378035	MYP
RAN-EZETIMIBE 10 MG TABLET	EZETIMIBE	00002419548	RAN
SANDOZ EZETIMIBE 10 MG TABLET	EZETIMIBE	00002416778	SDZ
TARO-TESTOSTERONE 40 MG CAPSULE	TESTOSTERONE UNDECANOATE	00002421186	TAR
TEVA-EZETIMIBE 10 MG TABLET	EZETIMIBE	00002354101	TEV

Drug Product(s) with Changes to Criteria for Coverage

Trade Name / Strength / Form	Generic Description	DIN	MFR
GILENYA 0.5 MG CAPSULE	FINGOLIMOD HYDROCHLORIDE	00002365480	NOV
MYCOBUTIN 150 MG CAPSULE	RIFABUTIN	00002063786	PFI
SOLIRIS 300 MG / VIAL INJECTION	ECULIZUMAB	00002322285	API
TYSABRI 20 MG / ML INJECTION	NATALIZUMAB	00002286386	BIO

Drug Product(s) with Changes to Benefit Status

The following drug product(s) previously considered as Regular Benefits will now be considered as Restricted Benefits effective November 1, 2014.

Trade Name / Strength / Form	Generic Description	DIN	MFR
PMS-CHLORAL HYDRATE 100 MG / ML ORAL SYRUP	CHLORAL HYDRATE	00000792659	PMS

Restricted Benefit(s)

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

Trade Name / Strength / Form	Generic Description	DIN	MFR
PMS-ENTECAVIR 0.5 MG TABLET	ENTECAVIR	00002430576	PMS

Added Product(s)

Trade Name / Strength / Form	Generic Description	DIN	MFR
ABBOTT-OLANZAPINE ODT 5 MG DISINTEGRATING TABLET	OLANZAPINE	00002414538	ABB
ABBOTT-OLANZAPINE ODT 10 MG DISINTEGRATING TABLET	OLANZAPINE	00002414546	ABB
APO-ESCITALOPRAM 10 MG TABLET	ESCITALOPRAM	00002295016	APX
APO-ESCITALOPRAM 20 MG TABLET	ESCITALOPRAM	00002295024	APX
AURO-ESCITALOPRAM 10 MG TABLET	ESCITALOPRAM	00002397358	AUR
AURO-ESCITALOPRAM 20 MG TABLET	ESCITALOPRAM	00002397374	AUR
CO ESCITALOPRAM 10 MG TABLET	ESCITALOPRAM	00002313561	APH
CO ESCITALOPRAM 20 MG TABLET	ESCITALOPRAM	00002313588	APH
ESCITALOPRAM 10 MG TABLET	ESCITALOPRAM	00002430118	SNS
ESCITALOPRAM 20 MG TABLET	ESCITALOPRAM	00002430126	SNS
MYLAN-ESCITALOPRAM 10 MG TABLET	ESCITALOPRAM	00002309467	MYP
MYLAN-ESCITALOPRAM 20 MG TABLET	ESCITALOPRAM	00002309475	MYP
PENICILLIN G SODIUM 1,000,000 IU / VIAL INJECTION	PENICILLIN G SODIUM	00002220261	PPC
PENICILLIN G SODIUM 5,000,000 IU / VIAL INJECTION	PENICILLIN G SODIUM	00002220288	PPC
PENICILLIN G SODIUM 10,000,000 IU / VIAL INJECTION	PENICILLIN G SODIUM	00002220296	PPC
PMS-ESCITALOPRAM 10 MG TABLET	ESCITALOPRAM	00002303949	PMS
PMS-ESCITALOPRAM 20 MG TABLET	ESCITALOPRAM	00002303965	PMS
RAN-ESCITALOPRAM 10 MG TABLET	ESCITALOPRAM	00002385481	RAN
RAN-ESCITALOPRAM 20 MG TABLET	ESCITALOPRAM	00002385503	RAN
TEVA-ESCITALOPRAM 10 MG TABLET	ESCITALOPRAM	00002318180	TEV
TEVA-ESCITALOPRAM 20 MG TABLET	ESCITALOPRAM	00002318202	TEV
TUDORZA GENUAIR 400 MCG / DOSE INHALATION METERED INHALATION POWDER	ACLIDINIUM BROMIDE	00002409720	ALM

New Established Interchangeable (IC) Grouping(s)

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

Generic Description	Strength / Form	New LCA Price
ESCITALOPRAM	10 MG TABLET	0.4318
ESCITALOPRAM	20 MG TABLET	0.4597
EZETIMIBE	10 MG TABLET	0.4549
PENICILLIN G SODIUM	1,000,000 IU / VIAL INJECTION	2.4000
PENICILLIN G SODIUM	5,000,000 IU / VIAL INJECTION	5.1000
PENICILLIN G SODIUM	10,000,000 IU / VIAL INJECTION	8.9000

Least Cost Alternative (LCA) Price Change(s)

The following established IC Grouping(s) are affected and a revised LCA price has been established. Groupings affected by a price decrease, will be effective December 1, 2014.

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
ENTECAVIR	0.5 MG TABLET	11.0000
TESTOSTERONE UNDECANOATE	40 MG CAPSULE	0.4700
ZOPICLONE	5 MG TABLET	0.1906
ZOPICLONE	7.5 MG TABLET	0.2407

Product(s) With A Price Change

The following product(s) had a Price Decrease. The previous higher price will be recognized until November 30, 2014.

Trade Name / Strength / Form	Generic Description	DIN	MFR
APO-ENTECAVIR 0.5 MG TABLET	ENTECAVIR	00002396955	APX
CLINDOXYL ADV 1 % / 3 % TOPICAL GEL	CLINDAMYCIN PHOSPHATE/ BENZOYL PEROXIDE	00002382822	GSK
MAR-OLANZAPINE ODT 5 MG DISINTEGRATING TABLET	OLANZAPINE	00002389088	MAR
MEFENAMIC 250 MG CAPSULE	MEFENAMIC ACID	00002229452	AAP
METHOTREXATE SOD. (UNPRESERVED) 25 MG / ML INJECTION	METHOTREXATE SODIUM	00002182955	HSP

Product(s) With A Price Change, continued

Trade Name / Strength / Form	Generic Description	DIN	MFR
OLANZAPINE ODT 5 MG DISINTEGRATING TABLET	OLANZAPINE	00002343665	SIV
PMS-TESTOSTERONE 40 MG CAPSULE	TESTOSTERONE UNDECANOATE	00002322498	PMS
SEPTA-ZOPICLONE 5 MG TABLET	ZOPICLONE	00002386909	SEP
SEPTA-ZOPICLONE 7.5 MG TABLET	ZOPICLONE	00002386917	SEP

Discontinued Listing(s)

Notification of discontinuation has been received from the manufacturer(s). The Alberta government-sponsored drug programs previously covered the following drug product(s). Effective November 1, 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 November 30, 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 October 31, 2014, claims will no longer pay for these products.

Trade Name / Strength / Form	Generic Description	DIN	MFR
APO-SULIN 150 MG TABLET	SULINDAC	00000778354	APX
APO-SULIN 200 MG TABLET	SULINDAC	00000778362	APX
HALOPERIDOL LA 50 MG / ML INJECTION	HALOPERIDOL DECANOATE	00002130297	SDZ
NOVO-VERAMIL SR 240 MG SUSTAINED-RELEASE TABLET	VERAPAMIL HCL	00002211920	TEV
PAT-RABEPRAZOLE 10 MG ENTERIC-COATED TABLET	RABEPRAZOLE SODIUM	00002381737	PAT
PAT-RABEPRAZOLE 20 MG ENTERIC-COATED TABLET	RABEPRAZOLE SODIUM	00002381745	PAT
PROCHLORPERAZINE 5 MG / ML INJECTION	PROCHLORPERAZINE	00000789747	SDZ
SANDOZ CARBAMAZEPINE 100 MG CHEWABLE TABLET	CARBAMAZEPINE	00002261855	SDZ
TEVA-GALANTAMINE ER 8 MG EXTENDED-RELEASE CAPSULE	GALANTAMINE HYDROBROMIDE	00002377950	TEV
TEVA-GALANTAMINE ER 16 MG EXTENDED-RELEASE CAPSULE	GALANTAMINE HYDROBROMIDE	00002377969	TEV
TEVA-GALANTAMINE ER 24 MG EXTENDED-RELEASE CAPSULE	GALANTAMINE HYDROBROMIDE	00002377977	TEV

PART 2

Drug Additions

ACLIDINIUM BROMIDE

400 MCG / DOSE INHALATION METERED INHALATION POWDER

00002409720	TUDORZA GENUAIR	ALM	$	0.8850

CHLORAL HYDRATE

RESTRICTED BENEFIT - This Drug Product is restricted for use as a premedicant prior to surgery or procedure for patients less than 18 years of age. A limit of 2 doses per procedure will be allowed and coverage will be granted for a total of 4 procedures per year. Chloral Hydrate will continue to be a regular benefit for patients greater than or equal to 18 years of age.

100 MG / ML ORAL SYRUP

00000792659	PMS-CHLORAL HYDRATE	PMS	$	0.0466

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

00002396955	**APO-ENTECAVIR**	**APX**	$	**11.0000**
00002430576	**PMS-ENTECAVIR**	**PMS**	$	**11.0000**
00002282224	BARACLUDE	BMS	$	22.0000

ESCITALOPRAM

10 MG ORAL TABLET

00002295016	**APO-ESCITALOPRAM**	**APX**	$	**0.4318**
00002397358	**AURO-ESCITALOPRAM**	**AUR**	$	**0.4318**
00002313561	**CO ESCITALOPRAM**	**APH**	$	**0.4318**
00002430118	**ESCITALOPRAM**	**SNS**	$	**0.4318**
00002309467	**MYLAN-ESCITALOPRAM**	**MYP**	$	**0.4318**
00002303949	**PMS-ESCITALOPRAM**	**PMS**	$	**0.4318**
00002385481	**RAN-ESCITALOPRAM**	**RAN**	$	**0.4318**
00002318180	**TEVA-ESCITALOPRAM**	**TEV**	$	**0.4318**
00002263238	CIPRALEX	LBC	$	1.7270

20 MG ORAL TABLET

00002295024	**APO-ESCITALOPRAM**	**APX**	$	**0.4597**
00002397374	**AURO-ESCITALOPRAM**	**AUR**	$	**0.4597**
00002313588	**CO ESCITALOPRAM**	**APH**	$	**0.4597**
00002430126	**ESCITALOPRAM**	**SNS**	$	**0.4597**
00002309475	**MYLAN-ESCITALOPRAM**	**MYP**	$	**0.4597**
00002303965	**PMS-ESCITALOPRAM**	**PMS**	$	**0.4597**
00002385503	**RAN-ESCITALOPRAM**	**RAN**	$	**0.4597**
00002318202	**TEVA-ESCITALOPRAM**	**TEV**	$	**0.4597**
00002263254	CIPRALEX	LBC	$	1.8387

MEFENAMIC ACID

250 MG ORAL CAPSULE

00002229452	MEFENAMIC	AAP	$	0.4499

METHOTREXATE SODIUM

25 MG / ML (BASE) INJECTION

00002099705	**METHOTREXATE SOD.(UNPRESERVED)**	**TEV**	$	**5.6250**
00002182955	**METHOTREXATE SOD.(UNPRESERVED)**	**HSP**	$	**5.6250**

OLANZAPINE

5 MG ORAL DISINTEGRATING TABLET

00002327562	**CO OLANZAPINE ODT**	**APH**	$	**0.8936**
00002389088	**MAR-OLANZAPINE ODT**	**MAR**	$	**0.8936**
00002382709	**MYLAN-OLANZAPINE ODT**	**MYP**	$	**0.8936**
00002343665	**OLANZAPINE ODT**	**SIV**	$	**0.8936**
00002352974	**OLANZAPINE ODT**	**SNS**	$	**0.8936**
00002414090	**RAN-OLANZAPINE ODT**	**RAN**	$	**0.8936**
00002327775	**SANDOZ OLANZAPINE ODT**	**SDZ**	$	**0.8936**
00002321343	**TEVA-OLANZAPINE OD**	**TEV**	$	**0.8936**
00002414538	ABBOTT-OLANZAPINE ODT	ABB	$	0.8937
00002360616	APO-OLANZAPINE ODT	APX	$	0.8937
00002406624	JAMP-OLANZAPINE ODT	JPC	$	0.8937
00002303191	PMS-OLANZAPINE ODT	PMS	$	0.8937
00002243086	ZYPREXA ZYDIS	LIL	$	3.5746

10 MG (BASE) ORAL DISINTEGRATING TABLET

00002414546	**ABBOTT-OLANZAPINE ODT**	**ABB**	$	**1.7857**
00002360624	**APO-OLANZAPINE ODT**	**APX**	$	**1.7857**
00002327570	**CO OLANZAPINE ODT**	**APH**	$	**1.7857**
00002406632	**JAMP-OLANZAPINE ODT**	**JPC**	$	**1.7857**
00002389096	**MAR-OLANZAPINE ODT**	**MAR**	$	**1.7857**
00002382717	**MYLAN-OLANZAPINE ODT**	**MYP**	$	**1.7857**
00002343673	**OLANZAPINE ODT**	**SIV**	$	**1.7857**
00002352982	**OLANZAPINE ODT**	**SNS**	$	**1.7857**
00002303205	**PMS-OLANZAPINE ODT**	**PMS**	$	**1.7857**
00002414104	**RAN-OLANZAPINE ODT**	**RAN**	$	**1.7857**
00002327783	**SANDOZ OLANZAPINE ODT**	**SDZ**	$	**1.7857**
00002321351	**TEVA-OLANZAPINE OD**	**TEV**	$	**1.7857**
00002243087	ZYPREXA ZYDIS	LIL	$	7.1429

PENICILLIN G SODIUM

1,000,000 IU / VIAL INJECTION

00002220261	**PENICILLIN G SODIUM**	**PPC**	$	**2.4000**
00001930672	PENICILLIN G SODIUM	TEV	$	2.9703

5,000,000 IU / VIAL INJECTION

00002220288	**PENICILLIN G SODIUM**	**PPC**	$	**5.1000**
00000883751	PENICILLIN G SODIUM	TEV	$	6.3104

10,000,000 IU / VIAL INJECTION

00002220296	**PENICILLIN G SODIUM**	**PPC**	$	**8.9000**
00001930680	PENICILLIN G SODIUM	TEV	$	11.0132

ZOPICLONE

5 MG ORAL TABLET

00002386909	**SEPTA-ZOPICLONE**	**SEP**	$	**0.1906**
00002245077	APO-ZOPICLONE	APX	$	0.2199
00002271931	CO ZOPICLONE	APH	$	0.2199
00002406969	JAMP-ZOPICLONE	JPC	$	0.2199
00002386771	MAR-ZOPICLONE	MAR	$	0.2199
00002391716	MINT-ZOPICLONE	MPI	$	0.2199
00002296616	MYLAN-ZOPICLONE	MYP	$	0.2199
00002251450	NOVO-ZOPICLONE	TEV	$	0.2199
00002243426	PMS-ZOPICLONE	PMS	$	0.2199
00002267918	RAN-ZOPICLONE	RAN	$	0.2199
00002246534	RATIO-ZOPICLONE	RPH	$	0.2199
00002257572	SANDOZ ZOPICLONE	SDZ	$	0.2199
00002344122	ZOPICLONE	SNS	$	0.2199
00002385821	ZOPICLONE	SIV	$	0.2199
00002216167	IMOVANE	SAV	$	1.0589

7.5 MG ORAL TABLET

00002386917	**SEPTA-ZOPICLONE**	**SEP**	$	**0.2407**
00002218313	APO-ZOPICLONE	APX	$	0.3125
00002271958	CO ZOPICLONE	APH	$	0.3125
00002356805	JAMP-ZOPICLONE	JPC	$	0.3125
00002386798	MAR-ZOPICLONE	MAR	$	0.3125
00002391724	MINT-ZOPICLONE	MPI	$	0.3125
00002238596	MYLAN-ZOPICLONE	MYP	$	0.3125
00002251469	NOVO-ZOPICLONE	TEV	$	0.3125
00002240606	PMS-ZOPICLONE	PMS	$	0.3125
00002267926	RAN-ZOPICLONE	RAN	$	0.3125
00002242481	RATIO-ZOPICLONE	RPH	$	0.3125
00002008203	RHOVANE	SDZ	$	0.3125
00002282445	ZOPICLONE	SNS	$	0.3125
00002385848	ZOPICLONE	SIV	$	0.3125
00001926799	IMOVANE	SAV	$	1.3370

PART 3

Special Authorization

CLINDAMYCIN PHOSPHATE/ BENZOYL PEROXIDE

"For the treatment of severe acne as defined by scarring acne.
Special Authorization may be granted for 6 months."
The following product(s) are eligible for auto-renewal.

1 % * 3 % TOPICAL GEL

00002382822	CLINDOXYL ADV	GSK	$	0.8582

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**
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

ECULIZUMAB

ECULIZUMAB

1. ELIGIBILITY CRITERIA FOR ECULIZUMAB COVERAGE

In order to maintain the integrity of the ADBL, and having regard to the financial and social implications of covering eculizumab for the treatment of paroxysmal nocturnal hemoglobinuria (PNH), the following special authorization criteria must be satisfied.

In order to be eligible for eculizumab coverage for the treatment of PNH, a patient must have submitted a completed Application and have satisfied all of the following requirements:

The patient must:
1) Be diagnosed with PNH in accordance with the requirements specified in the Clinical Criteria for eculizumab;
2) Have Alberta government-sponsored drug coverage;
3) Meet the Registration Requirements;
4) Satisfy the Clinical Criteria for eculizumab (initial or continued coverage, as appropriate); AND
5) Meet the criteria specified in Contraindications to Coverage and Discontinuance of Coverage.

There is no guarantee that any application, whether for initial or continued coverage, will be approved. Depending on the circumstances of each case, the Minister or the Minister's delegate may:
- approve an Application;
- approve an Application with conditions;
- deny an Application;
- discontinue an approved Application; OR
- defer an Application pending the provision of further supporting information.

The process for review and approval is explained in further detail below.

2. REGISTRATION REQUIREMENTS

If the patient is a citizen or permanent resident of Canada, the patient must be continuously registered in the Alberta Health Care Insurance Plan for a minimum of one (1) year prior to an application for coverage unless:
- the patient is less than one (1) year of age at the date of the application, then the patient's parent/guardian/legal representative must be registered continuously in the Alberta Health Care Insurance Plan for a minimum of one (1) year; OR
- the patient has moved to Alberta from another province or territory in Canada (the" province of origin"), and immediately prior to moving to Alberta, was covered for eculizumab in the province of origin by a provincial or territorial government sponsored drug plan, (or the province of origin provided equivalent coverage for eculizumab as does Alberta) and the patient has been registered in the Alberta Health Care Insurance Plan (the patient must provide supporting documentation from the province of origin to prove prior coverage).

If the patient is not a citizen or permanent resident of Canada, the patient must be continuously registered in the Alberta Health Care Insurance Plan for a minimum of five (5) years prior to an application for coverage unless:
- the patient is less than five years of age at the date of the application, then the patients parent/guardian/legal representative must be registered continuously in the Alberta Health Care Insurance Plan for a minimum of five years; OR
- the patient has moved to Alberta from another province or territory in Canada (the "province of origin"), and immediately prior to moving to Alberta, was covered for eculizumab in the province of origin by a provincial or territorial government sponsored drug plan, (or the province of origin provided equivalent coverage for eculizumab as does Alberta) and the patient has been registered in the Alberta Health Care Insurance Plan (the patient must provide supporting documentation from the province of origin to prove prior coverage).

The Minister reserves the right to modify or waive the Registration Requirements applicable to a

ECULIZUMAB

given patient if the patient or the patient's parent/guardian/legal representative can establish to the satisfaction of the Minister that the patient has not moved to Alberta for the sole/primary purpose of obtaining coverage of eculizumab.

3. CLINICAL CRITERIA

In addition to meeting Sections 1 and Sections 2 herein, to be considered for coverage of eculizumab, a patient must be assessed by a Specialist in Hematology (i.e. a physician who holds specialty certification in Hematology from the Royal College of Physicians and Surgeons of Canada) and meet all of the following clinical criteria (initial or continued coverage, as appropriate).

a. Clinical Criteria - Initial Coverage
All of the following Clinical Criteria must be established on the basis of evidence to the satisfaction of the Minister or the Minister's delegate for initial coverage:

1) The diagnosis of PNH must have been established by flow cytometry and/or a FLAER test. The proportion of circulating cells of each type which are GPI-deficient and hence of the PNH clone is quantitated by flow cytometry. Patients must have a:
- PNH granulocyte clone size equal to or greater than 10%, AND
- Raised LDH (value at least 1.5 times the upper limit of normal for the reporting laboratory).

2) Patients with a clone size equal to or greater than 10% also require AT LEAST ONE of the following:
- Thrombosis: Evidence that the patient has had a thrombotic or embolic event which required the institution of therapeutic anticoagulant therapy;
- Transfusions: Evidence that the patient has been transfused with at least four (4) units of red blood cells in the last twelve (12) months;
- Anemia: Evidence that the patient has chronic or recurrent anemia where causes other than hemolysis have been excluded and demonstrated by more than one measure of less than or equal to 70g/L or by more than one measure of less than or equal to 100 g/L with concurrent symptoms of anemia;
- Pulmonary insufficiency: Evidence that the patient has debilitating shortness of breath and/or chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded;
- Renal insufficiency: Evidence that the patient has a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60mL/min/1.73m2, where causes other than PNH have been excluded; OR
- Smooth muscle spasm: Evidence that the patient has recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded.

AND

3) All patients must receive meningococcal vaccination with a quadravalent vaccine (A, C, Y and W135) at least two (2) weeks prior to receiving the first dose of eculizumab. All patients must be monitored and revaccinated according to current medical guidelines for vaccine use. Treating physicians will be required to submit confirmation of meningococcal vaccination in order for their patients to continue to be eligible for treatment with eculizumab.

b. Clinical Criteria - Continued Coverage
All of the following Clinical Criteria must be established on the basis of evidence to the satisfaction of the Minister or the Minister's delegate for continued coverage:
1) Patient eligibility must be reviewed six (6) months after commencing therapy and every six (6) months thereafter;

AND

ECULIZUMAB

2) Continued eligibility will be subject to the assessment of evidence, in accordance with the following monitoring requirements, which demonstrates:
- Clinical improvement in the patient, OR
- Stabilization of the patient's condition;

Monitoring requirements;

The patient's Specialist in Hematology must provide the following monitoring information every six (6) months:
- Lactate dehydrogenase (LDH);
- Full blood count and reticulocytes;
- Transfusion history for previous six months;
- Iron studies;
- Urea, electrolytes and eGFR;
- Recent clinical history; AND
- Any other information requested by the Minister, the Minister's delegate, or an Expert Advisor.

The patient's Specialist in Hematology must provide the following monitoring information every twelve (12) months:
- Confirmation that the patient has been vaccinated or revaccinated (meningococcal) according to current medical guidelines for vaccine use;
- Progress reports on the clinical symptoms that formed the basis of initial eligibility;
- Quality of life, through clinical narrative;
- Granulocyte clone size (by flow cytometry): AND
- Any other information requested by the Minister, the Minister's delegate, or an Expert Advisor.

c. Contraindications to Coverage

In addition to meeting all of the Initial Coverage Clinical Criteria or the Continued Coverage Clinical Criteria referred to above (as appropriate), the patient must not have any of the following contraindications:
- Small granulocyte clone size - a granulocyte clone size below 10%;
- Aplastic anaemia with two or more of the following: neutrophil count below 0.5 x 109/L, platelet count below 20 x 109/L, reticulocytes below 25 x 109/L, or severe bone marrow hypocellularity;
- Patients with a presence of another life threatening or severe disease where the long term prognosis is unlikely to be influenced by therapy (for example acute myeloid leukaemia or high-risk myelodysplastic syndrome); OR
- The presence of another medical condition that in the opinion of the Minister or Minister's delegate might reasonably be expected to compromise a response to therapy.

d. Discontinuation of Coverage

Coverage may be discontinued where one or more of the following situations apply:
- The patient or the patient's Specialist in Hematology fails to comply adequately with treatment or measures, including monitoring requirements, taken to evaluate the effectiveness of the therapy;
- There is a failure to provide the Minister, the Minister's delegate, or an Expert Advisor with information as required or as requested;
- If in the opinion of the Minister or the Minister's delegate, therapy fails to relieve the symptoms of disease that originally resulted in the patient being approved by the Minister or the Minister's delegate;
- The patient has (or develops) a condition referred to in Contraindications to Coverage.

The patient's Specialist in Hematology will be advised if their patient is at risk of being withdrawn from treatment for failure to comply with the above requirements or other perceived "non-compliance" and given a reasonable period of time to respond prior to coverage being discontinued.

4. PROCESS FOR ECULIZUMAB COVERAGE

ECULIZUMAB

For both initial and continued coverage the following documents (the Application) must be completed and submitted:

- An Eculizumab Special Authorization Request Form completed by the patient's Specialist in Hematology;
- An Eculizumab Consent Form completed by the patient, or a patient's parent/guardian/legal representative, and the patients Specialist in Hematology (for any initial coverage application); AND
- Any other documentation that may be required by the Minister or the Minister's delegate.

a. Expert Review

Once the Minister or the Minister's delegate has confirmed that the patient meets the Registration Requirement or granted a waiver of the Registration Requirement, the Application will be given to one or more Expert Advisors for review.

The Application, together with the recommendation or recommendations of the Expert Advisor(s), is then forwarded to the Minister or the Minister's delegate for a decision regarding coverage.

After the Minister or Minister's delegate has rendered a decision, the patient's Specialist in Hematology and the patient or patient's parent/guardian/legal representative will be notified by letter of the Minister's decision.

5. APPROVAL OF COVERAGE
The Minister or the Minister's delegate's decision in respect of an Application will specify the effective date of eculizumab coverage, if coverage is approved.

Initial coverage may be approved for a period of up to six (6) months as follows: One dose of 600mg of eculizumab administered weekly for the first four (4) weeks of treatment (total of four 600mg doses), followed by one dose of 900mg of eculizumab administered every two (2) weeks from week five (5) of treatment (total of eleven 900mg doses).

Continued coverage may be approved for up to one dose of 900mg of eculizumab administered every two (2) weeks, for a period of six (6) months (total of thirteen 900mg doses).

If a patient is approved for coverage, prescriptions for eculizumab must be written by a Specialist in Hematology. To avoid wastage, prescription quantities are limited to a two week supply. Extended quantity and vacation supplies are not permitted. The Government is not responsible and will not pay for costs associated with wastage or improper storage of eculizumab.

Approval of coverage is granted for a specific period, to a maximum of six (6) months. If continued treatment is necessary, it is the responsibility of the patient or patient's parent/guardian/legal representative and the Specialist in Hematology to submit a new Application to re-apply for eculizumab coverage, and receive a decision thereon, prior to the expiry date of the authorization period.

6. WITHDRAWAL

Therapy may be withdrawn at the request of the patient or the patient's parent/guardian/legal representative at any time. Notification of withdrawal from therapy must be made by the Specialist in Hematology or patient in writing.

Applications, withdrawal requests, and any other information to be provided must be sent to Clinical Drug Services, Alberta Blue Cross.

ECULIZUMAB

300 MG / VIAL INJECTION

00002322285	SOLIRIS	API	$ 6742.5000

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

00002414716	**ACT EZETIMIBE**	**APH**	$	**0.4549**
00002378035	**MYLAN-EZETIMIBE**	**MYP**	$	**0.4549**
00002419548	**RAN-EZETIMIBE**	**RAN**	$	**0.4549**
00002416778	**SANDOZ EZETIMIBE**	**SDZ**	$	**0.4549**
00002354101	**TEVA-EZETIMIBE**	**TEV**	$	**0.4549**
00002247521	EZETROL	MFC	$	1.8196

FINGOLIMOD HYDROCHLORIDE

Relapsing Remitting Multiple Sclerosis (RRMS):

Special authorization coverage may be provided for the treatment of relapsing remitting multiple sclerosis (RRMS) to reduce the frequency of clinical relapses and to delay the progression of physical disability in adult patients (18 years of age or older) who are refractory or intolerant to at least ONE of the following:
- interferon beta
- glatiramer acetate
- dimethyl fumarate.

Definition of 'intolerant'

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

Definition of 'refractory'

-Development of neutralizing antibodies to interferon beta.

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

1) Been adherent to the MS DMT (greater than 80% of approved doses have been administered);

2) Experienced at least two relapses* of MS confirmed by the presence of neurologic deficits on examination.
i. The first qualifying clinical relapse must have begun at least one month after treatment initiation.
ii. Both qualifying relapses must be classified with a relapse severity of moderate, severe or very severe**.

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

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

Coverage

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

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

Initial Coverage

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

2) The patient must have active disease which is defined as at least two relapses* of MS during

FINGOLIMOD HYDROCHLORIDE

the previous two years or in the two years prior to starting an MS DMT. In most cases this will be satisfied by the refractory to treatment criterion but if a patient failed interferon beta, glatiramer acetate, or dimethyl fumarate more than one year earlier, ongoing active disease must be confirmed.

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

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

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

Following assessment of the request, coverage may be approved for up to 12 months. Patients will be limited to receiving a one-month supply of fingolimod per prescription at their pharmacy for the first 12 months of coverage.

Continued Coverage

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

1) The patient must be assessed by a registered MS Neurologist;

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

3) The registered MS Neurologist must provide a current updated EDSS score. The patient must not have an EDSS score of 7.0 or above sustained for one year or more;

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

4) The registered MS Neurologist must confirm in writing that the patient is a 'responder' who has experienced no more than one inflammatory event in the last year (defined as either a clinical relapse or gadolinium-enhancing lesion). In instances where a patient has had four or more clinical relapses in the year prior to starting treatment, there must be at least a 50% reduction in relapse rate over the entire treatment period.

Following assessment of the request, continued coverage may be approved for maintenance therapy for up to 12 months. Patients may receive up to 100 days supply of fingolimod per prescription at their pharmacy.

Restarting After an Interruption in Therapy Greater Than 12 Months

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

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

All requests (including renewal requests) for fingolimod must be completed using the Fingolimod Hydrochloride Special Authorization Request Form (ABC 60000).

0.5 MG ORAL CAPSULE

00002365480	GILENYA	NOV	$	85.1648

NATALIZUMAB

Relapsing Remitting Multiple Sclerosis (RRMS):

Special authorization coverage may be provided for the treatment of relapsing remitting multiple sclerosis (RRMS) to reduce the frequency of clinical relapses, to decrease the number and volume of active brain lesions identified on magnetic resonance imaging (MRI) scans and to delay the progression of physical disability, in adult patients (18 years of age or older) who are refractory or intolerant to at least TWO of the following:
- interferon beta
- glatiramer acetate
- dimethyl fumarate.

Definition of 'intolerant'

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

Definition of 'refractory'

-Development of neutralizing antibodies to interferon beta.

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

1) Been adherent to the MS DMT (greater than 80% of approved doses have been administered);

2) Experienced at least two relapses* of MS confirmed by the presence of neurologic deficits on examination.
i. The first qualifying clinical relapse must have begun at least one month after treatment initiation.
ii. Both qualifying relapses must be classified with a relapse severity of moderate, severe or very severe**.

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

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

Coverage

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

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

Initial Coverage

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

NATALIZUMAB

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

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

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

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

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

Continued Coverage

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

1) The patient must be assessed by a registered MS Neurologist;

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

3) The registered MS Neurologist must provide a current updated EDSS score. The patient must not have an EDSS score of 7.0 or above sustained for one year or more;

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

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

5) The registered MS Neurologist must confirm in writing that the patient is a 'responder' who has experienced no more than one inflammatory event in the last year (defined as either a clinical relapse or gadolinium-enhancing lesion). In instances where a patient has had four or more clinical relapses in the year prior to starting treatment, there must be at least a 50% reduction in relapse rate over the entire treatment period.

Following assessment of the request, continued coverage may be approved for maintenance therapy of 300 mg every 4 weeks for a period up to 12 months. Patients will be limited to receiving one dose of natalizumab per prescription at their pharmacy.

Restarting After an Interruption in Therapy Greater Than 12 Months

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

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

All requests (including renewal requests) for natalizumab must be completed using the

NATALIZUMAB

Natalizumab Special Authorization Request Form (ABC 60003).

20 MG / ML INJECTION

00002286386	TYSABRI	BIO	$	167.7721

RIFABUTIN

"For susceptible infections when prescribed in consultation with a Specialist in Infectious Diseases".

Special authorization may be granted for 6 months.

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

150 MG ORAL CAPSULE

00002063786	MYCOBUTIN	PFI	$	4.0782

TESTOSTERONE UNDECANOATE

"For use in males for the treatment of congenital and acquired primary and secondary hypogonadism."

"Coverage cannot be considered when used for the treatment of androgen decline in the aging male (ADAM)."

"Special authorization may be granted for 6 months."

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

40 MG ORAL CAPSULE

00002322498	**PMS-TESTOSTERONE**	**PMS**	$	**0.4700**
00002421186	**TARO-TESTOSTERONE**	**TAR**	$	**0.4700**
00000782327	ANDRIOL	MFC	$	0.9400