Updates to the Alberta Drug Benefit List

Effective March 1, 2015

Alberta Government

Inquiries should be directed to:

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

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

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

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

Administered by Alberta Blue Cross
on behalf of Alberta Health.

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

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

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

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

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Special Authorization

Drug Product(s) with Changes to Criteria for Coverage

Trade Name / Strength / Form	Generic Description	DIN	MFR
SOLIRIS 300 MG / VIAL INJECTION	ECULIZUMAB	00002322285	API
XARELTO 15 MG TABLET	RIVAROXABAN	00002378604	BAI
XARELTO 20 MG TABLET	RIVAROXABAN	00002378612	BAI

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 March 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 March 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 February 28, 2015, claims will no longer pay for these products.

Trade Name / Strength / Form	Generic Description	DIN	MFR
AMLODIPINE-ODAN 5 MG TABLET	AMLODIPINE BESYLATE	00002378760	ODN
AMLODIPINE-ODAN 10 MG TABLET	AMLODIPINE BESYLATE	00002378779	ODN
DIODOQUIN 210 MG TABLET	IODOQUINOL	00001997769	GLE
DIODOQUIN 650 MG TABLET	IODOQUINOL	00001997750	GLE
JAMP-AMLODIPINE 5 MG TABLET	AMLODIPINE BESYLATE	00002331071	JPC
JAMP-AMLODIPINE 10 MG TABLET	AMLODIPINE BESYLATE	00002331098	JPC
PHL-AMLODIPINE 2.5 MG TABLET	AMLODIPINE BESYLATE	00002326760	PHH
PHL-AMLODIPINE 5 MG TABLET	AMLODIPINE BESYLATE	00002326779	PHH
PHL-AMLODIPINE 10 MG TABLET	AMLODIPINE BESYLATE	00002326787	PHH
PHL-CITALOPRAM 20 MG TABLET	CITALOPRAM HYDROBROMIDE	00002248944	PHH
PHL-CITALOPRAM 40 MG TABLET	CITALOPRAM HYDROBROMIDE	00002248945	PHH
PHL-SIMVASTATIN 5 MG TABLET	SIMVASTATIN	00002281546	PHH
PHL-SIMVASTATIN 10 MG TABLET	SIMVASTATIN	00002281554	PHH
PHL-SIMVASTATIN 20 MG TABLET	SIMVASTATIN	00002281562	PHH
PHL-SIMVASTATIN 40 MG TABLET	SIMVASTATIN	00002281570	PHH
PHL-SIMVASTATIN 80 MG TABLET	SIMVASTATIN	00002281589	PHH
POTABA 500 MG TABLET	AMINOBENZOATE POTASSIUM	00000550175	GLE
POTABA 500 MG CAPSULE	AMINOBENZOATE POTASSIUM	00000611271	GLE
RATIO-SALBUTAMOL SULF U.D.P.F. 1 MG / ML INHALATION SOLUTION	SALBUTAMOL SULFATE	00001986864	RPH
SIMVASTATIN-ODAN 5 MG TABLET	SIMVASTATIN	00002378884	ODN

Discontinued Listing(s), continued

Trade Name / Strength / Form	Generic Description	DIN	MFR
SIMVASTATIN-ODAN 10 MG TABLET	SIMVASTATIN	00002378892	ODN
SIMVASTATIN-ODAN 20 MG TABLET	SIMVASTATIN	00002378906	ODN
SIMVASTATIN-ODAN 40 MG TABLET	SIMVASTATIN	00002378914	ODN
SIMVASTATIN-ODAN 80 MG TABLET	SIMVASTATIN	00002378922	ODN

PART 3

Special Authorization

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

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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 or monocyte 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 granulocyte or monocyte 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 immunization with a quadravalent vaccine (A, C, Y and W135) at least two (2) weeks prior to receiving the first dose of eculizumab. Treating physicians will be required to submit confirmation of meningococcal immunizations in order for their patients to continue to be eligible for treatment with eculizumab. Pneumococcal immunization with a 23-valent polysaccharide vaccine and a 13-valent conjugate vaccine, and a Haemophilus influenza type b (Hib) vaccine must be given according to current clinical guidelines. All patients must be monitored and reimmunized according to current clinical guidelines for vaccine use.

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;

ECULIZUMAB

AND

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 immunized or reimmunized (meningococcal, pneumococcal 23-valent, pneumococcal 13-valent and Hib) according to current clinical guidelines for vaccine use;
- Progress reports on the clinical symptoms that formed the basis of initial eligibility;
- Quality of life, through clinical narrative;
- Granulocyte or monocyte 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

- Small clone size - granulocyte and monocyte clone sizes 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

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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 the patient restarts treatment after a lapse in therapy, continued 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).

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.

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

300 MG / VIAL INJECTION

00002322285	SOLIRIS	API	$ 6742.5000

RIVAROXABAN

NON-VALVULAR ATRIAL FIBRILLATION

SPECIAL AUTHORIZATION (step therapy approval process)

FIRST-LINE DRUG PRODUCT(S): WARFARIN

Coverage

Members of Alberta Government Sponsored Drug Plans who are at-risk with non-valvular atrial fibrillation (AF) who require the Drug Products for the prevention of stroke and systemic embolism AND in whom one of the following is also present:

- Inadequate Anticoagulation following a Reasonable Trial on Warfarin; OR
- Anticoagulation with warfarin is contraindicated or not possible due to inability to regularly monitor via International Normalized Ratio (INR) testing (i.e. no access to INR testing services at a laboratory, clinic, pharmacy, and at home).

At-risk patients with atrial fibrillation are defined as those with a CHADS2 score of greater than or equal to 1. Although the ROCKET-AF trial included patients with higher CHADS2 scores (greater than or equal to 2), other landmark studies with the other newer oral anticoagulants demonstrated a therapeutic benefit in patients with a CHADS2 score of 1. Coverage may be considered for an antiplatelet regimen or oral anticoagulation for patients with a CHADS2 score of 1.

Exclusion from Coverage:
- Patients with impaired renal function (creatinine clearance or estimated glomerular filtration rate <30 mL/min) OR
- Greater than or equal to 75 years of age and without Documented Stable Renal Function; OR
- hemodynamically significant rheumatic valvular heart disease, especially mitral stenosis; OR
- prosthetic heart valves.

Definitions:
- Documented Stable Renal Function is defined as creatinine clearance or estimated glomerular filtration rate that is maintained for at least 3 months (i.e. 30-49 mL/min for 15 mg once daily dosing or greater than or equal to 50 mL/Min for 20 mg once daily dosing).
- Inadequate anticoagulation is defined as INR testing results that are outside the desired INR range for at least 35% of the tests during the monitoring period (i.e. adequate anticoagulation is defined as INR test results that are within the desired INR range for at least 65% of the tests during the monitoring period).
- Reasonable Trial on Warfarin is defined as at least 2 months of therapy.

OTHER CRITERIA:
- Since renal impairment can increase bleeding risk, renal function should be regularly monitored. Other factors that increase bleeding risk should also be assessed and monitored (see Drug Product monograph).
- Patients starting the Drug Product should have ready access to appropriate medical services to manage a major bleeding event.
- There is currently no data to support that the Drug Product provides adequate anticoagulation in patients with rheumatic valvular disease or those with prosthetic heart valves, so Drug Product is not recommended in these populations.

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

RIVAROXABAN

code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

UP - First-line therapy ineffective
UQ - First-line therapy not tolerated

VENOUS THROMBOLIC EVENTS

SPECIAL AUTHORIZATION

COVERAGE:

For the treatment of deep vein thrombosis (DVT) or pulmonary embolism (PE).

OTHER CRITERIA:

The recommended dose of rivaroxaban for patients initiating DVT or PE treatment is 15 mg twice daily for 3 weeks, followed by 20 mg once daily.

Drug plan coverage for rivaroxaban is an alternative to heparin/warfarin for up to 6 months. When used for greater than 6 months, rivaroxaban is more costly than heparin/warfarin. As such, patients with an intended duration of therapy greater than 6 months should be considered for initiation on heparin/warfarin.

Since renal impairment can increase bleeding risk, it is important to monitor renal function regularly. Other factors that increase bleeding risks should also be assessed and monitored (see product monograph).

Special authorization may be granted for up to 6 months."

All requests for rivaroxaban must be completed using the Apixaban/Dabigatran/Rivaroxaban Special Authorization Request Form (ABC 60019).

15 MG ORAL TABLET

00002378604	XARELTO	BAI	$	2.8400

RIVAROXABAN

NON-VALVULAR ATRIAL FIBRILLATION

SPECIAL AUTHORIZATION (step therapy approval process)

FIRST-LINE DRUG PRODUCT(S): WARFARIN

Coverage

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Special authorization may be granted for up to 6 months."

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20 MG ORAL TABLET				
00002378612	XARELTO	BAI	$	2.8400