APRIL 2024 • VOLUME 24-07
PRESCRIBER EDITION

NOVA SCOTIA

PharmacareNEWS

inside

Nova Scotia Formulary Updates

New Exception Status Benefits

The following new products have been listed with the following criteria, effective **May 1, 2024.**

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Benlysta (belimumab)	120mg/5mL Vial	02370050	DNP	E (SF)	GSK
	400mg/20mL Vial	02370069	DNP	E (SF)	GSK
	200mg/mL Autoinjector	02470489	DNP	E (SF)	GSK

Criteria

Active Lupus Nephritis

For the treatment of active lupus nephritis (LN) as adjunctive therapy in patients who meet all the following criteria:

- Diagnosed LN with any of the following:
  - class III with or without class V;
  - class IV with or without class V;
  - class V (i.e., pure class V).
- Must have started standard induction therapy within the previous 60 days.
- Must not have any of the following:
  - previously failed both cyclophosphamide and mycophenolate mofetil (or other forms of mycophenolate) induction therapies;
  - an estimated glomerular filtration rate (eGFR) < 30mL/min/1.73m^2.

Initial Renewal Criteria:

- Must provide proof of beneficial clinical effect, defined as all of the following:
  - reduction in glucocorticoids to ≤ 7.5mg/day after 12 months of therapy

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Benlysta (belimumab)	120mg/5mL Vial	02370050	DNP	E (SF)	GSK
	400mg/20mL Vial	02370069	DNP	E (SF)	GSK
	200mg/mL Autoinjector	02470489	DNP	E (SF)	GSK
Criteria	○ an estimated eGFR that is no more than 20% below the value before the renal flare (preflare value) or ≥ 60mL/min/1.73m^2 after 12 months of therapy. • Must provide proof of improvement in proteinuria, defined as either: ○ proteinuria no greater than 0.7g/24 hours after 12 months of therapy if baseline proteinuria is < 3.5g/24 hours ○ proteinuria no greater than 0.7g/24 hours after 18 to 24 months of therapy if baseline proteinuria is in the nephrotic range (i.e., > 3.5g/24 hours). **Subsequent Renewal Criteria:** • Must provide proof that the initial response achieved after the first 12 months of therapy has been maintained. **Discontinuation Criteria:** • Patient has any of the following: ○ Does not meet all of the renewal criteria; OR ○ An eGFR decrease to less than 30mL/min/1.73m^2; OR ○ The addition of other immunosuppressant agents (other than as part of the induction and maintenance regimens), corticosteroid use outside of the limits, anti-tumour necrosis factor therapy, or other biologics. **Claim Notes:** • The patient must be under the care of a rheumatologist or a nephrologist experienced in the management of LN. • Intravenous infusion: Approvals will be for a maximum of 10mg/kg every two weeks for three doses, and every 4 weeks thereafter. • Subcutaneous injection: Approvals will be for a maximum of 400mg once weekly for four doses, then 200mg once weekly thereafter. • Approvals: 12 months.				

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Ultomiris (ravulizumab)	300mg/30mL Vial	02491559	DNP	E (SF)	ALX
	300mg/3mL Vial	02533448	DNP	E (SF)	ALX
	1100mg/11mL Vial	02533456	DNP	E (SF)	ALX

Criteria

Paroxysmal Nocturnal Hemoglobinuria

Initiation Criteria:

For the treatment of patients with paroxysmal nocturnal hemoglobinuria (PNH) who meet the following criteria:

- The diagnosis of PNH has been made based on the following confirmatory results:
  - Flow cytometry/FLAER exam with granulocytes or monocyte clone ≥ 10%; AND
  - LDH > 1.5 ULN; AND
  - At least one of the following:
    - A thrombotic or embolic event which required the institution of therapeutic anticoagulant therapy,
    - Minimum transfusion requirement of 4 units of red blood cells in the previous 12 months,
    - 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 100g/L with concurrent symptoms of anemia,
    - Pulmonary insufficiency: 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: History of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m^2, where causes other than PNH have been excluded,
    - Smooth muscle spasm: Recurrent episodes of severe pain requiring hospitalization and/or narcotic analgesia, where causes other than PNH have been excluded.

Renewal Criteria:

- Renewals will be considered for patients who;
  - Demonstrate clinical improvement while on therapy or
  - Where therapy has been shown to stabilize the patient's condition
- Requests for renewal should be accompanied by confirmation of granulocyte clone size (by flow cytometry).

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Ultomiris (ravulizumab)	300mg/30mL Vial	02491559	DNP	E (SF)	ALX
	300mg/3mL Vial	02533448	DNP	E (SF)	ALX
	1100mg/11mL Vial	02533456	DNP	E (SF)	ALX

Criteria

Exclusion Criteria:

Exclusion criteria for both initiation and renewal requests:

- Small granulocyte or monocyte clone size - the treatment of patients with a granulocyte and monocyte clone size below 10% will not be eligible for treatment; OR
- Aplastic anemia with two or more of the following: neutrophil count below 0.5 x 10^9/L, platelet count below 20 x 10^9/L, reticulocytes below 25 x 10^9/L, or severe bone marrow hypocellularity; OR
- Patients afflicted with PNH and another life-threatening or severe disease where the long term prognosis is unlikely to be influenced by therapy (for example acute myeloid leukemia or high-risk myelodysplastic syndrome); OR
- The presence of another medical condition that might reasonably be expected to compromise a response to therapy.

Exclusion criteria for renewal requests:

- The patient or treating physician fails to comply adequately with treatment or measures, including monitoring requirements, taken to evaluate the effectiveness of the therapy; OR
- If therapy fails to relieve the symptoms of disease that originally resulted in the patient being approved for subsidized treatment.

Clinical Notes:

- Patients with insufficient initial response or who have failed treatment with eculizumab at the Health Canada–recommended dosage are not eligible for reimbursement of ravulizumab.
- All patients must receive meningococcal vaccination with a tetravalent vaccine at least two weeks prior to receiving the first dose of ravulizumab.

Claim Notes:

- Approvals will be for a maximum of:

Body Weight Range (kg)	Loading Dose (mg)	Maintenance Dose (mg)	Dosing Interval
≥ 5 to < 10	600	300	Every 4 weeks
≥ 10 to < 20	600	600	Every 8 weeks
≥ 20 to < 30	900	2,100	Every 8 weeks
≥ 30 to < 40	1,200	2,700	Every 8 weeks
≥ 40 to < 60	2,400	3,000	Every 8 weeks
≥ 60 to < 100	2,700	3,300	Every 8 weeks
≥ 100	3,000	3,600	Every 8 weeks

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Ultomiris (ravulizumab)	300mg/30mL Vial	02491559	DNP	E (SF)	ALX
	300mg/3mL Vial	02533448	DNP	E (SF)	ALX
	1100mg/11mL Vial	02533456	DNP	E (SF)	ALX

Criteria

- Supplemental dosing following treatment with plasma exchange, plasmapheresis, or intravenous immunoglobulin is approved.
- Initial Approval: 6 months
- Renewal Approval: 1 year
- The patient must be under the care of a pediatric nephrologist, a nephrologist, a pediatric hematologist or a hematologist.

Atypical Hemolytic Uremic Syndrome

Initiation Criteria:

- For the treatment of adult and pediatric patients 1 month of age and older with atypical hemolytic uremic syndrome (aHUS) who meet all of the following criteria:
    - Confirmed diagnosis of aHUS at initial presentation, defined by presence of thrombotic microangiopathy (TMA), who meet all the following criteria:
        - A disintegrin and metalloproteinase with a thrombospondin type 1 motif, member 13 (ADAMTS-13) activity ≥ 10% on blood samples taken before plasma exchange or plasma infusion (PE/PI); AND
        - Shiga toxin–producing Escherichia coli (STEC) test negative in patients with a history of bloody diarrhea in the preceding 2 weeks; and
        - TMA must be unexplained (not a secondary TMA).
    - Evidence of ongoing active TMA and progressing, defined by laboratory test abnormalities despite plasmapheresis, if appropriate. Patients must demonstrate:
        - Unexplained (not a secondary TMA) thrombocytopenia (platelet count < 150 × 10^9/L); and hemolysis as indicated by the documentation of 2 of the following: schistocytes on the blood film; low or absent haptoglobin; or lactate dehydrogenase (LDH) above normal. OR
        - Tissue biopsy confirms TMA in patients who do not have evidence of platelet consumption and hemolysis.
    - Evidence of at least 1 of the following documented clinical features of active organ damage or impairment:
        - Kidney impairment, as demonstrated by one of the following:
            - A decline in estimated glomerular filtration rate (eGFR) of > 20% in a patient with pre-existing renal impairment; AND/OR
            - Serum creatinine (SCr) > upper limit of normal (ULN) for age or GFR < 60mL/min and renal function deteriorating despite prior PE/PI in patients who have no history of preexisting renal impairment (i.e., who have no baseline eGFR measurement); OR

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Ultomiris (ravulizumab)	300mg/30mL Vial	02491559	DNP	E (SF)	ALX
	300mg/3mL Vial	02533448	DNP	E (SF)	ALX
	1100mg/11mL Vial	02533456	DNP	E (SF)	ALX

Criteria

- SCr > the age-appropriate ULN in pediatric patients (as determined by or in consultation with a pediatric nephrologist) OR
  - The onset of neurological impairment related to TMA.
  - Other TMA-related manifestations, such as cardiac ischemia, bowel ischemia, pancreatitis, and retinal vein occlusion.
- For transplant patients with a documented history of aHUS (i.e., history of TMA [not a secondary TMA only] with ADAMTS 13 > 10%) who meet the following criteria:
  - Develop TMA immediately (within hours to 1 month) following a kidney transplant; OR
  - Previously lost a native or transplanted kidney due to the development of TMA; OR
  - Have a history of proven aHUS and require prophylaxis with ravulizumab at the time of a kidney transplant
- Patients should not have a history of ravulizumab treatment failure (i.e., treated with ravulizumab with a previous aHUS recurrence). Treatment failure is defined as:
  - Dialysis-dependent at 6 months, and failed to demonstrate resolution or stabilization of neurological or extrarenal complications if these were originally present; OR
  - On dialysis for ≥ 4 of the previous 6 months while receiving ravulizumab and failed to demonstrate resolution or stabilization of neurological or extrarenal complications if these were originally present; OR
  - Worsening of kidney function with a reduction in eGFR or increase in SCr ≥ 25% from baseline.

Renewal Criteria:

- Treatment with ravulizumab can be renewed as long as the patient exhibits a response to treatment or as per physician discretion (e.g., long-term funding based on factors like limited organ reserve or high-risk genetic mutation such as Factor H deficiency).
  - Response to treatment is defined as, but not limited to, hematological normalization (e.g., platelet count, LDH), stabilization of end-organ damage (such as acute kidney injury and brain ischemia), transplant graft survival in susceptible individuals, and dialysis avoidance in patients who are pre- end-stage kidney disease (ESKD).
- Assessment of treatment response should be conducted at 6-months, at 12-months, then annually thereafter.
  - At the 6-month assessment, treatment response and no treatment failure (defined in Initiation Criteria) is required.

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Ultomiris (ravulizumab)	300mg/30mL Vial	02491559	DNP	E (SF)	ALX
	300mg/3mL Vial	02533448	DNP	E (SF)	ALX
	1100mg/11mL Vial	02533456	DNP	E (SF)	ALX

Criteria

- At the 12-month and annual assessments, treatment response, no treatment failure, and the patient has limited organ reserve or high-risk genetic mutation are required.
  - Limited organ reserve is defined as significant cardiomyopathy, neurological, gastrointestinal, or pulmonary impairment related to TMA; or Grade 4 or 5 chronic kidney disease (eGFR < 30mL/min) is required.

- A patient previously diagnosed with aHUS and who responded to treatment with ravulizumab and has not failed ravulizumab is eligible to restart ravulizumab if the patient redevelops a TMA related to aHUS and meets the following clinical conditions:
  - Significant hemolysis as evidenced by presence of schistocytes on the blood film, or low or absent haptoglobin, or LDH above normal; AND
  - EITHER
    - Platelet consumption as measured by either ≥ 25% decline from patient baseline or thrombocytopenia (platelet count < 150,000 × 10^9/L); OR
    - TMA-related organ impairment (e.g., unexplained rise in serum creatinine with onset of urine dipstick positive for hemoglobin) including on recent biopsy.

Claim Notes:

- Approvals will be for a maximum of:

Body Weight Range (kg)	Loading Dose (mg)	Maintenance Dose (mg)	Dosing Interval
≥ 5 to < 10	600	300	Every 4 weeks
≥ 10 to < 20	600	600	Every 8 weeks
≥ 20 to < 30	900	2,100	Every 8 weeks
≥ 30 to < 40	1,200	2,700	Every 8 weeks
≥ 40 to < 60	2,400	3,000	Every 8 weeks
≥ 60 to < 100	2,700	3,300	Every 8 weeks
≥ 100	3,000	3,600	Every 8 weeks

- Supplemental dosing following treatment with plasma exchange, plasmapheresis, or intravenous immunoglobulin is approved.
- The patient must be under the care of a pediatric nephrologist, a nephrologist, a pediatric hematologist or a hematologist.
- Initial approval: 6 months
- Renewal approval: 1 year

Criteria Update

The following criteria has been updated to include criteria codes effective **May 1, 2024.**

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Pegfilgrastim	Various	Various	DNP	E (SFC)	VAR
Criteria	• For the prevention of febrile neutropenia in patients with non-myeloid malignancies receiving myelosuppressive chemotherapy with curative intent who: ○ are at high risk of febrile neutropenia due to chemotherapy regimen, co-morbidities or pre-existing severe neutropenia; **[Criteria Code 01]** or ○ have had an episode of febrile neutropenia, neutropenic sepsis or profound neutropenia in a previous cycle of chemotherapy; **[Criteria Code 02]** or ○ have had a dose reduction, or treatment delay greater than one week due to neutropenia **[Criteria Code 03]** **Clinical Note:** • Patients with non-curative cancer receiving chemotherapy with palliative intent are not eligible for coverage of pegfilgrastim for prevention of febrile neutropenia.				

Change in Benefit Status

Effective **May 1, 2024**, the following products will be delisted.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Odan-Indomethacin	50mg Supp	02231799	N/A	**Not Insured**	ODN
Odan-Indomethacin	100mg Supp	02231800	N/A	**Not Insured**	ODN
Odan-Prochlorperazine	10mg Supp	00789720	N/A	**Not Insured**	ODN
Proctol	5/5/10/10mg Supp	02247882	N/A	**Not Insured**	ODN

New Benefits

Effective **May 1, 2024,** the following products will be added as benefits in the Nova Scotia Formulary. The benefit status within the Pharmacare Programs is indicated and existing criteria will apply.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Rymti	50mg/mL Prefilled Syringe	02530295	DNP	E (SF)	LUP
Rymti	50mg/mL Prefilled Autoinjector	02530309	DNP	E (SF)	LUP

Temporary Benefit – US-Labelled Colesevelam Hydrochloride Tablets

Glenmark Pharmaceuticals Canada Inc has received approval from Health Canada for the import and release of US-labelled Colesevelam tablets to help mitigate shortages in Canada.

The Nova Scotia Pharmacare Programs will be adding this product as a temporary benefit effective, immediately.

When prescribing or dispensing this product, pharmacists may consult Glenmark Pharmaceuticals Canada Inc. Dear Healthcare Professional at the following link https://glenmarkpharma.ca/wp-content/uploads/Glenmark-risk-communication-letter.pdf

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Colesevelam Hydrochloride	625mg Tab	09858334	DNP	SF	GLM

Legend

PRESCRIBER CODES		BENEFIT STATUS		MANUFACTURER CODES	
D	- Physician / Dentist	S	- Seniors' Pharmacare	ALX	- Alexion Pharma Canada Corp
N	- Nurse Practitioner	F	- Community Services Pharmacare	GLM	- Glenmark Pharmaceuticals Canada Inc.
P	- Pharmacist		- Family Pharmacare	GSK	- GlaxoSmithKline Inc.
M	- Midwife	C	- Drug Assistance for Cancer Patients	LUP	- Lupin Pharma Canada Limited
O	- Optometrist	D	- Diabetes Assistance Program	ODN	- Odan Laboratories Ltd.
		E	- Exception status applies	VAR	- *various manufacturers*