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NOVA SCOTIA

PharmacareNEWS

inside

Nova Scotia Formulary Updates

New Exception Status Products

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

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Bylvay (odevixibat)	200mcg Cap	02542641	E (SF)	MDP
	400mcg Cap	02542676	E (SF)	MDP
	600mcg Cap	02542684	E (SF)	MDP
	1200mcg Cap	02542692	E (SF)	MDP
Criteria	For the treatment of pruritus in patients aged 6 months or older with progressive familial intrahepatic cholestasis (PFIC) who meet all of the following criteria: • Diagnosis of PFIC1 or PFIC2 • Severe pruritus with an ObsRO scratching score of ≥ 2, while receiving usual care with at least 1 therapy used for symptomatic relief of pruritus. • sBA levels ≥ 100 µmol/L. **Initial Renewal Criteria:** • The prescriber must document response in pruritus, defined as an ObsRO scratching score of ≤ 1 or at least a 1-point decrease from baseline. • If no response is observed after 3 months following the initial authorization, renewal of odevixibat will be for a 3-month trial of up to 120 mcg/kg per day dose (maximum of 7,200 mcg per day) and the patient will be required to then demonstrate response in pruritus, defined as an ObsRO scratching score of ≤ 1 or at least a 1-point decrease from baseline. **Subsequent Renewal Criteria:** • Subsequent renewals require documentation of continued maintenance of pruritus response.			

New Exception Status Products Continued…

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Bylvay	200mcg Cap	02542641	E (SF)	MDP
(odevixibat)	400mcg Cap	02542676	E (SF)	MDP
	600mcg Cap	02542684	E (SF)	MDP
	1200mcg Cap	02542692	E (SF)	MDP
Criteria	**Clinical Notes:** • Genetic testing must be conducted to confirm patients' PFIC subtype. • Usual care treatment of pruritus may include UDCA, rifampicin, cholestyramine, or antihistamines. • Odevixibat should be discontinued upon liver transplant. • Odevixibat must be prescribed by an expert in managing PFIC. **Claim Notes:** • Initial approval: 3 months • Renewal approval: 6 months **Maximum dosage approved** • The maximum duration of initial authorization is 3 months of treatment with a dose of 40 mcg/kg per day. • Odevixibat will be renewed at the 40 mcg/kg per day dose only if patients experience a documented response in pruritis after 3 months of treatment.			

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Fruzaqla	1mg Cap	02551454	E (SFC)	TAK
(fruquintinib)	5mg Cap	02551462	E (SFC)	TAK
Criteria	As monotherapy for the treatment of adult patients with metastatic colorectal adenocarcinoma who: • Have been previously treated with, or are not candidates for, available therapies including fluoropyrimidine, oxaliplatin, and irinotecan-based chemotherapy, anti-VEGF agents, anti-EGFR agents (if RAS wild-type), and trifluridine-tipiracil. • For MSI-H or dMMR tumors: have been treated with an immune checkpoint inhibitor, if eligible. • For BRAF-mutant positive tumors: have been treated with a BRAF inhibitor, if eligible. **Clinical Notes:** • Patients should have a good performance status. • Treatment should continue until disease progression or unacceptable toxicity. • No active CNS metastases (eligible if treated/stable). • Patients with small bowel or appendiceal adenocarcinoma are eligible.			

New Exception Status Products Continued…

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Fruzaqla (fruquintinib)	1mg Cap 5mg Cap	02551454 02551462	E (SFC) E (SFC)	TAK TAK
Criteria	• Patients who have received adjuvant/neoadjuvant chemotherapy and had recurrence during or within six months of completion can count the adjuvant/neoadjuvant therapy as one of the required minimum three prior regimens.			

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Rystiggo (rozanolixizumab)	140mg/mL Single Dose Vial	02556081	E (SF)	UCB

Criteria

Initiation Criteria:

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

- Positive serologic test for:
  - AChR antibodies; OR
  - MuSK antibodies
- An MG-ADL score at baseline of ≥ 3, with at least 3 points from nonocular symptoms
- 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)

Exclusion Criteria:

Rozanolixizumab should not be initiated:

- During a gMG exacerbation or crisis OR
- Within 6 months of thymectomy.

Renewal Criteria:

- Reimbursement of treatment with rozanolixizumab should be continued if, after the initial 6 weeks of treatment, there is documented improvement in MG-ADL score of 2 points or greater.
- Reassessment should occur every 12 months thereafter.

Subsequent Renewal Criteria:

- The physician must provide proof of no worsening of MG-ADL score.

New Exception Status Products Continued…

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Rystiggo (rozanolixizumab)	140mg/mL Single Dose Vial	02556081	E (SF)	UCB

Criteria

Claim Notes:

- MG-ADL score must be measured and provided by the physician at baseline.
- Rozanolixizumab should be prescribed by or in consultation with a neurologist with expertise in managing patients with gMG.
- Rozanolixizumab should not be used concomitantly with rituximab, efgartigimod alfa, and/or complement inhibitors such as eculizumab.
- Approvals will be for a maximum of:

Body Weight	≥35 to <50 kg	≥50 to <70 kg	≥70 to <100 kg	≥100 kg
Dosage	280 mg	420 mg	560 mg	840 mg

- Therapy is administered once weekly for 6 weeks with subsequent treatment cycles based on clinical evaluation with a minimum of 4 weeks between treatment cycles.
- Initial Approval: 6 weeks
- Renewal Approval: 12 months

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Tibsovo (ivosidenib)	250mg Tab	02549980	E (SFC)	SEV

Criteria

In combination with azacitadine for the treatment of adult patients with newly diagnosed AML with an IDH1 R132 mutation who are not eligible to receive intensive induction chemotherapy.

Clinical Notes:

- Patients are not eligible to receive intensive induction chemotherapy due to the presence of at least one of the following:
  - Age ≥75 years
  - ECOG performance status ≥2
  - Severe cardiac disorder
  - Severe pulmonary disorder
  - Creatinine clearance <45 mL/minute
  - Bilirubin level >1.5x ULN

New Exception Status Products Continued…

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Tibsovo (ivosidenib)	250mg Tab	02549980	E (SFC)	SEV
Criteria	○ Any other comorbidity judged to be incompatible with intensive induction chemotherapy. • Treatment should continue until disease progression or unacceptable toxicity. • No prior treatment for AML, except treatments to stabilize the disease (ex: hydroxyurea, leukapheresis). • No prior IDH1 inhibitor use. • Patients who have been previously treated with a hypomethylating agent or chemotherapy for the treatment of myelodysplastic syndromes (MDS) are not eligible. • Must be given in combination with azacitadine (ivosidenib monotherapy is not funded). • Patients with high risk MDS are not eligible.			

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Zilbrysq (zilucoplan)	16.6mg/0.416mL Pre-filled Syringe 23mg/0.574mL Pre-filled Syringe 32.4mg/0.81mL Pre-filled Syringe	02549220 02549239 02549247	E (SF) E (SF) E (SF)	UCB UCB UCB
Criteria	**Initiation Criteria:** For the treatment of adult patients with generalized myasthenia gravis (gMG) who have all 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. **Exclusion Criteria:** Zilucoplan should not be initiated: • During a gMG exacerbation or crisis OR • Within 12 months of thymectomy.			

New Exception Status Products Continued…

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Zilbrysq (zilucoplan)	16.6mg/0.416mL Pre-filled Syringe	02549220	E (SF)	UCB
	23mg/0.574mL Pre-filled Syringe	02549239	E (SF)	UCB
	32.4mg/0.81mL Pre-filled Syringe	02549247	E (SF)	UCB
Criteria	**Renewal Criteria:** • Reimbursement of treatment with zilucoplan should be continued if, after the initial 6 months of treatment, there is documented improvement in MG-ADL score of 2 points or greater. • Reassessment should occur every 6 months thereafter. **Subsequent Renewal:** • The physician must provide proof that the initial response achieved after the first 6 months of therapy with zilucoplan for the MG-ADL score has been maintained. **Claim Notes:** • MG-ADL score must be measured and provided by the physician at baseline. • Treatment with zilucoplan should be discontinued in case of serious adverse events related to zilucoplan or secondary infection, such as meningococcal infection. • Zilucoplan should be prescribed by or in consultation with a neurologist with expertise in managing patients with gMG. • Zilucoplan should not be used concomitantly with rituximab, complement inhibitors or efgartigimod alfa. • Approvals will be for a maximum dose of 16.6mg daily for patients <56 kg, 23 mg daily for patients ≥56 kg to <77 kg and 32.4mg daily for patients ≥77 kg. • Initial Approval: 6 months • Renewal Approval: 6 months			

The Nova Scotia Biosimilar Initiative aims to expand the use of lower cost biosimilars on the Pharmacare Programs. On November 1, 2025, a new omalizumab biosimilar drug, Omlyclo, will be listed on the Nova Scotia Formulary.

Effective November 1, 2025, patients currently taking the originator drug product are required to switch to the biosimilar version by April 30, 2026.

For omalizumab-naïve patients whose therapy is initiated after November 1, 2025, the omalizumab biosimilar will be the product approved.

Prescribers can apply for an exemption if a patient can't switch to a biosimilar for clinical reasons. More information on this process can be found on our website: https://novascotia.ca/dhw/pharmacare/information-for-prescribers-about-biosimilars.asp

New Exception Status Products Continued…

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Omlyclo	75mg/0.5mL Pre-filled Syringe	02553805	E (SF)	CLT
(omalizumab)	150mg/1.0mL Pre-filled Syringe	02553813	E (SF)	CLT

Criteria

Allergic Asthma

Initiation Criteria:

For the treatment of moderate to severe asthma in patients 6 years or older who meet all of the following criteria:

- Asthma remains inadequately controlled despite the use of a high-dose inhaled corticosteroid (ICS) and a long-acting inhaled beta2-agonist (LABA).
- Has within the past 12 months required:
    - hospitalization for asthma; OR
    - two or more urgent visits for asthma to a physician or an emergency department; OR
    - two or more courses of high-dose oral corticosteroids.
- The patient has a documented positive skin test or in vitro reactivity to a perennial aeroallergen.

Discontinuation Criteria:

- Baseline asthma control questionnaire score has not improved since the initiation of treatment, OR
- Number of clinically significant asthma exacerbations has increased since the initiation of treatment.

Clinical Notes:

- High-dose inhaled corticosteroids is defined as greater than or equal to 500 mcg of fluticasone propionate or equivalent daily dose.
- For patients 6 to 11 years old, medium dose ICS is defined as between 200 mcg and 400 mcg of fluticasone propionate or equivalent daily dose and high-dose ICS is defined as greater than 400 mcg of fluticasone propionate or equivalent daily dose.
- A baseline and a re-assessment of asthma symptom control using an asthma control questionnaire score must be provided.
- A baseline and a re-assessment of the number of clinically significant asthma exacerbations must be provided.

Claim Notes:

- Should be prescribed by a respirologist, clinical immunologist or allergist. Individual consideration may be given for extenuating circumstances where access to these specialists is not possible.
- Combined use of omalizumab with other biologics used to treat asthma will not be reimbursed.
- Approvals will be for a maximum dose of 375 mg every 2 weeks
- Initial approval duration: 6 months

New Exception Status Products Continued…

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Omlyclo (omalizumab)	75mg/0.5mL Pre-filled Syringe 150mg/1.0mL Pre-filled Syringe	02553805 02553813	E (SF) E (SF)	CLT CLT
Criteria	• Renewal approval duration: Long-term **Chronic Idiopathic Urticaria (CIU)** **Initiation Criteria:** For the treatment of adults and adolescents (12 years of age or older) with moderate to severe chronic idiopathic urticaria (CIU) who remain symptomatic (presence of hives and/or associated itching) despite optimum management with available oral therapies. **Renewal Criteria:** • Continued coverage will be authorized if the patient has achieved: o complete symptom control for less than 12 consecutive weeks; or o partial response to treatment, defined as at least a ≥ 9.5 point reduction in baseline urticaria activity score over 7 days (UAS7); or o complete symptom control on omalizumab and tried stopping therapy but experienced symptom relapse of their urticaria while off treatment **Clinical Notes:** • Treatment cessation could be considered for patients who experience complete symptom control for at least 12 consecutive weeks at the end of a 24 week treatment period. **Claim Notes:** • Prescribed by a specialist (allergist, immunologist, dermatologist, etc.) or other authorized prescriber with knowledge of CIU treatment. • Combined use of omalizumab with other biologics used to treat CIU will not be reimbursed. • Approvals will be for a maximum dose of 300mg every 4 weeks. • Initial Approval: 6 months • Renewal Approval: Long-term			

Criteria Updates

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

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Venclexta (venetoclax)	10mg Tab	02458039	E (SFC)	ABV
	50mg Tab	02458047	E (SFC)	ABV
	100mg Tab	02458055	E (SFC)	ABV
	Starter Kit	02458063	E (SFC)	ABV
Criteria	In combination with obinutuzumab for the treatment of adult patients with previously untreated chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL). **Clinical Notes:** • Patients should require treatment according to the International Workshop on CLL criteria. • Treatment should be given for a total of 12 months (six 28-day cycles in combination with obinutuzumab, followed by six months of monotherapy), or until disease progression or unacceptable toxicity, whichever occurs first. • Retreatment with a venetoclax based regimen is funded if relapse is greater than 12 months from completion of venetoclax in combination with obinutuzumab. • Either ibrutinib, acalabrutinib or zanubrutinib is funded as a subsequent treatment option, provided all other funding criteria are met. • If obinutuzumab is discontinued for toxicity, treatment with venetoclax may continue.			

The following new indication has been added to existing criteria effective **November 1, 2025** and applies to the following new and existing products.

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Steqeyma (ustekinumab)	45mg/0.5mL Single-use Vial	02558270	E (SF)	CLT

Criteria	**Ulcerative Colitis**
	• For the treatment of patients with moderately to severely active ulcerative colitis who have a partial Mayo score > 4, and a rectal bleeding subscore ≥ 2 and are:
	  ○ refractory or intolerant to conventional therapy (i.e. 5-ASA for a minimum of 4 weeks, and prednisone ≥ 40mg daily for two weeks or IV equivalent for one week); OR
	  ○ corticosteroid dependent (i.e. cannot be tapered from corticosteroids without disease recurrence; or have relapsed within three months of stopping corticosteroids; or require two or more courses of corticosteroids within one year.)
	• Renewal requests must include information demonstrating the beneficial effects of the treatment, specifically:
	  ○ a decrease in the partial Mayo score ≥ 2 from baseline, AND			

Criteria Update Continued…

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Steqeyma (ustekinumab)	45mg/0.5mL Single-use Vial	02558270	E (SF)	CLT
Criteria	○ a decrease in the rectal bleeding subscore ≥ 1. **Clinical Notes:** • Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above. • Intolerant is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs. The nature of intolerance(s) must be clearly documented. • Patients with severe disease do not require a trial of 5-ASA. **Claim Notes:** • Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology. • Combined use of more than one biologic DMARD will not be reimbursed. • Initial reimbursement will be for a single intravenous dose of up to 520mg at Week 0 and a subcutaneous dose of 90mg at Week 8 and 16. Subsequent reimbursement for maintenance dosing is 90mg subcutaneously every 8 weeks. • Initial Approval: 6 months. • Renewal Approval: Long term.			

Change in Benefit Status

Effective **November 1, 2025**, the following products will be delisted as benefits under the Pharmacare Programs.

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Anthralin Oint	0.4%	00901113	**Non Insured**	N/A
Anthralin Soft Paste	0.05%	00902063	**Non Insured**	N/A
Anthralin Soft Paste	0.1%	00900907	**Non Insured**	N/A
Anthralin Soft Paste	0.2%	00900915	**Non Insured**	N/A
Anthralin Weak Oint	0.2%	00901105	**Non Insured**	N/A
Levetiracetam Oral Susp*		99099941	**Non Insured**	N/A
LCD Preparations**	(20%)	00358495	**Non Insured**	N/A

* Please note this product is now commercially available.

** LCD (coal tar) preparations PIN 00358494 is still available for use.

Legend

BENEFIT STATUS	MANUFACTURER CODES
S - Seniors' Pharmacare	ABV - AbbVie Corporation
F - Community Services Pharmacare	CLT - Celltrion Healthcare Ltd
- Family Pharmacare	MDP - Medison Pharma Canada Inc.
C - Drug Assistance for Cancer Patients	SEV - Servier Canada Inc.
D - Diabetes Assistance Program	TAK - Takeda Canada Inc.
E - Exception status applies	UCB - UCB Pharma Canada Inc.
G - Sensor-based Glucose Monitoring Program	