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NOVA SCOTIA

PharmacareNEWS

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Nova Scotia Formulary Updates

New Exception Status Products

The following new products have been listed with the following criteria, effective **October 1, 2025**.

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Aflivu (aflibercept)	40mg/mL Pre-filled Syringe	02554178	E (SF)	APX
	40mg/mL Vial	02554194	E (SF)	APX
Yesafili (aflibercept)	40mg/mL Pre-filled Syringe	02558238	E (SF)	BIL
	40mg/mL Vial	02535858	E (SF)	BIL
Criteria	**Effective October 1, 2025, patients currently taking the originator drug Eylea, are required to switch to a biosimilar version by January 1, 2026.** **For aflibercept-naïve patients whose therapy is initiated after October 1, 2025, an aflibercept biosimilar will be the product approved.** **Active (Wet) Age-Related Macular Degeneration** For the treatment of patients with neovascular (wet) age-related macular degeneration (AMD) who meet all of the following criteria: • Best Corrected Visual Acuity (BCVA) is greater than 6/96. • The lesion size is ≤ 12 disc areas in greatest linear dimension. • There is evidence of recent (<3 months) presumed disease progression [blood vessel growth, as indicated by fluorescein angiography, optical coherence tomography (OCT), or recent visual acuity changes].			

New Exception Status Products Continued…

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Aflivu	40mg/mL Pre-filled Syringe	02554178	E (SF)	APX
(aflibercept)	40mg/mL Vial	02554194	E (SF)	APX
Yesafili	40mg/mL Pre-filled Syringe	02558238	E (SF)	BIL
(aflibercept)	40mg/mL Vial	02535858	E (SF)	BIL

Criteria

- There is active disease activity and no permanent structural damage to the central fovea (as defined in the Royal College of Ophthalmologists guidelines).

Renewal Criteria:

- Patient must meet all of the following criteria:
  - Evidence of continued disease activity.
  - Maintaining adequate response to therapy.
  - Absolute BCVA maintained above 6/120.
  - Reductions in BCVA of < 6 lines compared to either baseline and/or best recorded level since baseline.

Claim Notes:

- Must be prescribed and administered by a retina specialist or an ophthalmologist with experience in administering intravitreal injections.
- Will not be insured in combination with other anti-VEGF drugs for ophthalmic use.
- Approvals will be for a maximum of 1 vial per eye every 30 days.
- Approval period: 1 year. Confirmation of continued response is required.

Diabetic Macular Edema

For the treatment of patients with diabetic macular edema (DME) for who meet the following criteria:

- Clinically significant center-involving macular edema.
- Best Corrected Visual Acuity (BCVA) is greater than 6/120.

Renewal Criteria:

- Patient must meet all of the following criteria.
  - Evidence of continued disease activity.
  - Maintaining adequate response to therapy.
  - Absolute BCVA maintained above 6/120.
  - Reductions in BCVA of < 6 lines compared to either baseline and/or best recorded level since baseline.

Claim Notes:

- Must be prescribed and administered by a retina specialist or an ophthalmologist with experience in administering intravitreal injections.

New Exception Status Products Continued…

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Aflivu	40mg/mL Pre-filled Syringe	02554178	E (SF)	APX
(aflibercept)	40mg/mL Vial	02554194	E (SF)	APX
Yesafili	40mg/mL Pre-filled Syringe	02558238	E (SF)	BIL
(aflibercept)	40mg/mL Vial	02535858	E (SF)	BIL

Criteria

- Will not be insured in combination with other anti-VEGF drugs for ophthalmic use.
- Approvals will be for a maximum of 1 vial per eye every 30 days.
- Approval period: 1 year. Confirmation of continued response is required.

Retinal Vein Occlusion

For the treatment of patients with clinically significant center-involving macular edema secondary to non-ischemic branch retinal vein occlusion (BRVO), or central retinal vein occlusion (CRVO) who meet the following criteria:

- Best Corrected Visual Acuity (BCVA) is greater than 6/120.

Renewal Criteria:

- Patient must meet all of the following criteria:
  - Evidence of continued disease activity.
  - Maintaining adequate response to therapy.
  - Absolute BCVA maintained above 6/120.
  - Reductions in BCVA of <6 lines compared to either baseline and/or best recorded level since baseline.

Claim Notes:

- Must be prescribed and administered by a retina specialist or an ophthalmologist with experience in administering intravitreal injections.
- Will not be insured in combination with other anti-VEGF drugs for ophthalmic use.
- Approvals will be for a maximum of 1 vial per eye every 30 days.
- Approval period: 1 year. Confirmation of continued response is required.

New Exception Status Products Continued…

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Evkeeza (evinacumab)	345mg/2.3mL Vial	02541769	E (SF)	UGX

Criteria	**Initiation Criteria:**
	For the treatment of homozygous familial hypercholesterolemia (HoFH) in adult and pediatric patients 5 years of age and older with a clinically or genetically confirmed diagnosis if the following criteria are met:
	• Clinical criteria:
	  ○ Untreated TC > 12.93 mmol/L and TGs < 3.39 mmol/L, AND
	  ○ Both parents with documented TC > 6.47 mmol/L, indicative of HeFH, or patient with cutaneous or tendinous xanthoma before the age of 10 years
	• Genetic criteria:
	  ○ Documented functional mutation or mutations in both LDLR alleles, OR
	  ○ Documented homozygous or compound heterozygous mutations in Apo B or PCSK9, or LDLRAP1, or at least 2 such variants at different loci
	• Elevated LDL-C despite an adequate trial of other accessible lipid-lowering therapies; "elevated LDL-C" is defined as LDL-C greater than 1.8 mmol/L at baseline for adult patients and greater than 3.4 mmol/L for children.
	Initial and Subsequent Renewals:
	The prescriber must provide proof of beneficial clinical effect when requesting continuation of reimbursement, defined as reduction in LDL-C from baseline that is considered clinically beneficial by the treating prescriber.
	Claim Notes:
	• Initial approval: 24 weeks
	• Renewal approval: 1 year
	• Approvals will be for a maximum of 15 mg/kg every 4 weeks
	• The prescriber must provide the baseline LDL-C when the initial request for reimbursement occurs after all other treatment options of lipid-lowering therapies have been exhausted.
	• Evinacumab must be prescribed by specialists with qualifications and experience in the diagnosis and management of HoFH (e.g., [pediatric] endocrinologists, cardiologists, lipidologists).			

New Exception Status Products Continued…

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Leqvio (inclisiran)	284mg/1.5 mL Pre-filled Syringe	02518376	E (SF)	NVR

Criteria

For the treatment of heterozygous familial hypercholesterolemia (HeFH) in adult patients who require additional lowering of low-density lipoprotein cholesterol (LDL-C) if the following criteria are met:

- Definite or probable diagnosis of HeFH using the Simon Broome or Dutch Lipid Network criteria or genetic testing; and
- Patient is unable to reach LDL-C target (less than 2.0 mmol/L or at least a 50% reduction in LDL-C from untreated baseline) despite confirmed adherence to at least 3 months of continuous treatment with:
    - high-dose statin (e.g., atorvastatin 80 mg, rosuvastatin 40 mg) in combination with ezetimibe; or
    - ezetimibe alone if high dose statin is not possible due to rhabdomyolysis, contraindication or intolerance.

Initial Renewal Criteria:

- A reduction in LDL-C of at least 40% from baseline or has reached a target LDL-C less than 2.0 mmol/L.

Subsequent Renewal Criteria:

- The patient continues to maintain a reduction in LDL- C of at least 40% from baseline or has reached a target LDL-C less than 2.0 mmol/L.

Clinical Notes:

- LDL-C levels must be provided.
- Intolerance to high dose statin will be considered if patient has developed documented, myopathy or abnormal biomarkers (i.e. creatinine kinase greater than 5 times the upper limit of normal) after trial of at least two statins and
    - for each statin, dose reduction was attempted rather than statin discontinuation, and intolerance was reversible upon statin discontinuation, but reoccurred with statin re-challenge where clinically appropriate; and
    - at least one statin was initiated at the lowest daily starting dose; and
    - other known causes of intolerance or abnormal biomarkers have been ruled out.
- For patients who cannot take a statin due to an intolerance or contraindication, details must be provided (i.e. confirmed rhabdomyolysis, active liver disease, unexplained persistent elevations of serum transaminases exceeding three times the upper limit of normal).
- For patients who cannot take ezetimibe due to an intolerance or contraindication, details must be provided.

Claim Notes:

- Initial approval: 6 months

New Exception Status Products Continued…

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Leqvio (inclisiran)	284mg/1.5 mL Pre-filled Syringe	02518376	E (SF)	NVR
Criteria	• Renewal approval: 1 year • Maximum dose approved: 284 mg initially, at 3 months, then every 6 months thereafter • Inclisiran and PCSK9 inhibitors will not be insured in combination.			

Criteria Update

The following new indications have been added to existing criteria effective **October 1, 2025**.

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Ultomiris (ravulizumab)	300mg/30mL Vial 300mg/3mL Vial 1,100mg/11mL Vial	02491559 02533448 02533456	E (SF) E (SF) E (SF)	ALX ALX ALX
Criteria	**Neuromyelitis Optica Spectrum Disorder (NMOSD)** **Initiation Criteria:** For the treatment of adult patients with neuromyelitis optica spectrum disorder (NMOSD) who are anti-aquaporin-4 immunoglobulin G (AQP4-IgG) seropositive who meet all of the following criteria: • The patient must have had at least 1 attack or relapse of NMOSD in the previous 12 months. • Patients must have an EDSS score of 7 points or less. **Renewal Criteria:** • The physician should measure and provide EDSS scores every 12 months after the initial authorization to determine if the continuation of ravulizumab reimbursement should occur. **Discontinuation Criteria:** • Reimbursement of ravulizumab treatment will be discontinued if the patient's EDSS score is greater than 8 points. **Clinical Notes:** • Ravulizumab should not be initiated during an NMOSD relapse episode.			

Criteria Update Continued…

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Ultomiris (ravulizumab)	300mg/30mL Vial	02491559	E (SF)	ALX
	300mg/3mL Vial	02533448	E (SF)	ALX
	1,100mg/11mL Vial	02533456	E (SF)	ALX

Criteria

Claim Notes:

- Approvals will be for a maximum of:

Body Weight Range (kg)	Loading Dose (mg)	Maintenance Dose (mg)	Dosing Interval
≥ 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.
- Ravulizumab will not be reimbursed when used in combination with rituximab, satralizumab, eculizumab, or inebilizumab.
- The prescribing of ravulizumab for the treatment of NMOSD should be restricted to neurologists with expertise in treating NMOSD.
- Initial approval period: 12 months
- Renewal approval period: 12 months

Generalized Myasthenia Gravis (gMG)

Initiation Criteria:

For the treatment of adult patients with generalized myasthenia gravis (gMG) who have all of the following:

- Positive serologic test for anti-AChR antibodies
- An MG-ADL score at baseline of ≥ 6
- MGFA class II to IV disease
- MG symptoms persist despite an adequate trial and stable dose of the below conventional therapies in the previous 12 months:
    - Acetylcholinesterase inhibitors (pyridostigmine) AND
    - Corticosteroids (prednisone) AND/OR nonsteroidal immunosuppressants (azathioprine, cyclosporine, mycophenolate mofetil, methotrexate or tacrolimus)
- Vaccination against meningococcal infections.

Criteria Update Continued…

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Ultomiris (ravulizumab)	300mg/30mL Vial	02491559	E (SF)	ALX
	300mg/3mL Vial	02533448	E (SF)	ALX
	1,100mg/11mL Vial	02533456	E (SF)	ALX

Criteria

Exclusion Criteria:

- Ravulizumab should not be initiated:
  - during a gMG exacerbation or crisis OR
  - within 12 months of thymectomy.

Renewal Criteria:

- Reimbursement of ravulizumab treatment should be continued if, after the initial 6 months of treatment, there is a documented MG-ADL score improvement of 2 points or more.
- Reassessment for renewal should occur every 6 months.

Subsequent Renewal Criteria:

- The physician must provide proof that the initial MG-ADL score response achieved after the first 6 months of therapy with ravulizumab has been maintained.

Claim Notes:

- Approvals will be for a maximum of:

Body Weight Range (kg)	Loading Dose (mg)	Maintenance Dose (mg)	Dosing Interval
≥ 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.
- MG-ADL score must be measured and provided by the physician at baseline.
- Ravulizumab should not be used concomitantly with rituximab, efgartigimod alfa, and/or complement inhibitors such as eculizumab.
- Ravulizumab should be prescribed by or in consultation with a neurologist with expertise in managing patients with gMG.
- Initial approval period: 6 months
- Renewal approval period: 6 months

Legend

BENEFIT STATUS	MANUFACTURER CODES
S - Seniors' Pharmacare	ALX - Alexion Pharma Canada Corp
F - Community Services Pharmacare	APX - Apotex Inc.
- Family Pharmacare	BIL - Biocon Biologics Canada Inc
C - Drug Assistance for Cancer Patients	NVR - Novartis Pharmaceuticals Canada Inc
D - Diabetes Assistance Program	UGX - Ultragenyx
E - Exception status applies	
G - Sensor-based Glucose Monitoring Program	