AUGUST 2025 • VOLUME 25-11
PHARMACY EDITION

NOVA SCOTIA

PharmacareNEWS

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Nova Scotia Formulary Updates

Criteria and Benefit Status Updates for Chronic Obstructive Pulmonary Disease (COPD) and Asthma Inhalers

An Atlantic Common Drug Review (ACDR) of inhaler therapies for COPD has been completed. This review included:

- A comprehensive assessment of clinical evidence (meta-analyses, RCTs etc.).
- Consideration of the 2023 Canadian Thoracic Society Guideline COPD Pharmacotherapy in Patients with Stable COPD recommendations.
- Consultation with respiratory specialists in Atlantic Canada.

Following this review, the benefit status and criteria for coverage for inhalers used in COPD and asthma will be updated, effective September 1, 2025, as outlined below.

Key Changes to COPD Criteria:

- LAMA inhalers will move **to full benefit status** and no longer require exception status approval.
- LABA inhalers will be considered for patients who have failed or are intolerant to a LAMA inhaler.
- LABA/ICS inhalers will continue to be funded only as a component of triple therapy (LABA/ICS + LAMA) when criteria for triple therapy is met for patients who cannot use fixed dose triple therapy (Trelegy or Breztri).
- LABA/ICS inhalers will continue to be a benefit for patients with a diagnosis of overlapping asthma and COPD.
- Updated criteria for LAMA/LABA and LAMA/LABA/ICS inhalers are outlined below and will enable quicker access to therapy for patients with moderate to severe COPD.
- A new COPD exception status drug form has been created to reflect these changes and streamline requests for therapy.

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Criteria and Benefit Status Updates for Chronic Obstructive Pulmonary Disease (COPD) and Asthma Inhalers Continued…

Key Changes to Asthma Criteria:

- LABA inhalers will no longer be listed as benefits for the treatment of asthma as they are contraindicated for use as single entity agents.
- A new asthma exception status drug form has been created to account for these changes and to streamline requests for therapy.

LAMA Inhalers

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Spiriva Respimat	2.5mcg Inh	02435381	SF	BOE
Spiriva and Generic Brands	18mcg Cap for Inh	Various	SF	VAR
Tudorza Genuair	400mcg Pwr for Inh	02409720	SF	CPC
Seebri	50mcg Cap for Inh	02394936	SF	NVR
Incruse Ellipta	62.5mcg Pwr for Inh	02423596	SF	GSK

LABA Inhalers

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Serevent Diskus (salmeterol)	50mcg	02231129	E (SF)	GSK
Criteria	For the treatment of chronic obstructive pulmonary disease (COPD), as defined by spirometry, in patients who: • experience inadequate control while being treated with a long-acting muscarinic antagonist; OR • are intolerant to a long-acting muscarinic antagonist. ** **[Criteria Code 16]** has been added for use effective June 3, 2024. Criteria code 16 is for inhalers prescribed by a respirologist, clinical immunologist, allergist, internist, medical oncologist or thoracic surgeons. **Clinical Note:** • COPD is defined by spirometry as a post-bronchodilator FEV1/FVC ratio less than 0.7. Spirometry reports from any point in time will be accepted. If spirometry cannot be obtained, reasons must be clearly explained and other evidence of COPD severity provided (i.e. mMRC score and/or CAT score).			

Criteria and Benefit Status Updates for Chronic Obstructive Pulmonary Disease (COPD) and Asthma Inhalers Continued…

LAMA/LABA Inhalers

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Anoro Ellipta **(vilanterol and umeclidinium bromide)**	62.5/25mcg Pwr for Inh	02418401	E (SF)	GSK
Duaklir Genuair **(formoterol and aclidinium bromide)**	12/400mcg Pwr for Inh	02439530	E (SF)	CPC
Inspiolto Respimat **(olodaterol and tiotropium bromide)**	2.5/2.5mcg Inh	02441888	E (SF)	BOE
Ultibro Breezehaler **(indacaterol and glycopyrronium bromide)**	110/50mcg Cap for Inh	02418282	E (SF)	NVR
Criteria	For the treatment of chronic obstructive pulmonary disease (COPD), as defined by spirometry, in patients who: • have moderate to severe COPD (i.e. CAT score ≥ 10 or mMRC score ≥ 2); OR • have experienced an exacerbation in the previous year while on monotherapy i.e. long-acting beta-2 agonist (LABA) OR long-acting muscarinic antagonist (LAMA) ** **[Criteria Code 16]** has been added for use effective June 3, 2024. Criteria code 16 is for inhalers prescribed by a respirologist, clinical immunologist, allergist, internist, medical oncologist or thoracic surgeons. **Clinical Notes:** • COPD is defined by spirometry as a post-bronchodilator FEV1/FVC ratio less than 0.7. Spirometry reports from any point in time will be accepted. If spirometry cannot be obtained, reasons must be clearly explained and other evidence of COPD severity provided (i.e. mMRC score and/or CAT score). • LAMA/LABA combinations are not intended to be used with an inhaled corticosteroid (ICS) unless criteria for triple inhaled therapy (LAMA/LABA/ICS) is met and the patient is unable to use fixed dose triple therapy options (Trelegy 100-62.5-25 mcg or Breztri 160-7.2-5 mcg).			

Criteria and Benefit Status Updates for Chronic Obstructive Pulmonary Disease (COPD) and Asthma Inhalers Continued...

LABA/ICS Inhalers

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Advair Diskus and Generic Brands (salmeterol and fluticasone)	50/100mcg	Various	E (SF)	VAR
Advair Diskus and Generic Brands (salmeterol and fluticasone)	50/250mcg	Various	E (SF)	VAR
Advair Diskus and Generic Brands (salmeterol and fluticasone)	50/500mcg	Various	E (SF)	VAR
Advair HFA (salmeterol and fluticasone)	25/125mcg Inh	02245126	E (SF)	GSK
Advair HFA (salmeterol and fluticasone)	25/250mcg Inh	02245127	E (SF)	GSK
Atectura Breezhaler (indacaterol and mometasone)	150/80mcg Cap	02498685	E (SF)	VAL
Atectura Breezhaler (indacaterol and mometasone)	150/160mcg Cap	02498707	E (SF)	VAL
Atectura Breezhaler (indacaterol and mometasone)	150/320mcg Cap	02498693	E (SF)	VAL
Breo Ellipta (vilanterol and fluticasone furoate)	100/25mcg Pwr for Inh	02408872	E (SF)	GSK
Breo Ellipta (vilanterol and fluticasone furoate)	200/25mcg Pwr for Inh	02444186	E (SF)	GSK
Symbicort Turbuhaler (formoterol and budesonide)	100/6mcg	02245385	E (SF)	AZE

Criteria and Benefit Status Updates for Chronic Obstructive Pulmonary Disease (COPD) and Asthma Inhalers Continued…

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Symbicort Turbuhaler (formoterol and budesonide)	200/6mcg	02245386	E (SF)	AZE
Zenhale (formoterol and mometasone)	5/100mcg Inh	02361752	E (SF)	ORG
Zenhale (formoterol and mometasone)	5/200mcg Inh	02361760	E (SF)	ORG

Criteria

Asthma

For the treatment of asthma in patients who:

- are compliant with optimal doses of inhaled corticosteroids; AND
- remain poorly controlled.

** **[Criteria Code 16]** has been added for use effective June 3, 2024. Criteria code 16 is for inhalers prescribed by a respirologist, clinical immunologist, allergist, internist, medical oncologist or thoracic surgeons.

Clinical Notes:

- Poorly controlled asthma is defined by the presence of persistent symptoms (such as frequent daytime symptoms, nighttime awakenings, activity limitations, increased use of short-acting beta2-agonists, and/or frequent exacerbations) indicating the need for additional symptom management.

Products and Strengths Approved:

Atectura	• 150mcg/80mcg, 150mcg/160mcg and 150mcg/320mcg Capsule for Inhalation
Advair and generic brands	• 50/100mcg, 50/250mcg and 50/500mcg Diskus • HFA 25/125 mcg/dose • HFA 25/250 mcg/dose Inhaler
Breo Ellipta	• 100mcg/25mcg and 200mcg/25mcg dry powder for inhalation
Symbicort	• 100/6mcg Turbuhaler • 200/6mcg Turbuhaler
Zenhale	• 5/100mcg and 5/200mcg

Criteria and Benefit Status Updates for Chronic Obstructive Pulmonary Disease (COPD) and Asthma Inhalers Continued…

Criteria

Overlapping Asthma and Chronic Obstructive Pulmonary Disease

For the treatment of patients with asthma and chronic obstructive pulmonary disease (ACO) overlap, based on patient history and lung function studies indicating an ACO diagnosis.

- Please provide details to support the ACO diagnosis (patient symptoms, risk factors, spirometry etc.).

**** [Criteria Code 16]** has been added for use effective June 3, 2024. Criteria code 16 is for inhalers prescribed by a respirologist, clinical immunologist, allergist, internist, medical oncologist or thoracic surgeons.

Products and Strengths Approved:

Advair and generic brands	• 50/100mcg Diskus • 50/250mcg Diskus • 50/500mcg Diskus
Breo Ellipta	• 100mcg/25mcg dry powder for inhalation
Symbicort	• 100/6mcg Turbuhaler • 200/6mcg Turbuhaler

Chronic Obstructive Pulmonary Disease

For the treatment of chronic obstructive pulmonary disease (COPD), as defined by spirometry, in combination with a long-acting muscarinic antagonist (LAMA), for patients who:

- meet criteria for triple therapy (LAMA/LABA/ICS); AND
- are unable to use fixed dose triple therapy options (Trelegy 100-62.5-25 mcg or Breztri 160-7.2-5 mcg).

**** [Criteria Code 16]** has been added for use effective June 3, 2024. Criteria code 16 is for inhalers prescribed by a respirologist, clinical immunologist, allergist, internist, medical oncologist or thoracic surgeons.

Clinical Note:

- COPD is defined by spirometry as a post-bronchodilator FEV1/FVC ratio less than 0.7. Spirometry reports from any point in time will be accepted. If spirometry cannot be obtained, reasons must be clearly explained and other evidence of COPD severity provided (i.e. mMRC score and/or CAT score).

Products and Strengths Approved:

Advair and generic brands	• 50/100mcg Diskus • 50/250mcg Diskus • 50/500mcg Diskus
Breo Ellipta	• 100mcg/25mcg dry powder for inhalation
Symbicort	• 100/6mcg Turbuhaler • 200/6mcg Turbuhaler

Criteria and Benefit Status Updates for Chronic Obstructive Pulmonary Disease (COPD) and Asthma Inhalers Continued…

LAMA/LABA/ICS Inhalers

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Breztri Aerosphere Inh (formoterol, glycopyrronium bromide and budesonide)	160/7.2/5mcg	02518058	E (SF)	AZE
Trelegy Pwr for Inh (vilanterol, umeclidinium bromide and fluticasone furoate)	100/62.5/25mcg	02474522	E (SF)	GSK
Criteria	For the treatment of chronic obstructive pulmonary disease (COPD), as defined by spirometry, for patients who • have experienced two or more exacerbations of COPD requiring treatment with antibiotics and/or systemic corticosteroids; OR • at least one exacerbation of COPD requiring hospitalization or an emergency department visit; OR • have moderate symptom burden (i.e. CAT score ≥ 10 or mMRC score ≥ 2) despite treatment with dual therapy with a long-acting muscarinic antagonist plus a long-acting beta2-agonist (LAMA/LABA) or a long-acting beta2-agonist plus an inhaled corticosteroid (LABA/ICS). ** **[Criteria Code 16]** has been added for use effective June 3, 2024. Criteria code 16 is for inhalers prescribed by a respirologist, clinical immunologist, allergist, internist, medical oncologist or thoracic surgeons. **Clinical Note:** • COPD is defined by spirometry as a post-bronchodilator FEV1/FVC ratio less than 0.7. Spirometry reports from any point in time will be accepted. If spirometry cannot be obtained, reasons must be clearly explained and other evidence of COPD severity provided (i.e. mMRC score and/or CAT score).			

New Exception Status Benefits

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

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Apretude	30mg Tab	02547465	E (SF)	VIV
(cabotegravir)	600mg/3mL Vial	02547473	E (SF)	VIV
Criteria	• For individuals aged 12 years and older, weighing at least 35 kg, who are considered at risk of acquiring HIV-1 infection as defined by clinical guidelines, for use as pre-exposure prophylaxis (PrEP) to reduce the risk of acquiring HIV-1 infection. **Clinical Notes:** • PrEP should be part of a combination prevention strategy that includes behavioural interventions such as condoms and risk reduction counseling. • PrEP is not recommended for clinical use where there is no or negligible risk of transmissible HIV-1. **Claim Notes:** • Oral tablets are approved for short term use as lead-in therapy or as bridge therapy in the event of a missed injection.			

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Imcivree	10mg/mL Vial	02537745	E (SF)	RYT
(setmelanotide)				
Criteria	For weight management in adult and pediatric patients 6 years of age and older with obesity due to clinically or genetically confirmed Bardet-Biedl syndrome (BBS). **Initial Renewal Criteria:** The physician must provide proof of beneficial clinical effect, including: • at least a 5% reduction in BMI or total body weight in patients who are at least 12 years of age, OR • a reduction in BMI Z score that is considered clinically beneficial by the treating physician as appropriate for patients who are 6 to 11 years of age. **Subsequent Renewal Criteria:** The physician must provide proof that the initial response achieved after the first 26 weeks of therapy with setmelanotide has been maintained, including: • maintenance of BMI or total body weight, OR • maintenance of BMI Z score. **Clinical Notes:** • Obesity is defined as BMI ≥ 30 for patients aged ≥ 16 years, or weight > 97th percentile for age and sex in patients aged < 16 years. • Clinical diagnosis of BBS is to be based on the Beales criteria.			

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Imcivree (setmelanotide)	10mg/mL Vial	02537745	E (SF)	RYT
Criteria	**Claim Notes:** • Initial approval: 26 weeks • Renewal approval: 1 year • The patient must be under the care of an endocrinologist, pediatric endocrinologist, and/or specialist in weight management or obesity. • Approvals will be for a maximum of 2.0 mg daily for patients aged 6 to 17 years old and up to 3.0 mg daily for patients aged 18 years and older.			

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Livmarli (maralixibat)	9.5mg/mL Oral Sol	02539888	E (SF)	MMP

Criteria	For treatment of patients aged 12 months and older with a diagnosis of Alagille syndrome (ALGS) who have demonstrated the following:
	• Evidence of cholestasis (must include at least 1 of the following):
	  ○ total serum bile acid (sBA) > 3 × ULN for age
	  ○ conjugated bilirubin > 1 mg/dL
	  ○ fat-soluble vitamin deficiency otherwise unexplainable
	  ○ GGT > 3 × ULN for age
	  ○ intractable pruritus explainable only by liver disease
	• Moderate to severe itch defined as an average daily score of 2 or more on the ItchRO or CSS for 2 consecutive weeks.
	• Currently treated with, or have received an adequate trial with, a systemic treatment for pruritus before initiating maralixibat.
	Exclusion Criteria:
	Patients with biliary diversion, previous liver transplant, decompensated cirrhosis, or history or presence of other concomitant liver disease.
	Renewal Criteria:
	• Requests for renewal must provide proof of beneficial clinical effect defined as an improvement in pruritus to minimal or no itch (a score of 1 or less) on the ItchRO or CSS.
	• For patients who begin treatment with severe itch (equivalent to an ItchRO or CSS score of 4), an improvement in pruritus by a score of 1 will be considered for coverage renewal.			

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Livmarli (maralixibat)	9.5mg/mL Oral Sol	02539888	E (SF)	MMP
Criteria	**Discontinuation Criteria:** • Reimbursement of maralixibat will be discontinued if the patient receives liver transplantation or biliary diversion surgery. **Clinical Notes:** An adequate trial for systemic treatment of pruritus is defined as a trial of 1 to 3 months with appropriate dosing of a systemic treatment for pruritus based on usual care. This may include UDCA, rifampicin, sertraline, naltrexone, cholestyramine, or antihistamines. **Claim Notes:** • Initial approval duration: 6 months • Renewal approval duration: 1 year • The patient should be under the care of a hepatologist with experience in managing ALGS. • Approvals will be for a maximum of 28.5 mg (3 mL) daily.			

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Myalepta (metreleptin)	3mg Vial	02544555	E (SF)	MDP
	5.8mg Vial	02544563	E (SF)	MDP
	11.3mg Vial	02544571	E (SF)	MDP

Criteria	For the treatment of patients with either of the following:
	• Confirmed congenital generalized lipodystrophy (GL) (Berardinelli-Seip syndrome) or acquired GL (Lawrence syndrome) in adults and children aged 2 years and older with at least 1 metabolic abnormality (diabetes mellitus, insulin resistance, or hypertriglyceridemia).
	• Confirmed familial partial lipodystrophy (PL) or acquired PL (Barraquer-Simons syndrome) in adults and children aged 12 years and older with persistent significant metabolic abnormalities (as defined by baseline hemoglobin A1C ≥ 6.5% and/or fasting TGs ≥ 5.65 mmol/L), for whom standard treatments have failed to achieve adequate metabolic control after at least 12 months since initiating standard treatments.
	• Genetic testing must be conducted and:
	  ○ If genetic testing is positive, then diagnosis is confirmed and treatment with metreleptin can be initiated.
	  ○ If after conducting genetic testing lipodystrophy is not confirmed, treatment can be initiated in patients with confirmed clinical diagnosis based on a comprehensive clinician assessment and if fasting leptin			

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Myalepta	3mg Vial	02544555	E (SF)	MDP
(metreleptin)	5.8mg Vial	02544563	E (SF)	MDP
	11.3mg Vial	02544571	E (SF)	MDP
Criteria	levels are < 12.0 ng/mL in females and < 8.0 ng/mL in males older than 5 years of age or < 6 ng/mL in children aged 6 months to 5 years. **Exclusion Criteria:** Patients should not be pregnant or lactating or have HIV-associated LD. **Initial Renewal Criteria:** The prescriber must provide proof of beneficial metabolic effect defined as 1 or both of the following: • Actual hemoglobin A1C reduction of at least 0.5% from baseline. • Percent fasting TG reduction of at least 15% from baseline. **Subsequent Renewal Criteria:** The prescriber must provide proof of maintenance of reduction in hemoglobin A1C and/or fasting TG from baseline every 12 months for subsequent authorizations. **Clinical Notes:** • A1C and/or fasting TG levels must be provided. **Claim Notes:** • Initial and renewal approval duration: 12 months • Prescribing should be limited to endocrinologists or pediatric endocrinologists with expertise in treating lipodystrophy. • Approvals will be for a maximum dose of 0.13 mg/kg daily for patients ≤40kg and 10mg daily for patients >40 kg.			

New Exception Status Benefits Continued…

Effective **September 1, 2025,** the following anti-vascular endothelial growth factor (VEGF) drugs will be added to the Pharmacare Formulary and can be administered by a community ophthalmologist and dispensed by a community pharmacy.

Please note, existing coverage through current means (i.e., hospital-based or previously designated clinics) will remain an available option.

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Byooviz (ranibizumab)	10mg/mL Inj	02525852	E (SF)	BIG

Criteria	**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]
	• 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:
	• Patients 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) who meet the following criteria:
	• Clinically significant center-involving macular edema
	• Best Corrected Visual Acuity (BCVA) is greater than 6/120			

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Byooviz (ranibizumab)	10mg/mL Inj	02525852	E (SF)	BIG

Criteria	**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.
	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 Benefits Continued…

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Eylea (aflibercept)	2mg/0.05mL Vial	02415992	E (SF)	BAY

Criteria

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]
  - 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) 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

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Eylea (aflibercept)	2mg/0.05mL Vial	02415992	E (SF)	BAY
Criteria	○ 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. **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 Benefits Continued…

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Eylea HD (aflibercept)	8mg/0.07mL Vial	02545004	E (SF)	BAY

Criteria	**Active Wet Age-Related Macular Degeneration**
	For the treatment of adult patients with neovascular (wet) Age-Related Macular Degeneration (nAMD) who meet all of the following criteria:
	• treatment **naive** to anti-VEGF drugs for nAMD
	• 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]
	• 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:
	• Patients must meet all of the following criteria:
	  ○ Able to be maintained on a 12-week or greater interval between injections
	  ○ 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 1 vial per eye every 30 days for the first 3 doses, followed by 1 vial per eye every 12 to 16 weeks.
	• Approval period: 1 year. Confirmation of continued response is required.
	Diabetic Macular Edema
	For the treatment of adult patients with diabetic macular edema who meet all of the following criteria:
	• Clinically significant center-involving macular edema
	• Best Corrected Visual Acuity (BCVA) is greater than 6/120			

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Eylea HD (aflibercept)	8mg/0.07mL Vial	02545004	E (SF)	BAY

Criteria	**Renewal Criteria:**
	• Patients must meet all of the following criteria:
	  ○ Able to be maintained on a 12-week or greater interval between injections.
	  ○ 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 1 vial per eye every 30 days for the first 3 doses, followed by 1 vial per eye every 12 to 16 weeks.
	• Approval period: 1 year. Confirmation of continued response is required.			

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Ranopto (ranibizumab)	10mg/mL Inj	02542250	E (SF)	TEV
Criteria	**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] • There is active disease activity and no permanent structural damage to the central fovea (as defined in the Royal College of Ophthalmologists guidelines)			

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Ranopto (ranibizumab)	10mg/mL Inj	02542250	E (SF)	TEV

Criteria	**Renewal Criteria:**
	• Patients 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) 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.
	• 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 Benefits Continued…

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Ranopto (ranibizumab)	10mg/mL Inj	02542250	E (SF)	TEV
Criteria	**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: o Evidence of continued disease activity. o Maintaining adequate response to therapy. o Absolute BCVA maintained above 6/120. o 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.			

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Vabysmo (faricimab)	6mg/0.05mL Vial	02527618	E (SF)	HLR
	6mg/0.05mL Prefilled Syringe	02554003	E (SF)	HLR
Criteria	**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 Benefits Continued…

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Vabysmo	6mg/0.05mL Vial	02527618	E (SF)	HLR
(faricimab)	6mg/0.05mL Prefilled Syringe	02554003	E (SF)	HLR
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:** • Patients must meet all of the following criteria: o Evidence of continued disease activity o Maintaining adequate response to therapy o Absolute BCVA maintained above 6/120 o 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. • Approvals will be for a maximum of 1 vial per eye every 4 weeks for 16 weeks, followed by 1 vial per eye every 8 weeks thereafter. • Approval period: 1 year. Confirmation of continued response is required. **Diabetic Macular Edema** For the treatment of patients with diabetic macular edema (DME) who meet the following criteria: • Clinically significant center-involving macular edema • Best Corrected Visual Acuity (BCVA) is greater than 6/120 **Renewal Criteria:** • Patients must meet all of the following criteria: o Evidence of continued disease activity o Maintaining adequate response to therapy o Absolute BCVA maintained above 6/120 o 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. Approvals will be for a maximum of 1 vial per eye every 4 weeks. • Approval period: 1 year. Confirmation of continued response is required.			

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Vabysmo	6mg/0.05mL Vial	02527618	E (SF)	HLR
(faricimab)	6mg/0.05mL Prefilled Syringe	02554003	E (SF)	HLR
Criteria	**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:** • Patients must meet all of the following criteria: o Evidence of continued disease activity o Maintaining adequate response to therapy o Absolute BCVA maintained above 6/120 o 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. • Approvals will be for a maximum of 1 vial per eye every 4 weeks. • Approval period: 1 year. Confirmation of continued response is required.			

Criteria Updates

The following new indication has been added to existing criteria effective **September 1, 2025**.

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Xtandi	40mg Cap	02407329	E (SFC)	ASL
(enzalutamide)				
Criteria	**Non-Metastatic Castration-Sensitive Prostate Cancer** For the treatment of patients with non-metastatic castration-sensitive prostate cancer (nmCSPC) with biochemical recurrence at high risk for metastasis after radical prostatectomy or radiation, with or without androgen deprivation therapy (ADT). **Clinical Notes:** • Patients should meet all of the following: o PSA doubling time of ≤9 months o PSA level ≥1 mcg/mL if prior radical prostatectomy (with or without radiation) or ≥2 mcg/mL above nadir in prior radiation			

Criteria Updates Continued…

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Xtandi (enzalutamide)	40mg Cap	02407329	E (SFC)	ASL
Criteria	○ Testosterone ≥5.2 nmol/L (150 mg/dl) ○ No evidence of metastases on conventional imaging. ○ Not a candidate for salvage radiation • Patients should have a good performance status. • Treatment should continue until progression or unacceptable toxicity. Enzalutamide should be held after 36 weeks if PSA is suppressed to ≤0.2mcg/mL and may be restarted based on PSA level. For patients with no prior radical prostatectomy, the PSA level threshold to restart treatment is ≥5 mcg/mL. For patients with prior radical prostatectomy, the PSA level threshold to restart treatment is ≥2 mcg/mL.			

The following criteria has been updated and will replace existing criteria effective **September 1, 2025**

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Emtricitabine and Tenofovir Disoproxil	200mg/300mg Tab	02452006	E (SF)	APX
	200mg/300mg Tab	02490684	E (SF)	ARO
	200mg/300mg Tab	02487012	E (SF)	JPC
	200mg/300mg Tab	02521547	E (SF)	MNT
	200mg/300mg Tab	02443902	E (SF)	MYL
	200mg/300mg Tab	02461110	E (SF)	PMS
	200mg/300mg Tab	02399059	E (SF)	TEV
	200mg/300mg Tab	02274906	E (SF)	GIL
Criteria	• For individuals who are considered at risk of acquiring HIV-1 infection as defined by clinical guidelines, for use as pre-exposure prophylaxis (PrEP) to reduce the risk of acquiring HIV-1 infection. **Clinical Notes:** • PrEP should be part of a combination prevention strategy that includes behavioural interventions such as condoms and risk reduction counseling. • PrEP is not recommended for clinical use where there is no or negligible risk of transmissible HIV-1.			

Change in Benefit Status

Effective **September 1, 2025,** the following products will move to full benefit and no longer require exception status approval.

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Betahistine	16mg Tab	Various	SF	VAR
Betahistine	24mg Tab	Various	SF	VAR

New Benefits

Effective **September 1, 2025,** 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 applies.

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Cyanocobalamin	1000mcg/mL Inj	02465507	E (SFC)	HIK
Vemlidy	25mg Tab	02464241	SF	GIL

Temporary Benefit: Australian-Authorized Anagrelide Capsules

Septa Pharmaceuticals Inc. has received approval from Health Canada for the import and release of Australian-authorized Anagrelide 0.5mg capsules to help mitigate a critical shortage in Canada.

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

For more information, you can contact Septa Pharmaceuticals Inc. at (905) 564-5665 or via email at orders@septapharma.com.

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Anagrelide	0.5mg Cap	09858363	E (SF)	SPT

Temporary Benefit: Ireland-Labelled Pegasys Prefilled Syringe

Accelera Pharma Canada Inc. has received approval from Health Canada for the import and release of Ireland-labelled Pegasys 180mcg/0.5mL PFS to help mitigate a critical shortage in Canada.

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

For more information you can contact Accelera Pharma Canada Inc. at 1-855-611-2724 or via email at orders@apcipharma.com.

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Pegasys	180mcg/0.5mL Prefilled Syringe	09858366	SF	ARN

Temporary Benefit: US-Authorized Disopyramide Capsules

Dr. Reddy's Laboratories Canada Inc. has received approval from Health Canada for the import and release of US-authorized Disopyramide 100mg capsules to help mitigate a critical shortage in Canada.

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

For more information you can contact Dr. Reddy's Laboratories Canada Inc. at 1-855-550-5528 or via email at drlca-customerservice@drreddys.com.

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Disopyramide	100mg Cap	09858365	SF	RCH