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Cystic Fibrosis Therapies Update - Trikafta

The following products are not funded in the Pharmacare Programs; however, they are funded through the Cystic Fibrosis Program with specific criteria, effective immediately.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Trikafta	100mg/50mg/ 75mg & 75mg Granules	02542277	N/A	Not Insured	VTX
Trikafta	80mg/40mg/ 60mg & 59.5mg Granules	02542285	N/A	Not Insured	VTX

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Criteria Update

The following new indication and updated criteria for an existing indication is effective **February 1, 2024**.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Nubeqa (darolutamide)	300mg Tab	02496348	DNP	E (SFC)	BAY

Criteria **Non-Metastatic Castration-Resistant Prostate Cancer (nmCRPC)**

- In combination with androgen deprivation therapy (ADT) for the treatment of patients with non-metastatic castration-resistant prostate cancer (nmCRPC) who have no detectable distant metastases (M0) by either CT, MRI or technetium-99m bone scan and who are at high risk of developing metastases¹.

¹High risk of developing metastases is defined as a prostate-specific antigen (PSA) doubling time of ≤ 10 months during continuous ADT.

Clinical Notes:

- Patients should have a good performance status.
- Treatment should continue until radiographic disease progression or unacceptable toxicity.
- Castration-resistance must be demonstrated during continuous ADT and is defined as 3 PSA rises at least one week apart, with the last PSA greater than 2 ng/mL.
- Castrate levels of testosterone must be maintained.
- Patients with N1 disease, pelvic lymph nodes less than 2cm in short axis located below the aortic bifurcation are eligible for darolutamide.
- Darolutamide will not be funded for patients who experience disease progression on apalutamide or enzalutamide.

Criteria Update Continued...

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Nubeqa (darolutamide)	300mg Tab	02496348	DNP	E (SFC)	BAY
Criteria	<p>Metastatic Castration-Sensitive Prostate Cancer (mCSPC)</p> <ul style="list-style-type: none"> In combination with docetaxel and androgen deprivation therapy (ADT) for the treatment of patients with metastatic castration-sensitive prostate cancer (mCSPC). <p>Clinical Notes:</p> <ul style="list-style-type: none"> Patients should have a good performance status and be eligible for chemotherapy. Treatment should continue until disease progression or unacceptable toxicity. Patients should have had no prior ADT in the metastatic setting, or are within 6 months of initiating ADT in the metastatic setting with no disease progression. Patients will be eligible if they received ADT in the non-metastatic setting as long as at least a one year interval has passed since completion. Darolutamide will not be funded for patients who experience disease progression on enzalutamide or apalutamide. 				

Change in Benefit Status

Effective **February 1, 2024**, the following products will be added as a benefit in the Nova Scotia Formulary. The benefit status within the Pharmacare Programs is indicated.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Alfuzosin	10mg Tab	Various	DNP	SF	VAR

Effective **February 1, 2024**, the following products will be added to the Drug Assistance for Cancer Patients Program.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Cotazym	8000u Cap	00263818	DNP	SFC	ORG
Cotazym ECS	Various	Various	DNP	SFC	ORG
Creon	Various	Various	DNP	SFC	BGP
Cyclomen	Various	Various	DNP	SFC	SAV
Pancrease	Various	Various	DNP	SFC	VVS
Viokace	Various	Various	DNP	SFC	ARN

Diabetic Supplies Benefit List Update

Effective **February 1, 2024**, the following products will no longer be covered under the Nova Scotia Pharmacare Programs.

PRODUCT	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Medi+Sure BG Test Strips (100)	97799403	N/A	Not Insured	MSR
MediSure Empower Test Strips (100)	97799053	N/A	Not Insured	MSR
MediSure Empower Test Strips (50)	97799054	N/A	Not Insured	MSR
Medi+Sure Soft 30G Twist Lancet	97799388	N/A	Not Insured	MSR
Medi+Sure Soft 33G Twist Lancet	97799389	N/A	Not Insured	MSR

Mifegymiso Coverage

As a reminder and as outlined in the Nova Scotia Pharmacy Guide, Mifegymiso is insured as a full benefit for all women in Nova Scotia with a valid health card number. Any other sources of insurance, such as a private plan, must be billed first. Authorized prescribers include nurse practitioners and medical doctors.

Auditors' Corner

Updates to Documentation Requirements for Changes Made to an Existing Prescription

Effective February 1, 2024, pharmacists may make changes to a prescription without authorization from the prescriber under the following conditions:

1. Pharmacists may change the quantity on a prescription for **creams, lotions and eye drops** if in their clinical judgement there is insufficient quantity noted to meet dosing directions. The reason for the change must be documented on the original prescription with a signature and license number for the pharmacist who made the change.

If no quantity is available on a prescription, it is an incomplete prescription and may not be adjusted by a pharmacist. In these instances, the pharmacist may write a prescription or seek a verbal order from the prescriber.

2. Pharmacists may use their clinical judgement to change the quantity on a drug prescription for a product **sold by the manufacturer** in a blister pack, bottle, tube, or device to align with the pack size if the new quantity remains appropriate for patient care. For example, adjusting a quantity of 30 to 28, 60 to 56 and 90 to 84 (e.g. Ondansetron or Alendronate). **NOTE:** *this does not apply to internal blister/compliance packaging for safety or cost reasons.*

These changes will not be subject to the documentation requirements for changes made to an existing prescription.

Reminder: Billing for Pharmacy Services

All pharmacy services completed must be billed on the same day as the service was provided. This will protect the integrity of the patient's medical record.

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Ozempic Billing

Criteria Update

- Ozempic (semaglutide)

New Exception Status Benefit

- Rybelsus (semaglutide)

Nova Scotia Formulary Updates

Ozempic Billing

Please note that effective **immediately**, Ozempic Prefilled Pens are to be billed per pen (previously billed per mL).

Criteria Update

The following criteria has been updated and applies to new and existing products, effective **immediately**.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Ozempic (semaglutide)	2mg/3mL Prefilled Pen	02540258	DNP	E (SF)	NNO
	2mg/1.5mL Prefilled Pen	02471477	DNP	E (SF)	NNO
	4mg/3mL Prefilled Pen	02471469	DNP	E (SF)	NNO
Criteria	<ul style="list-style-type: none">• For the treatment of type 2 diabetes in combination with metformin and a sulfonylurea, when diet and exercise plus dual therapy with metformin and a sulfonylurea do not achieve adequate glycemic control. <p>Claim Note:</p> <ul style="list-style-type: none">• Approvals will be for a maximum of 1 prefilled pen every 4 weeks.				

New Exception Status Benefit

The following new products have been listed with the following criteria, effective **immediately**.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Rybelsus (semaglutide)	3mg Tab	02497581	DNP	E (SF)	NNO
	7mg Tab	02497603	DNP	E (SF)	NNO
	14mg Tab	02497611	DNP	E (SF)	NNO
Criteria	<ul style="list-style-type: none"> For the treatment of type 2 diabetes in combination with metformin and a sulfonylurea, when diet and exercise plus dual therapy with metformin and a sulfonylurea do not achieve adequate glycemic control. <p>Claim Note:</p> <ul style="list-style-type: none"> Approvals will be for a maximum of one tablet per day. 				

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New Exception Status Benefits

- Kerendia (finerenone)
- Saphnelo (anifrolumab)
- Zeposia (ozanimod)

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- Brukinsa (zanubrutinib)

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Nova Scotia Formulary Updates

New Exception Status Benefits

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

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Kerendia	10mg Tab	02531917	DNP	E (SF)	BAY
	(finerenone) 20mg Tab	02531925	DNP	E (SF)	BAY
Criteria	<ul style="list-style-type: none"> • For the treatment of patients with chronic kidney disease (CKD) and type 2 diabetes (T2D) who have an estimated glomerular filtration rate (eGFR) level of at least 25 mL/min/1.73 m² and albuminuria level of at least 30 mg/g (or 3 mg/mmol). <p>Exclusion Criteria:</p> <ul style="list-style-type: none"> • Patients with chronic heart failure (CHF) New York Heart Association (NYHA) class II to IV; OR • Patients receiving a mineralocorticoid receptor antagonist (MRA). <p>Discontinuation Criteria:</p> <ul style="list-style-type: none"> • eGFR less than 15 mL/min/1.73 m²; OR • Urinary albumin-to-creatinine ratio (UACR) increased from baseline level. <p>Claim Notes:</p> <ul style="list-style-type: none"> • Must be prescribed by, or in consultation with, a nephrologist with experience in the diagnosis and management of patients with CKD and T2D. • Approval: 1 year 				

New Exception Status Benefits Continued...

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Saphnelo (anifrolumab)	150mg/mL IV Inj	02522845	DNP	E (SF)	AZE
Criteria	<ul style="list-style-type: none"> For the treatment of adult patients with active, autoantibody positive, systemic lupus erythematosus (SLE), in addition to standard therapy, who meet all the following criteria: <ul style="list-style-type: none"> Moderate to severe SLE, defined as Systemic Lupus Erythematosus Disease Activity Index 2000 (SLEDAI-2K) score of at least 6; AND Unable to control their disease while using an oral corticosteroid (OCS) dose of at least 10mg/day of prednisone or equivalent. <p>Exclusion Criteria:</p> <ul style="list-style-type: none"> Severe or unstable neuropsychiatric SLE Active severe SLE nephritis <p>Initial Renewal Criteria:</p> <ul style="list-style-type: none"> OCS dose decreased to ≤ 7.5mg/day of prednisone or equivalent, or OCS dose decreased by at least 50% from baseline; AND Reduction in disease activity measured by: <ul style="list-style-type: none"> Reducing the SLEDAI-2K score to 5 or less; OR British Isles Lupus Activity Group (BILAG) improvement in organ systems and no new worsening. <p>Subsequent Renewal Criteria:</p> <ul style="list-style-type: none"> The initial response achieved after the first 12 months of therapy has been maintained. <p>Clinical Notes:</p> <ul style="list-style-type: none"> SLEDAI-2K and BILAG scores must be provided. <p>Claim Notes:</p> <ul style="list-style-type: none"> Approval: 12 months. Patient should be under the care of a physician with expertise in the diagnosis and management of SLE. Not to be used in combination with other biologic treatments. 				

New Exception Status Benefits Continued...

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Zeposia (ozanimod)	0.23mg & 0.46mg Initiation Pack	02506009	DNP	E (SF)	CEL
	0.92mg Cap	02505991	DNP	E (SF)	CEL
Criteria	<ul style="list-style-type: none"> For the treatment of adult patients with moderately to severely active ulcerative colitis (UC) who have a partial Mayo score > 4, and have a rectal bleeding subscore ≥ 2, and are: <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> a decrease in the partial Mayo score ≥ 2 from baseline, AND a decrease in the rectal bleeding subscore ≥ 1. <p>Clinical Notes:</p> <ul style="list-style-type: none"> 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. <p>Claim Notes:</p> <ul style="list-style-type: none"> Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology. Concurrent use of biologics or Janus kinase inhibitors not approved. Initial Approval: 16 weeks. Maximum dose of 0.92mg daily with no dose escalation permitted. Renewal Approval: 1 year. 				

Criteria Update

The following new indications have been added to existing criteria effective **March 1, 2024**.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Brukinsa (zanubrutinib)	80mg Cap	02512963	DNP	E (SFC)	BGN
Criteria	<p>Previously Untreated Chronic Lymphocytic Leukemia (CLL) or Small Lymphocytic Lymphoma (SLL)</p> <ul style="list-style-type: none"> As monotherapy for the treatment of adult patients with previously untreated chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) for whom a fludarabine-based regimen is considered inappropriate due to a high risk of relapse or refractory disease based on prognostic biomarkers. <p>Clinical Notes:</p> <ul style="list-style-type: none"> Patients should have a good performance status. Treatment should be continued until disease progression or unacceptable toxicity. High risk for relapse or refractory disease includes 17p deletion, TP53 mutation, 11q deletion and unmutated IGHV. <p>Claim Notes:</p> <ul style="list-style-type: none"> Patients are not eligible if they have prolymphocytic leukemia or Richter's transformation. Requests will not be considered for patients who experience disease progression on a Bruton's tyrosine kinase (BTK) inhibitor or idelalisib. Requests will be considered for patients who are not suitable candidates for intravenous therapy. Venetoclax with or without rituximab is funded as a subsequent line of therapy in patients who have experienced disease progression during first-line zanubrutinib treatment, provided all other funding eligibility criteria are met. <p>Relapsed/Refractory Chronic Lymphocytic Leukemia (CLL) or Small Lymphocytic Lymphoma (SLL)</p> <ul style="list-style-type: none"> As monotherapy for the treatment of adult patients with relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) who have received at least one prior systemic therapy. <p>Clinical Notes:</p> <ul style="list-style-type: none"> Patients should have a good performance status. Treatment should be continued until disease progression or unacceptable toxicity. <p>Claim Notes:</p> <ul style="list-style-type: none"> Patients are not eligible if they have prolymphocytic leukemia or Richter's transformation. Requests will not be considered for patients who experience disease progression on a Bruton's tyrosine kinase (BTK) inhibitor or idelalisib. 				

New Benefits

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

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Bijuva	1mg/100mg Cap	02505223	DNP	SF	KNI
Mezera	500mg DR Tab	02524481	DNP	SF	AVI

Temporary Benefit – US-Labelled Glucagon Injection

Amphastar Pharmaceuticals Inc. has received approval from Health Canada for the import and release of US-labelled glucagon injection 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 Amphastar Pharmaceuticals Inc. Dear Healthcare Professional at the following link: [risk-communication-letter-glucagon-en.pdf \(amphastar.com\)](https://www.amphastar.com/risk-communication-letter-glucagon-en.pdf)

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Glucagon	1mg/1mL Inj	09858279	DNP	SFD*	APM

*quantity limit of two (2) kits per fiscal year. The prescriber can submit a request for consideration should beneficiaries require more than two (2) kits per fiscal year.

Pharmacare News Bulletins Online

If you are reading a paper copy of this bulletin, we would like to remind you that all bulletins can be found on our website at the following link: <https://novascotia.ca/dhw/pharmacare/pharmacare-news-bulletins.asp>

Updating Pharmacy Licence In CANImmunize

As a reminder, if your pharmacy is issued a new licence number, you must update the licence number in CANImmunize Clinic Flow to ensure payments for vaccinations can be processed. Incorrect or inactive licence numbers will result in payments not being processed. To update your licence in Clinic Flow, please contact the Vaccination Information Technology Team at Cathy.M.McPhee@novascotia.ca and Glenn.Bartlett@novascotia.ca.

Ozempic Billing Reminder

Please note, Ozempic Prefilled Pens are to be billed per pen (previously billed per mL).



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Paxlovid Availability in Nova Scotia

Paxlovid Availability in Nova Scotia

This communication is to provide you with updated information related to Paxlovid (nirmatrelvir/ritonavir) availability in Nova Scotia. Paxlovid is used for the treatment of mild to moderate COVID-19 in patients who are at high risk for progression to severe disease.

To date, Paxlovid has been supplied by the federal government and has been provided at no cost to patients who meet established criteria in Nova Scotia. The federal supply of Paxlovid is ending.

While federal procurement has ended, supply remains in Nova Scotia that can be used at no cost to patients until May 31, 2024 (last day of dispense May 26, 2024 for a 5 day treatment course). This supply is only available through patient self-referral by completing the provincial Report and Support Form. The [form](#) can be filled out when the patient **books** a PCR test or as soon they test positive on a rapid COVID test either online at <https://c19hc.nshealth.ca/self-report> or by **calling 1-833-797-7772**.

If you receive a prescription before May 26th from a non-designated prescriber (i.e. a prescriber who is not listed as a [designated prescriber](#) with the NS Health COVID-19 Non-Severe Treatment Team), depending on the circumstances, you may want to advise the patient that they may qualify for the publicly funded supply, and they can be referred to the provincial Report and Support Form to self-refer for an assessment by the NS Health COVID-19 Non-Severe Treatment Team. The [form](#) can be filled out online at <https://c19hc.nshealth.ca/self-report> or by **calling 1-833-797-7772**.

The NS Health COVID-19 Non-Severe Treatment Team can be reached by email at COVIDTreatment@nshealth.ca or by phone at 1-833-714-2784 and will continue to be available for consultations from health care professionals as required.

We encourage all pharmacists to become more familiar with Paxlovid as it is becoming available on the market and you may receive prescriptions from non-[designated prescribers](#). Dose adjustments may be required for renal function. Very importantly, Paxlovid has numerous serious drug interactions with many commonly used medications. Paxlovid may be contraindicated in combination with some

Paxlovid Availability in Nova Scotia Continued...

medications (e.g. post-transplant immunosuppressants, anticonvulsants) or require modifications to the patient's other drug therapies (e.g. anticoagulants, psychiatric medications and more). Paxlovid specific resources to aid drug interaction management are provided below:

- [Liverpool COVID-19 Drug Interaction Checker](#)
- [Ontario: Paxlovid Prescribing & Drug Interaction Information | Immunodeficiency Clinic \(hivclinic.ca\)](#)

The list price for a 5-day course of Paxlovid is \$1288. A patient's private insurance may or may not provide coverage. At this time, Paxlovid is not funded by the Nova Scotia Pharmacare Programs as we continue to utilize the federally procured supply until the end of May and await recommendations from the Canadian Agency for Drugs and Technologies in Health (CADTH).

If you are currently one of the designated pharmacies that has been dispensing the federal supply of Paxlovid you will receive more detailed information.

In summary, the availability of federally procured Paxlovid at no charge to the patient continues through established channels in Nova Scotia for patients who meet specific clinical [criteria](#). We encourage the use of [Report and Support](#) referrals to the NS Health COVID-19 Non-Severe Treatment Team at this time to reach a [designated prescriber](#) and access federally procured Paxlovid for those at high risk of progression to severe disease. Further updates regarding coverage will be provided in the coming weeks.

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New Exception Status Benefits

- Skyrizi (risankizumab)
- Xydalba (dalbavancin hydrochloride)

Criteria Updates

- Temodal and generic brands (temozolomide)
- Exjade and generic brands (deferasirox)
- Jadenu and generic brands (deferasirox)

Change in Benefit Status

- Olanzapine

New Benefits

Nova Scotia Formulary Updates

New Exception Status Benefits

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

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Skyrizi	600mg/10mL Vial	02532107	DNP	E (SF)	ABV
(risankizumab)	360mg/2.4mL Prefilled Ctg Inj	02532093	DNP	E (SF)	ABV

Criteria

- For patients with moderate to severely active Crohn's disease and are refractory or have contraindications to an adequate course of 5-aminosalicylic acid and corticosteroids and other immunosuppressive therapy.

Clinical Note:

- Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above.

Claim Notes:

- Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology.
- Combined use of more than one biologic disease-modifying antirheumatic drugs (DMARD) will not be reimbursed.
- Initial reimbursement will be for intravenous doses of 600mg at Weeks 0, 4 and 8, with clinical response to be assessed prior to Week 12. Subsequent reimbursement for maintenance dosing is 360mg subcutaneously at Week 12, every 8 weeks thereafter.
- Initial Approval: 16 weeks
- Renewal Approval: 1 year

New Exception Status Benefits Continued...

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Xydalba (dalbavancin hydrochloride)	500mg Vial	02480522	DNP	E (SF)	PAL
Criteria	<ul style="list-style-type: none"> For the treatment of adult patients with acute bacterial skin and skin structure infections (ABSSSI) who meet all the following criteria: <ul style="list-style-type: none"> known or suspected methicillin-resistant Staphylococcus aureus (MRSA) ABSSSI; AND high risk of nonadherence to outpatient antibiotic treatment or high risk of nonadherence to prolonged hospitalization. <p>Claim Notes:</p> <ul style="list-style-type: none"> Approvals will be for a maximum 1500mg per treatment course. 				

Criteria Updates

The following criteria has been updated and will replace existing criteria effective **April 1, 2024**.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Exjade and generic brands (deferasirox)	Various	Various	DNP	E (SF)	VAR
Criteria	<ul style="list-style-type: none"> For the treatment of chronic iron overload. 				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Jadenu and generic brands (deferasirox)	Various	Various	DNP	E (SF)	VAR
Criteria	<ul style="list-style-type: none"> For the treatment of chronic iron overload. 				

Criteria Updates Continued...

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Temodal and generic brands (temozolomide)	Various	Various	DNP	E (SFC)	VAR
Criteria	<ul style="list-style-type: none"> For the treatment of patients with high grade gliomas as monotherapy or in combination with other therapies such as radiation. <p>Clinical Notes:</p> <ul style="list-style-type: none"> Patients should have a good performance status. Treatment should be continued until there is no longer a clinical benefit or unacceptable toxicity. 				

Change in Benefit Status

Effective **April 1, 2024**, the following products will be added to the Drug Assistance for Cancer Patients Program.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Olanzapine	Various	Various	DNP	SFC	VAR
Olanzapine ODT	Various	Various	DNP	SFC	VAR

New Benefits

Effective **April 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
Erleada	240mg Tab	02540185	DNP	E (SFC)	JAN
Hyrimoz	20mg/0.2mL Prefilled Syringe	02542315	DNP	E (SF)	SDZ
Hyrimoz	40mg/0.4mL Autoinjector	02542331	DNP	E (SF)	SDZ
Hyrimoz	40mg/0.4mL Prefilled Syringe	02542323	DNP	E (SF)	SDZ
Hyrimoz	80mg/0.8mL Autoinjector	02542366	DNP	E (SF)	SDZ
Hyrimoz	80mg/0.8mL Prefilled Syringe	02542358	DNP	E (SF)	SDZ
Uceris	2mg/Act	02498057	DNP	SF	BSL

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New Exception Status Benefits

- Benlysta (belimumab)
- Ultomiris (ravulizumab)

Criteria Update

- Pegfilgrastim

Change in Benefit Status

- Odan-Indomethacin
- Odan-Indomethacin
- Odan-Prochlorperazine
- Proctol

New Benefits

Temporary Benefit – US-Labelled
Colesevelam Hydrochloride Tablets

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/1.73m².

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	<ul style="list-style-type: none"> ○ an estimated eGFR that is no more than 20% below the value before the renal flare (preflare value) or $\geq 60\text{mL}/\text{min}/1.73\text{m}^2$ after 12 months of therapy. • Must provide proof of improvement in proteinuria, defined as either: <ul style="list-style-type: none"> ○ proteinuria no greater than 0.7g/24 hours after 12 months of therapy if baseline proteinuria is $< 3.5\text{g}/24$ 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., $> 3.5\text{g}/24$ hours). <p>Subsequent Renewal Criteria:</p> <ul style="list-style-type: none"> • Must provide proof that the initial response achieved after the first 12 months of therapy has been maintained. <p>Discontinuation Criteria:</p> <ul style="list-style-type: none"> • Patient has any of the following: <ul style="list-style-type: none"> ○ Does not meet all of the renewal criteria; OR ○ An eGFR decrease to less than $30\text{mL}/\text{min}/1.73\text{m}^2$; 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. <p>Claim Notes:</p> <ul style="list-style-type: none"> • 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	<p>Paroxysmal Nocturnal Hemoglobinuria</p> <p>Initiation Criteria:</p> <p>For the treatment of patients with paroxysmal nocturnal hemoglobinuria (PNH) who meet the following criteria:</p> <ul style="list-style-type: none"> • The diagnosis of PNH has been made based on the following confirmatory results: <ul style="list-style-type: none"> ○ Flow cytometry/FLAER exam with granulocytes or monocyte clone $\geq 10\%$; AND ○ LDH > 1.5 ULN; AND ○ At least one of the following: <ul style="list-style-type: none"> ▪ 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/1.73m², 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. <p>Renewal Criteria:</p> <ul style="list-style-type: none"> • Renewals will be considered for patients who; <ul style="list-style-type: none"> ○ 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 $0.5 \times 10^9/L$, platelet count below $20 \times 10^9/L$, reticulocytes below $25 \times 10^9/L$, 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	<ul style="list-style-type: none"> 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. <p>Atypical Hemolytic Uremic Syndrome</p> <p>Initiation Criteria:</p> <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> Confirmed diagnosis of aHUS at initial presentation, defined by presence of thrombotic microangiopathy (TMA), who meet all the following criteria: <ul style="list-style-type: none"> A disintegrin and metalloproteinase with a thrombospondin type 1 motif, member 13 (ADAMTS-13) activity $\geq 10\%$ 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: <ul style="list-style-type: none"> Unexplained (not a secondary TMA) thrombocytopenia (platelet count $< 150 \times 10^9/L$); 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: <ul style="list-style-type: none"> Kidney impairment, as demonstrated by one of the following: <ul style="list-style-type: none"> 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 $< 60\text{mL}/\text{min}$ 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	<ul style="list-style-type: none"> • SCr > the age-appropriate ULN in pediatric patients (as determined by or in consultation with a pediatric nephrologist) OR <ul style="list-style-type: none"> ▪ 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: <ul style="list-style-type: none"> ○ 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: <ul style="list-style-type: none"> ○ 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. <p>Renewal Criteria:</p> <ul style="list-style-type: none"> • 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). <ul style="list-style-type: none"> ○ 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. <ul style="list-style-type: none"> ○ 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																																
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	1100mg/11mL Vial	02533456	DNP	E (SF)	ALX																																
Criteria	<ul style="list-style-type: none"> ○ 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. <ul style="list-style-type: none"> ▪ 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: <ul style="list-style-type: none"> ○ Significant hemolysis as evidenced by presence of schistocytes on the blood film, or low or absent haptoglobin, or LDH above normal; AND ○ EITHER <ul style="list-style-type: none"> ▪ Platelet consumption as measured by either ≥ 25% decline from patient baseline or thrombocytopenia (platelet count < 150,000 × 10⁹/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. <p>Claim Notes:</p> <ul style="list-style-type: none"> ● Approvals will be for a maximum of: <table border="1" data-bbox="560 1344 1396 1659"> <thead> <tr> <th>Body Weight Range (kg)</th> <th>Loading Dose (mg)</th> <th>Maintenance Dose (mg)</th> <th>Dosing Interval</th> </tr> </thead> <tbody> <tr> <td>≥ 5 to < 10</td> <td>600</td> <td>300</td> <td>Every 4 weeks</td> </tr> <tr> <td>≥ 10 to < 20</td> <td>600</td> <td>600</td> <td>Every 8 weeks</td> </tr> <tr> <td>≥ 20 to < 30</td> <td>900</td> <td>2,100</td> <td>Every 8 weeks</td> </tr> <tr> <td>≥ 30 to < 40</td> <td>1,200</td> <td>2,700</td> <td>Every 8 weeks</td> </tr> <tr> <td>≥ 40 to < 60</td> <td>2,400</td> <td>3,000</td> <td>Every 8 weeks</td> </tr> <tr> <td>≥ 60 to < 100</td> <td>2,700</td> <td>3,300</td> <td>Every 8 weeks</td> </tr> <tr> <td>≥ 100</td> <td>3,000</td> <td>3,600</td> <td>Every 8 weeks</td> </tr> </tbody> </table> ● 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 					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
Body Weight Range (kg)	Loading Dose (mg)	Maintenance Dose (mg)	Dosing Interval																																		
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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	<ul style="list-style-type: none"> For the prevention of febrile neutropenia in patients with non-myeloid malignancies receiving myelosuppressive chemotherapy with curative intent who: <ul style="list-style-type: none"> 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] <p>Clinical Note:</p> <ul style="list-style-type: none"> 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



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Nova Scotia Formulary Updates

Nirmatrelvir/Ritonavir (Paxlovid™)
Availability in Nova Scotia

New Exception Status Benefits

- Paxlovid (nirmatrelvir/ritonavir)

Nova Scotia Formulary Updates

Nirmatrelvir/Ritonavir (Paxlovid™) Availability in Nova Scotia

As previously communicated in the Pharmacare Bulletin in March (Volume 24-05), the availability of federally procured nirmatrelvir/ritonavir (Paxlovid™) has ended. Effective May 31, 2024, all federally procured nirmatrelvir/ritonavir (Paxlovid™) products expire. The last day of dispense for the federal supply is May 26, 2024, for a 5-day treatment course.

Nirmatrelvir/ritonavir (Paxlovid™) is being added as a benefit to the Nova Scotia Pharmacare Programs as per usual processes. The Pharmacare criteria for funding is included below and criteria codes are available to allow automatic payment when the criteria are met. Nirmatrelvir/ritonavir (Paxlovid™) is available for pharmacies to order through regular market channels, and you may receive prescriptions from a patient's physician, nurse practitioner, or from the NS Health COVID-19 Non-Severe Treatment Team. As nirmatrelvir/ritonavir (Paxlovid™) has transitioned to regular market supply the special services fee and PIN 93899829 (delivery charges), which were in use at designated pharmacies, will no longer apply.

As was the case throughout the pandemic, the NS Health COVID-19 Non-Severe Treatment Team continues to be available for consultations with health care professionals and patient referrals. They can be reached by health care professionals for consultation by email at COVIDTreatment@nshealth.ca or by phone at 1-833-714-2784 seven days per week. This team is available to you to help manage drug interactions and appropriate use of COVID-19 medications if needed.

Patients can continue to report their positive COVID-19 test via the provincial Report and Support Form to self-refer for treatment assessment by the Non-Severe COVID Treatment Team. The team will contact the patient if they are at high risk for developing severe disease and may benefit from medication or other supports. The self-referral form is available at <https://c19hc.nshealth.ca/self-report> or the patient may call 1-833-797-7772 (option 2) for assistance.

As highlighted in the March bulletin, pharmacists and other prescribers are encouraged to become familiar with this therapy. Dose adjustments may be required for renal function and, very importantly, nirmatrelvir/ritonavir (Paxlovid™) has

Nirmatrelvir/Ritonavir (Paxlovid™) Availability in Nova Scotia Continued...

numerous serious drug interactions with many commonly used medications. Nirmatrelvir/ritonavir (Paxlovid™) may be contraindicated in combination with some medications (e.g. post-transplant immunosuppressants, anticonvulsants) or require modifications to the patient's other drug therapies (e.g. anticoagulants, psychiatric medications and more).

New Exception Status Benefits

The following new products have been listed with the following criteria, effective **May 27, 2024**. As with other criteria codes, if the code has not been provided, pharmacists can select the code if they are able to verify the clinical information.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Paxlovid (nirmatrelvir/ ritonavir)	150mg/100mg Tab	02524031	DNP	E (SFC)	PFI
	150mg /100mg (Renal) Tab	02527804	DNP	E (SFC)	PFI
Criteria	<p>For the treatment of adult patients with a diagnosis of mild-to-moderate coronavirus disease 2019 (COVID-19), confirmed with a positive COVID-19 test, and within 5 days of symptom onset in patients who meet any one of the following criteria:</p> <ul style="list-style-type: none"> • severely immunosuppressed due to one or more of the following conditions [Criteria Code 01]: <ul style="list-style-type: none"> ○ Solid organ transplant recipients; or ○ Treated for malignant hematologic condition; or ○ Bone marrow, stem cell transplant or transplant-related immunosuppressant use; or ○ Receipt of an AntiCD20 agents or B-cell depleting agents (such as rituximab) in the previous 2 years; or ○ Severe primary immunodeficiencies • moderately immunosuppressed due to one or more of the following conditions [Criteria Code 02]: <ul style="list-style-type: none"> ○ Treatment for cancer including solid tumors; or ○ Significantly immunosuppressing drugs (e.g., biologic in the last three months, oral immune suppressing medication in the last months, oral steroid [20mg/day of prednisone equivalent taken on an ongoing basis] in the last month, or immune suppressing infusion or injection in the last three months); or ○ Advanced untreated HIV infection or treated HIV¹; or ○ Moderate primary immunodeficiencies; or ○ Renal conditions (i.e., hemodialysis, peritoneal dialysis, glomerulonephritis treated with steroids, eGFR<15mL/min <p>¹ Presence of a diagnosis code (2 MSP or 1 DAD/NACRS) for AIDS at any time or presence of 1 MSP diagnosis for AIDS within 2 weeks after a CD4 lab test, or presence of a CD4 lab test result with CD4 count ≤ 200/mm³ or CD4 fraction ≤ 15% at any time.</p>				



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Nova Scotia Formulary Updates

Sensor-based Glucose Monitoring Program Information

Nova Scotia Formulary Updates

Sensor-based Glucose Monitoring Program Information

As announced on February 28, the Province of Nova Scotia will fund Sensor-based Glucose Monitoring (SBGM) supplies through a new income-based program and through existing Nova Scotia Pharmacare Programs. SBGM will be available to Nova Scotia residents who have Type 1 or Type 2 diabetes who meet specific criteria included below.

Patients can choose to apply for coverage through their Pharmacare Program (Family, Seniors' or DCS) or through the new SBGM Program.

In the SBGM Program, there will be an annual maximum deductible based on family size and income. The SBGM program is the payer of last resort.

In the Pharmacare Programs, coverage will be accessed through Pharmacare Programs with usual copays and premiums.

Processing of applications for coverage of the following SBGM supplies will begin June 3, 2024. Residents opting to enroll in the SBGM program can be referred to the SBGM website (<https://beta.novascotia.ca/register-sensor-based-glucose-monitoring-program>). Residents opting to obtain coverage through their existing Pharmacare Program can be directed to the Pharmacare website for the exception status form <https://novascotia.ca/dhw/pharmacare/exception-status-drugs.asp>

Sensor-based Glucose Monitoring Program Information Continued...

PRODUCT	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Dexcom G6 Sensor	97799136	DNP	E(SFD), G ¹	DEX
Dexcom G6 Transmitter	97799135	DNP	E(SFD), G ¹	DEX
Dexcom G7 Sensor	97798972	DNP	E(SFD), G ¹	DEX
Dexcom G7 Receiver	97798973	DNP	E(SFD), G ¹	DEX
FreeStyle Libre 2 Sensor	97799075	DNP	E(SFD), G ¹	MID
Guardian 3 Sensor	97799158	DNP	E(SFD), G ¹	MDT
Guardian 4 Sensor	97798971	DNP	E(SFD), G ¹	MDT
Criteria	<ul style="list-style-type: none"> For patients 2 years of age or older with Diabetes Mellitus (DM) AND who require multiple daily injections of insulin or insulin pump therapy as part of intensive insulin therapy. Multiple daily injections of insulin are defined as 1 (or more) injection(s) of basal insulin and 3 (or more) injections of bolus insulin, with a minimum of at least of 4 total insulin injections per day. 			

¹ Benefit Status code G represents the income-based SBGM program

The following reimbursement rules will be applied:

Abbott FreeStyle Libre 2:

- A maximum of six (6) sensors will be covered within a 3-month period
- A reader (where required) is available at no cost by contacting Libre Customer Service (1-888-205-8296).

Dexcom G6 and G7:

- A maximum of nine (9) sensors will be covered within a 3- month period.
- A Dexcom G6 Receiver (where required) is available at no cost by contacting Dexcom Customer Service (1-844-832-1810).
- A Dexcom G6 Transmitter (where required) can be dispensed from a community pharmacy and covered every 3 months.
- A Dexcom G7 Receiver (where required – one per lifetime) can be dispensed from a community pharmacy.

Medtronic Guardian 3 and 4:

- A maximum of 15 sensors (5 per box) will be covered within a 3-month period.
- A Transmitter (one per year) is available at no cost by contacting Medtronic Customer Service (1-800-284-4416).

Other information

- If a sensor must be replaced early (stops working or falls off), a replacement will be provided by the manufacturer by contacting their Customer Service line. The replacement will be shipped at no cost to patients. Replacement sensors will not be reimbursed at the pharmacy.
- Patients will need to use any other sources of insurance that are available to them first (e.g. private insurance). This includes situations in which the patient must submit manual receipts. Portions unpaid by the private insurance would then be sent to the SBGM program for reimbursement consideration.

Sensor-based Glucose Monitoring Program Information Continued...

- Patients who wish to join the income-based program must complete the enrolment form and forward it to the SBGM Program office. A portion of the form must be completed by a physician, nurse practitioner, or pharmacist. This signature sign-off serves as verification the patient meets the clinical criteria for the glucose monitoring product, including being on the required daily injections of insulin.
- Patients who wish to use the Pharmacare programs must have an ESD form completed by a physician, nurse practitioner or pharmacist.

More information and forms can be found on the website: <https://beta.novascotia.ca/register-sensor-based-glucose-monitoring-program>)



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Nova Scotia Formulary Updates

Removal of Pharmacy Prescription Renewal Limits

Criteria Code for COPD and Asthma Inhalers

New Exception Status Benefits

- Jamteki (ustekinumab)
- Wezlana (ustekinumab)

Criteria Update: Plaque Psoriasis

Criteria Update: Crohn's Disease

Change in Benefit Status

New Benefits

Nova Scotia Formulary Updates

Removal of Pharmacy Prescription Renewal Limits

Effective June 1, 2024, the annual limit is being removed from pharmacy prescription renewals provided by pharmacists to Nova Scotia residents with a valid health card.

Currently, the criteria for prescription renewals indicates that there is 'a maximum of four (4) prescription renewals of any combination per resident within a one-year period. For example, three claims for 3 or fewer prescriptions and one claim for 4 or more prescriptions, or two claims for each services renewal.'

Prescription renewals by a pharmacist are eligible for coverage by DHW, provided specific criteria are met as laid out in the Pharmacy Guide. These criteria include:

- The renewal services are provided in compliance with the NS College of Pharmacists Standards of Practice: Prescribing Drugs (November 2023).
- The pharmacist must determine if there are other prescriptions that also require renewal in a reasonable timeframe and provide those renewals at the same time.
- The pharmacist renews prescriptions for Schedule 1 prescription drugs, insulin, epinephrine, or nitroglycerin. Prescription renewals for over-the-counter products are not eligible.
- The pharmacist renews prescriptions for duration not less than the patient's usual duration of therapy, unless it is the professional judgement of the pharmacist that it would be unsafe or unwise to do so. Usual duration will include usual day supply dispensed plus refills.

Please see the *Pharmacy Guide* for complete details on eligibility information on Prescription Renewals.

Removal of Pharmacy Prescription Renewal Limits Continued...

The renewals will continue to be paid at the same rate as existing prescription renewal services. **New PINS will be implemented with this change and are to be used effective June 1, 2024.**

- Pharmacy Prescription Renewal for 3 or Less Prescriptions Renewed – 93899860, fee \$12.00.
- Pharmacy Prescription Renewal for 4 or More Prescriptions Renewed - 93899859, fee \$20.00.

The current PINS (93899846 for 3 or fewer renewals and 93899845 for 4 or more renewals) will remain in place for one month from June 1, 2024.

Special service code 002 (pharmacist intervention) should be used for all PINs. Claims will require criteria codes to indicate whether they were delivered in person (91), by telephone (92) or by video (93). Claims will require a valid Nova Scotia Health Card Number and there is no age limit. Manual claims will not be accepted.

Criteria Code for COPD and Asthma Inhalers

Effective June 3, criteria code 16 can be used for COPD and asthma inhalers when prescribed by a respirologist, clinical immunologist, allergist, internist, medical oncologist, or thoracic surgeon. Once the code has been used, then the beneficiary will have long term approval for all similar funded inhalers as long as there is at least one dispense per year.

New Exception Status Benefits

The Nova Scotia Biosimilar Initiative aims to expand the use of lower cost biosimilars on the Pharmacare Programs. On June 1, 2024, two new ustekinumab biosimilar drugs, Jamteki and Wezlana, will be listed on the Nova Scotia Formulary.

Effective June 1, 2024, patients currently taking the originator drug product Stelara, are required to switch to a biosimilar version by December 1, 2024.

For ustekinumab-naïve patients whose therapy is initiated after June 1, 2024, an ustekinumab 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>.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Jamteki	45mg/0.5mL Prefilled Syringe	02543036	DNP	E (SF)	JPC
(ustekinumab)	90mg/1.0mL Prefilled Syringe	02543044	DNP	E (SF)	JPC
Criteria	Plaque Psoriasis <ul style="list-style-type: none"> • For the treatment of patients with chronic moderate to severe plaque psoriasis who meet all of the following: <ul style="list-style-type: none"> ○ Psoriasis Area Severity Index (PASI) greater than 10 and Dermatology Life Quality Index (DLQI) greater than 10, OR major involvement of visible areas, scalp, genitals, or nails; ○ Refractory, intolerant to or unable to access phototherapy; 				

New Exception Status Benefits Continued...

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Jamteki	45mg/0.5mL Prefilled Syringe	02543036	DNP	E (SF)	JPC
(ustekinumab)	90mg/1.0mL Prefilled Syringe	02543044	DNP	E (SF)	JPC
Criteria	<ul style="list-style-type: none"> ○ Refractory, intolerant to or have contraindications to methotrexate (oral or parenteral) at a dose of greater than or equal to 20 mg weekly (greater than or equal to 15 mg if patient is 65 years of age or older) for a minimum of 12 weeks OR cyclosporine (6 weeks treatment). ● For continued coverage, patients must meet the following criteria: <ul style="list-style-type: none"> ○ Greater than or equal to 75% reduction in PASI score, OR ○ Greater than or equal to 50% reduction in PASI and greater than or equal to 5 points in the DLQI OR ○ Significant reduction in BSA involved, with consideration of specific regions such as face, hands, feet or genital region and situations such as itch and recalcitrant plaques. <p>Clinical Notes:</p> <ul style="list-style-type: none"> ● For patients who do not demonstrate a clinical response to oral methotrexate, or who experience gastrointestinal intolerance, a trial of parenteral methotrexate may be considered if clinically appropriate. ● 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 to treatments. The nature of intolerance(s) must be clearly documented. <p>Claim Notes:</p> <ul style="list-style-type: none"> ● Must be prescribed by a dermatologist or prescriber with a specialty in dermatology. ● Combined use of more than one biologic will not be reimbursed. ● Approvals will be for a maximum of 45mg subcutaneously at Week 0, 4 and 16 weeks, followed by a maintenance dose of 45mg subcutaneously every 12 weeks. Response must be assessed prior to fourth dose. ● Initial Approval: 16 weeks. ● Renewal Approval: 1 year <p>Psoriatic Arthritis</p> <ul style="list-style-type: none"> ● For the treatment of patients with predominantly axial psoriatic arthritis who are refractory, intolerant or have contraindications to the sequential use of at least two NSAIDs at maximal tolerated dose for a minimum of two weeks each. ● For the treatment of patients with predominantly peripheral psoriatic arthritis who are refractory, intolerant or have contraindications to: <ul style="list-style-type: none"> ○ The sequential use of at least two NSAIDs at maximal tolerated dose for a minimum of two weeks each; AND ○ Methotrexate (oral or parenteral) at a dose of ≥ 20mg weekly (≥ 15mg if patient is ≥ 65 years of age) for a minimum of 8 weeks; AND 				

New Exception Status Benefits Continued...

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Jamteki (ustekinumab)	45mg/0.5mL Prefilled Syringe	02543036	DNP	E (SF)	JPC
	90mg/1.0mL Prefilled Syringe	02543044	DNP	E (SF)	JPC
Criteria	<ul style="list-style-type: none"> ○ Leflunomide for a minimum of 10 weeks or sulfasalazine for a minimum of 3 months. <p>Clinical Notes:</p> <ul style="list-style-type: none"> ● For patients who do not demonstrate a clinical response to oral methotrexate, or who experience gastrointestinal intolerance, a trial of parenteral methotrexate must be considered. ● 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 to treatments. The nature of intolerance(s) must be clearly documented. <p>Claim Notes:</p> <ul style="list-style-type: none"> ● Must be prescribed by a rheumatologist. ● Concurrent use of biologics not approved. ● Initial period 6 months. ● Approvals will be for a maximum of 45mg subcutaneously at Weeks 0 and 4, and maintenance dosing of 45mg subcutaneously every 12 weeks. For patients >100kg, doses of 90mg may be considered. ● Renewal approval: 1 year. Confirmation of continued response required. 				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Wezlana (ustekinumab)	45mg/0.5mL Prefilled Syringe	02544180	DNP	E (SF)	AGA
	90mg/1.0mL Prefilled Syringe	02544199	DNP	E (SF)	AGA
	45mg/0.5mL Vial	02544202	DNP	E (SF)	AGA
	130mg/26mL Vial	02544210	DNP	E (SF)	AGA
Criteria	<p>Plaque Psoriasis</p> <ul style="list-style-type: none"> ● For the treatment of patients with chronic moderate to severe plaque psoriasis who meet all of the following: <ul style="list-style-type: none"> ○ Psoriasis Area Severity Index (PASI) greater than 10 and Dermatology Life Quality Index (DLQI) greater than 10, OR major involvement of visible areas, scalp, genitals, or nails; ○ Refractory, intolerant to or unable to access phototherapy; <p>Refractory, intolerant to or have contraindications to methotrexate (oral or parenteral) at a dose of greater than or equal to 20 mg weekly (greater than or equal to 15 mg if patient is 65 years of age or older) for a minimum of 12 weeks OR cyclosporine (6 weeks treatment).</p>				

New Exception Status Benefits Continued...

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Wezlana (ustekinumab)	45mg/0.5mL Prefilled Syringe	02544180	DNP	E (SF)	AGA
	90mg/1.0mL Prefilled Syringe	02544199	DNP	E (SF)	AGA
	45mg/0.5mL Vial	02544202	DNP	E (SF)	AGA
	130mg/26mL Vial	02544210	DNP	E (SF)	AGA

Criteria

- For continued coverage, patients must meet the following criteria:
 - Greater than or equal to 75% reduction in PASI score, **OR**
 - Greater than or equal to 50% reduction in PASI and greater than or equal to 5 points in the DLQI **OR**
 - Significant reduction in BSA involved, with consideration of specific regions such as face, hands, feet or genital region and situations such as itch and recalcitrant plaques.

Clinical Notes:

- For patients who do not demonstrate a clinical response to oral methotrexate, or who experience gastrointestinal intolerance, a trial of parenteral methotrexate may be considered if clinically appropriate.
- 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 to treatments. The nature of intolerance(s) must be clearly documented.

Claim Notes:

- Must be prescribed by a dermatologist or prescriber with a specialty in dermatology.
- Combined use of more than one biologic will not be reimbursed.
- Approvals will be for a maximum of 45mg subcutaneously at Week 0, 4 and 16 weeks, followed by a maintenance dose of 45mg subcutaneously every 12 weeks. Response must be assessed prior to fourth dose.
- Initial Approval: 16 weeks.
- Renewal Approval: 1 year

Psoriatic Arthritis

- For the treatment of patients with predominantly axial psoriatic arthritis who are refractory, intolerant or have contraindications to the sequential use of at least two NSAIDs at maximal tolerated dose for a minimum of two weeks each.
- For the treatment of patients with predominantly peripheral psoriatic arthritis who are refractory, intolerant or have contraindications to:
 - The sequential use of at least two NSAIDs at maximal tolerated dose for a minimum of two weeks each; AND
 - Methotrexate (oral or parenteral) at a dose of ≥ 20 mg weekly (≥ 15 mg if patient is ≥ 65 years of age) for a minimum of 8 weeks; AND
 - Leflunomide for a minimum of 10 weeks or sulfasalazine for a minimum of 3 months.

New Exception Status Benefits Continued...

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Wezlana (ustekinumab)	45mg/0.5mL Prefilled Syringe	02544180	DNP	E (SF)	AGA
	90mg/1.0mL Prefilled Syringe	02544199	DNP	E (SF)	AGA
	45mg/0.5mL Vial	02544202	DNP	E (SF)	AGA
	130mg/26mL Vial	02544210	DNP	E (SF)	AGA
Criteria	<p>Clinical Notes:</p> <ul style="list-style-type: none"> For patients who do not demonstrate a clinical response to oral methotrexate, or who experience gastrointestinal intolerance, a trial of parenteral methotrexate must be considered. 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 to treatments. The nature of intolerance(s) must be clearly documented. <p>Claim Notes:</p> <ul style="list-style-type: none"> Must be prescribed by a rheumatologist. Concurrent use of biologics not approved. Initial period 6 months. Approvals will be for a maximum of 45mg subcutaneously at Weeks 0 and 4, and maintenance dosing of 45mg subcutaneously every 12 weeks. For patients >100kg, doses of 90mg may be considered. Renewal approval: 1 year. Confirmation of continued response required. <p>Ulcerative Colitis</p> <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> a decrease in the partial Mayo score ≥ 2 from baseline, AND a decrease in the rectal bleeding subscore ≥ 1. <p>Clinical Notes:</p> <ul style="list-style-type: none"> 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. 				

New Exception Status Benefits Continued...

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Wezlana (ustekinumab)	45mg/0.5mL Prefilled Syringe	02544180	DNP	E (SF)	AGA
	90mg/1.0mL Prefilled Syringe	02544199	DNP	E (SF)	AGA
	45mg/0.5mL Vial	02544202	DNP	E (SF)	AGA
	130mg/26mL Vial	02544210	DNP	E (SF)	AGA
Criteria	<p>Claim Notes:</p> <ul style="list-style-type: none"> • 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: 16 weeks • Renewal Approval: 1 year <p>Crohn's Disease</p> <ul style="list-style-type: none"> • For the treatment of patients with moderately to severely active Crohn's disease who are refractory to, intolerant or have contraindications to corticosteroids and other immunosuppressive therapy. <p>Clinical Notes:</p> <ul style="list-style-type: none"> • 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 to treatments. The nature of intolerance(s) must be clearly documented. <p>Claim Notes:</p> <ul style="list-style-type: none"> • Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology. • Combined use with other biologic drugs or janus kinase (JAK) inhibitors 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: 16 weeks • Renewal Approval: 1 year 				

Criteria Update: Plaque Psoriasis

The plaque psoriasis criteria for the following products has been updated effective June 1, 2024:

- Adalimumab biosimilars
- Bimzelx (bimekizumab)
- Cosentyx (secukinumab)
- Etanercept biosimilars
- Ilumya (tildrakizumab)
- Infliximab biosimilars
- Siliq (brodalumab)
- Skyrizi (risankizumab)
- Taltz (ixekizumab)
- Tremfya (guselkumab)

Please see the full criteria for plaque psoriasis under the ustekinumab listing on pages 2-3.

Criteria Update: Crohn's Disease

The Crohn's disease criteria for the following products has been updated effective June 1, 2024:

- Adalimumab biosimilars
- Entyvio (vedolizumab)
- Infliximab biosimilars
- Skyrizi (risankizumab)

Please see the full criteria for Crohn's disease under the ustekinumab listing on page 7.

Change in Benefit Status

Effective **June 1, 2024**, the following products will move to full benefit and no longer require exception status approval.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Pantoprazole Magnesium	40mg Tab	Various	DNP	SFC	VAR

New Benefits

Effective **June 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
Octasa	800mg Tab	02465752	DNP	SF	PDP
Octasa	1600mg Tab	02529610	DNP	SF	PDP

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New Exception Status Benefit

- Empaveli (pegcetacoplan)

Temporary Benefit – US – Labelled Carbamazepine Extended-Release (ER) Tablets

Temporary Benefit – US – Labelled Orencia SC Prefilled Syringe

Change in Benefit Status

Magic Mouthwash

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New Exception Status Benefit

The following new product has been listed with the following criteria, effective **July 1, 2024**.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Empaveli (pegcetacoplan)	1080mg/20mL (54mg/mL) Vial	02533294	DNP	E (SF)	SBI

Criteria **Initiation Criteria:**

For the treatment of patients with paroxysmal nocturnal hemoglobinuria (PNH) who meet all 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 $\geq 10\%$; 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)

New Exception Status Benefit Continued...

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Empaveli (pegcetacoplan)	1080mg/20mL (54mg/mL) Vial	02533294	DNP	E (SF)	SBI
Criteria	<p>and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded,</p> <ul style="list-style-type: none"> ▪ Renal insufficiency: History of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m², 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. <ul style="list-style-type: none"> • Have persistent anemia with hemoglobin levels < 105 g/L, despite an adequate trial of C5 inhibitor treatment and where causes other than extravascular hemolysis have been excluded, or have intolerable adverse events from C5 inhibitor treatment. <p>Renewal Criteria:</p> <ul style="list-style-type: none"> • Renewals will be considered for patients who; <ul style="list-style-type: none"> ○ 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). <p>Exclusion Criteria:</p> <p>Exclusion criteria for both initiation and renewal requests:</p> <ul style="list-style-type: none"> • 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 10⁹/L, platelet count below 20 x 10⁹/L, reticulocytes below 25 x 10⁹/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. <p>Exclusion criteria for renewal requests:</p> <ul style="list-style-type: none"> • 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. 				

New Exception Status Benefit Continued...

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Empaveli (pegcetacoplan)	1080mg/20mL (54mg/mL) Vial	02533294	DNP	E (SF)	SBI
Criteria	<p>Claim Notes:</p> <ul style="list-style-type: none"> • Approvals will be for a maximum of 1080mg twice a week (Day 1 and Day 4). • If lactate dehydrogenase (LDH) levels are greater than 2x the upper limit of normal (ULN) on twice weekly dosing, 1080mg every three days may be 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. • Pegcetacoplan will not be reimbursed in combination with other complement inhibitors except in the first 4 weeks of treatment. • Claims that exceed the maximum claim amount of \$9,999.99 must be divided and submitted as separate transactions using the DIN first and then the following PINs: <ul style="list-style-type: none"> ○ 00904879 				

Temporary Benefit – US – Labelled Carbamazepine Extended-Release (ER) Tablets

Septa Pharmaceuticals Inc. has received approval from Health Canada for the import and release of US-labelled carbamazepine extended release 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 the Healthcare Professional Risk Communication at the following link <https://recalls-rappels.canada.ca/en/alert-recall/importation-usa-authorized-carbamazepine-extended-release-tablets-usp-200-mg-and-400>

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Carbamazepine Extended-Release, USP	200mg Tab	09858341	DNP	SFC	SPT
Carbamazepine Extended-Release, USP	400mg Tab	09858342	DNP	SFC	SPT

Temporary Benefit – US – Labelled Orenzia SC Prefilled Syringe

Bristol-Myers Squibb Canada has received approval from Health Canada for the import and release of US-labelled Orenzia SC prefilled syringes to help mitigate shortages in Canada.

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

Information about US-labelled Orenzia SC for health care professionals is available for reference at <https://www.bms.com/patient-and-caregivers/our-medicines.html>

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Orenzia	125mg/mL Prefilled Syringe	09858343	DNP	E (SF)	BRI

Change in Benefit Status

Effective **July 1, 2024**, the following products will move to full benefit and no longer require exception status approval.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Darifenacin	7.5mg ER Tab	Various	DNP	SF	VAR
Darifenacin	15mg ER Tab	Various	DNP	SF	VAR
Sumatriptan	50mg Tab	Various	DNP	SF	VAR
Sumatriptan	100mg Tab	Various	DNP	SF	VAR
Trospium	20mg Tab	Various	DNP	SF	VAR

Effective **July 1, 2024**, the following products will be delisted as benefits under the Pharmacare Programs.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Fungizone	50mg/Vial Inj	00029149	N/A	Not Insured	XPI
Plerixafor	24mg/1.2mL (20mg/mL) Sol	02529815	N/A	Not Insured	JPC
Mozobil	24mg/1.2mL (20mg/mL) Sol	02377225	N/A	Not Insured	SAV
Suprefact Depot	6.3mg Implant	02228955	N/A	Not Insured	XPI
Viskazine	10mg/25mg Tab	00568627	N/A	Not Insured	XPI
Viskazine	10mg/50mg Tab	00568635	N/A	Not Insured	XPI
Zomig	2.5mg Nasal Spray	02248992	N/A	Not Insured	XPI
Zomig	5mg Nasal Spray	02248993	N/A	Not Insured	XPI

Magic Mouthwash

The following formulations will be referenced in the June Pharmacy Guide as approved formulations:

Diphenhydramine Syrup
 Lidocaine Viscous 2%
 Magnesium/Aluminum Conc. Suspension

Diphenhydramine Syrup
 Hydrocortisone Tablet
 Nystatin Suspension
 Distilled Water

Diphenhydramine Syrup
 Magnesium/Aluminum Suspension

Updates to the Nova Scotia Pharmacy Guide

The Nova Scotia Pharmacy Guide has been updated and the latest version can be found online at: <https://novascotia.ca/dhw/pharmacare/pharmacy-guide.asp>. Updates include the following:

- From title page and subsequent sections of Guide, removed notice about virtual care eligibility.
- In the **Administration** section:
 - Provided updated information on updating your pharmacy's license number with CANImmunize.
 - Removed reference to the Drugs and Therapeutics Committee.
 - Clarified a new Provider Confirmation of Agreement form is not required due to usual and customary dispensing fee increases in line with the tariff agreement.
- In the **Pharmacare Programs and Benefits** section:
 - Added information on new programs offering a wig rebate for cancer patients and coverage for sensor-based glucose monitors.
 - Clarified coverage and claims submission process for ostomy supplies under the Boarding, Transportation and Ostomy program.
 - Added COPD and asthma inhalers to the list of exception status products that can be adjudicated online based on the beneficiary's history.
 - Moved therapeutic substitution and prescription adaptation to the Benefits for All Residents section of the Guide.
- Under **Exception Status Drugs**, added reference to Arazlo 0.045% lotion not requiring prior approval for beneficiaries.
- In the **Benefits for All Residents** section:
 - In the **Administration of Publicly Funded Influenza Vaccinations Provided by a Pharmacy** section, updated the URL for the COVID chapter of the Canadian Immunization Guide. Updated the information on updating your pharmacy's license number with CANImmunize.

New Exception Status Benefit Continued...

- In the **Assessment and Prescribing Services** section, noted exception that allows non-residents to receive assessing and prescribing services for antibiotics (chemoprophylaxis) for select infectious diseases. Moved content for assessment and prescribing for antibiotics (chemoprophylaxis) into this section of the Guide.
- In the **Prescription Renewals** section, removed the frequency limit and updated the service PINs.
- Added content on therapeutic substitution and prescription adaptation that was previously in the Pharmacare Programs and Benefits section, and clarified requirement that services must result in a modified or new prescription.
- Removed dispensing of oral anti-viral medications for COVID-19.
- In the **Pharmacare Pricing Procedures** section:
 - Under **Quantitative Limits**, added the frequency limits for sensor-based glucose monitoring products, Foquest, Ozempic, Radicava, and Rybelsus, and removed the limit for Lynparza.
 - Under Compounded Products, updated information for Magic Mouthwash formulations.
- In the **Billing DHW and Nova Scotia Pharmacare** section, added the requirement that pharmacy services must be billed the same day service was provided.
- In the **Audit** section:
 - Added exceptions to documentation requirements for changes made to existing prescriptions.
 - In the **Pharmacare Prescription Audit Recovery Procedures** section, added reference to pharmacies being offered the option of an automatic recovery payment.
- Under **Pharmacy Service Audits**, added the requirement that documentation of Public Health's request is required for assessment and prescribing for antibiotic chemoprophylaxis, and the requirement for a record of a new or modified prescription resulting from therapeutic substitution or prescription adaptation.

Auditors' Corner

The newly updated [Pharmacy Guide](#) includes the following new Audit Requirements that are effective July 1, 2024:

- Documentation of Public Health's request is required for assessment and prescribing services for antibiotic chemoprophylaxis.
- A record of a new or modified prescription by the pharmacist resulting from therapeutic substitution or prescription adaptation services is required. The prescription can be either dispensed or logged.

Reminder: Billing for Pharmacy Services

All pharmacy services completed must be billed on the same day as the service was provided. This will protect the integrity of the patient's medical record.



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Nova Scotia Formulary Updates

Pharmacists Prescribing of Antimicrobial Therapy for the Treatment of Early Lyme Disease

Nova Scotia Formulary Updates

Pharmacists Prescribing of Antimicrobial Therapy for the Treatment of Early Lyme Disease

Effective July 15, public funding for pharmacists to assess and prescribe for **treatment** of early Lyme disease will be available.

This is in accordance with the changes to the Standards of Practice: Prescribing Drugs Appendix G – Prescribing for a Diagnosis Supported by a Protocol. [Standards of Practice: Prescribing Drugs \(nspharmacists.ca\)](https://www.nspharmacists.ca/standards-of-practice-prescribing-drugs). The standards set out the competencies required to provide this care by indicating;

- patient eligibility requirements for treatment of early Lyme disease by a pharmacist; and
- the treatment protocol must be consistent with the [Nova Scotia Infectious Disease Expert Group Guidance](#).

As per the Standards of Practice, the Services can be provided to individuals who:

- present with a localized erythema migrans rash (>5cm);
- do not require confirmatory laboratory testing; and
- are not presenting with complicating factors or signs and symptoms suggestive of early disseminated or late Lyme disease as set out in clinical practice guidelines.

Pharmacists who undertake prescribing for the treatment of early Lyme disease must ensure that they have taken steps to ensure that they are competent to reasonably identify an erythema migrans rash.

Pharmacists Prescribing of Antimicrobial Therapy for the Treatment of Early Lyme Disease Continued...

The new service PIN is identified below. This is in addition to the service PINS currently in place. Please note the existing PIN for assessment and prescribing for Lyme disease chemoprophylaxis that does not result in a prescription has been expanded to include early treatment of Lyme that **does not** result in a prescription.

Pharmacies can submit electronic claims for the fee associated with each PIN. Special service code 002 (pharmacist intervention) should be used for all PINs and claims will require criteria codes to indicate whether they were delivered in person (91), or by video (93). Since an erythema migrans rash must be visualized, telephone assessments are not acceptable. Claims will require a valid Nova Scotia health card number and there is no age limit. Manual claims will not be accepted.

Claims must be submitted electronically using the following CPhA Claims Standard field content. This new service PIN will provide public funding for pharmacists to assess and treat early Lyme disease at a rate of \$20.00.

CPhA Claims Standard – Fee to Assess and Prescribe an Antibiotic for the Treatment of Early Lyme Disease

Field #	Field Name	Content
D.56.03	DIN/GP#/PIN	93899729
D.57.03	Special Service Code	002 (pharmacist intervention)
D.58.03	Quantity	000001 (one)
D.61.03	Prescriber ID	License number
D.66.03	Drug Cost/Product Value	DDDDD (dollar value - not adjudicated)
D.67.03	Cost Upcharge	DDDDD (dollar value - not adjudicated)
D.68.03	Professional Fee	DDDDD (dollar value - not adjudicated)
D.72.03	Special Services Fee(s)	2000 (\$20.00)

CPhA Claims Standard – Fee to Assess for Chemoprophylaxis or Treatment of Early Lyme Disease that Does Not Result in a Prescription

Field #	Field Name	Content
D.56.03	DIN/GP#/PIN	93899839
D.57.03	Special Service Code	002 (pharmacist intervention)
D.58.03	Quantity	000001 (one)
D.61.03	Prescriber ID	License number
D.66.03	Drug Cost/Product Value	DDDDD (dollar value - not adjudicated)
D.67.03	Cost Upcharge	DDDDD (dollar value - not adjudicated)
D.68.03	Professional Fee	DDDDD (dollar value - not adjudicated)
D.72.03	Special Services Fee(s)	2000 (\$20.00)

Pharmacists Prescribing of Antimicrobial Therapy for the Treatment of Early Lyme Disease Continued...

As a reminder, the current PIN for chemoprophylaxis to assess for and prescribe for prophylaxis of Lyme disease can be found below:

CPhA Claims Standard – Fee for Assessment and Prescribing for Lyme Disease Chemoprophylaxis Resulting in a Prescription		
Field #	Field Name	Content
D.56.03	DIN/GP#/PIN	93899840
D.57.03	Special Service Code	002 (pharmacist intervention)
D.58.03	Quantity	000001 (one)
D.61.03	Prescriber ID	License number
D.66.03	Drug Cost/Product Value	DDDDD (dollar value - not adjudicated)
D.67.03	Cost Upcharge	DDDDD (dollar value - not adjudicated)
D.68.03	Professional Fee	DDDDD (dollar value - not adjudicated)
D.72.03	Special Services Fee(s)	2000 (\$20.00)

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New Exception Status Benefit

- Vyalev (foslevodopa-foscarbidopa)

Criteria Updates

- Nucala (mepolizumab)
- Vfend (voriconazole) and generics

New Products

Pharmacy Guide Update

Nova Scotia Formulary Updates

New Exception Status Benefit

The following new product has been listed with the following criteria, effective **August 1, 2024**.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Vyalev (foslevodopa-foscarbidopa)	240mg/12mg/mL SC Sol	02537702	DNP	E (SF)	ABV
Criteria	<p>For the treatment of patients with advanced levodopa-responsive Parkinson disease (PD) who meet all of the following criteria:</p> <ul style="list-style-type: none"> • Experiences severe disability associated with at least 25% of the waking day in the off state and/or ongoing, bothersome levodopa-induced dyskinesias, despite having tried frequent dosing of levodopa (at least five doses per day). • Have received an adequate trial of maximally tolerated doses of levodopa, with previously demonstrated clinical response. • Have failed an adequate trial of the following adjunctive medications, if not contraindicated and/or contrary to the clinical judgment of prescriber: maximally tolerated doses of levodopa in combination with carbidopa, a COMT inhibitor, a dopamine agonist, a MAO-B inhibitor, and amantadine. • Must be able to administer the medication and correctly use the delivery system. Alternatively, trained personnel or a care partner must be available to perform these tasks reliably. <p>Exclusion Criteria:</p> <ul style="list-style-type: none"> • Patients with severe psychosis or severe dementia. 				

New Exception Status Benefit Continued...

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Vyalev (foslevodopa-foscarbidopa)	240mg/12mg/mL SC Sol	02537702	DNP	E (SF)	ABV
Criteria	<p>Renewal:</p> <ul style="list-style-type: none"> Patients continue to demonstrate a significant reduction in the time spent in the off state and/or in ongoing levodopa-induced dyskinesias, along with an improvement in the related disability. <p>Claim Note:</p> <ul style="list-style-type: none"> Must be prescribed by neurologists who are movement disorder subspecialists or who have expertise in managing advanced PD. Approval period: 1 year 				

Criteria Updates

The following new indication has been added to existing criteria effective **August 1, 2024**.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Nucala (mepolizumab)	100mg/mL Prefilled Autoinjector	02492989	DNP	E (SF)	GSK
	100mg/mL Prefilled Syringe	02492997	DNP	E (SF)	GSK
Criteria	<p>For the treatment of patients with severe chronic rhinosinusitis with nasal polyps (CRSwNP) who meet all of the following criteria:</p> <ul style="list-style-type: none"> have endoscopically or CT-documented bilateral nasal polyps, and have undergone at least 1 prior surgical intervention for nasal polyps or have a contraindication to surgery, and are tolerant and able to continue use of inhaled nasal corticosteroids but have refractory symptoms despite use of inhaled corticosteroids for 3 months at maximally tolerated doses. <p>Renewal Criteria:</p> <ul style="list-style-type: none"> Requests for renewal must exhibit a clinically meaningful response defined as: <ul style="list-style-type: none"> a decrease of 8.9 points or greater on the Sino-nasal Outcome Test (SNOT-22) relative to their baseline score, or a decrease of 1 point or greater on the endoscopic Nasal Polyp Score (NPS) relative to their baseline score. <p>Clinical Notes:</p> <ul style="list-style-type: none"> A baseline and annual SNOT-22 or endoscopic NPS must be provided. Patients should be assessed for a response to mepolizumab every 12 months. 				

Criteria Updates Continued...

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Nucala (mepolizumab)	100mg/mL Prefilled Autoinjector	02492989	DNP	E (SF)	GSK
	100mg/mL Prefilled Syringe	02492997	DNP	E (SF)	GSK
Criteria	<ul style="list-style-type: none"> Maximum dose approved: 100mg every 4 weeks Renewal Approval: 12 months. <p>Claim Notes:</p> <ul style="list-style-type: none"> Must be prescribed by an otolaryngologist, allergist or respirologist with expertise in managing severe CRSwNP 				

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

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Vfend and generics (voriconazole)	50mg Tab	Various	DNP	E (SFC)	VAR
	200mg Tab	Various	DNP	E (SFC)	VAR
Criteria	<ul style="list-style-type: none"> For the management of invasive aspergillosis [Criteria Code 01] For the treatment of culture proven invasive candidiasis with documented resistance to fluconazole [Criteria Code 02] <p>Claim Notes:</p> <ul style="list-style-type: none"> Must be prescribed by a hematologist or specialist in infectious diseases or medical microbiology. Initial requests will be approved for a maximum of 3 months. 				

New Products

Effective **August 1, 2024**, the following products have been added to the Nova Scotia Formulary.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Potassium Chloride	100mg/mL Liq	Various	DNP	SFC	VAR

Pharmacy Guide Update

A minor update to the [Pharmacy Guide](#) was published on July 9, 2024: under Exception Status Drugs, modified reference to Arazlo 0.045% lotion not requiring prior approval for beneficiaries to indicate only for those under the age of 30.



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Nova Scotia Formulary Updates

Pharmacists' Administration of Pneumococcal Vaccine to Prevent Pneumococcal Disease

New Exception Status Benefits

- Livtency (maribavir)
- Oxlumo (lumasiran)
- Posaconazole (Posanol)

Criteria Updates

- Lonsurf (trifluridine/tipiracil)
- Lynparza (olaparib)
- Rinvoq (upadacitinib)

Change in Benefit Status

Nova Scotia Formulary Updates

Pharmacists' Administration of Pneumococcal Vaccine to Prevent Pneumococcal Disease

Effective September 1, 2024, the Nova Scotia Department of Health and Wellness (DHW) has approved funding for pharmacies to administer immunizations of pneumococcal conjugate vaccine (PCV20) to Nova Scotia residents 65 years and older who have not previously received a pneumococcal vaccine per the routine vaccination schedule [Routine-Immunization-Schedules-for-Children-Youth-Adults.pdf \(novascotia.ca\)](https://novascotia.ca/health/immunization/schedules-for-children-youth-adults.pdf).

PCV20 is a newer conjugate vaccine which is more effective, offers longer duration of protection, and allows for immune boosting compared to the older polysaccharide vaccine (PPV23). As the publicly funded pneumococcal vaccine is available free of charge to adults 65 years and older not previously vaccinated with a pneumococcal vaccine, no individual is to be charged for the vaccine.

The service fee for each dose of the vaccine is \$18.00. The fee applies to PCV20 vaccines administered by licensed pharmacists and any self-regulated health professional administering the vaccine under a pharmacist's direction and supervision when performed in compliance with the regulations and standards of practice.

Pharmacies will not submit individual claims for payment via the pharmacare adjudication system. All PCV 20 administrations will be entered into CANImmunize Clinic Flow and pharmacies will be reimbursed in the same manner as COVID-19 and Flu vaccines. DHW will use the Clinic Flow system to generate reports indicating the immunization volumes for each pharmacy based on the pharmacy's active license number with the immunization volumes for each pharmacy based on the pharmacy's active license number. DHW submits these reports to Medavie and payments are processed on a bi-weekly basis within two pay periods of report submission. The payments appear as a bottom-line adjustment on each pharmacy's pay statement, labelled as "PHV" with a date range for when the immunizations occurred. Any questions about payment can be directed to Medavie Blue Cross through the Pharmacare phone line at 1-800-305-5026.

Pharmacists' Administration of Pneumococcal Vaccine to Prevent Pneumococcal Disease Continued...

To ensure accurate and timely payment, all vaccines must be recorded in CANImmunize on the same day as administration. A delay in data entry may result in missed payments. If your pharmacy is issued a new licence number, you must update the licence number in CANImmunize Clinic Flow to ensure payments for vaccinations can be processed. Incorrect or inactive license numbers will result in payments not being processed.

New Exception Status Benefits

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

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Livtency (maribavir)	200mg Tab	02530740	DNP	E (SF)	TAK
Criteria	<p>For the treatment of adult patients with post-transplant cytomegalovirus (CMV) infection/disease who are refractory¹ (with or without genotypic resistance) to 1 or more of the following antiviral therapies: valganciclovir, ganciclovir, foscarnet, or cidofovir.</p> <p>¹Refractory to an antiviral is defined as a lack of change in CMV viral load or increase in CMV viral load after at least 2 weeks of appropriately dosed treatment.</p> <p>Renewal Criteria:</p> <ul style="list-style-type: none"> Subsequent treatment may be considered for patients who have a recurrence of CMV viremia after a previous successful course of therapy with maribavir. <p>Discontinuation Criteria:</p> <ul style="list-style-type: none"> Patients exhibit any of the following: <ul style="list-style-type: none"> No change or an increase in CMV viral load after at least 2 weeks of maribavir treatment; OR Confirmed CMV genetic mutation associated with resistance to maribavir. <p>Claim Notes:</p> <ul style="list-style-type: none"> Must be prescribed by clinicians with experience and expertise in transplant medicine, transplant infectious disease, or infectious diseases. Approvals: 6 month 				

New Exception Status Benefits Continued...

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR												
Oxlumo (lumasiran)	94.5mg/0.5mL Vial	02525755	DNP	E (SF)	ALN												
Criteria	<p>For the treatment of pediatric and adult patients with primary hyperoxaluria type 1 (PH1) to lower urinary oxalate levels who meet the following criteria:</p> <ul style="list-style-type: none"> A confirmed genetic diagnosis of PH1. In whom urinary oxalate can be measured must be unable to normalize urine oxalate excretion while staying compliant with standard of care therapy, including vitamin B6 for a duration of 3 to 6 months. <p>Renewal Criteria:</p> <ul style="list-style-type: none"> Has not undergone a liver transplant with or without a kidney transplant. Has not shown evidence of loss of response or no response, defined as lowering 24-hour urine oxalate to less than 1.5 times the ULN or patients in whom urinary oxalate can be measured. <p>Claim Notes:</p> <ul style="list-style-type: none"> Must be initially prescribed by a nephrologist or metabolic diseases specialist with experience in the diagnosis and management of PH1. Renewals can be through a pediatrician instead of nephrologist or metabolic diseases physician. Approvals will be for a maximum of: <table border="1"> <thead> <tr> <th>Body Weight Range (kg)</th> <th>Loading Dose</th> <th>Maintenance Dose</th> </tr> </thead> <tbody> <tr> <td>Less than 10 kg</td> <td>6mg/kg once monthly for 3 doses</td> <td>3 mg/kg once monthly, beginning 1 month after the last loading dose.</td> </tr> <tr> <td>10 kg to less than 20 kg</td> <td>6mg/kg once monthly for 3 doses</td> <td>6 mg/kg once every 3 months: give the first maintenance dose 1 month after the last loading dose and quarterly thereafter</td> </tr> <tr> <td>20 kg and above</td> <td>3mg/kg once monthly for 3 doses</td> <td>3 mg/kg once every 3 months: give the first maintenance dose 1 month after the last loading dose and quarterly thereafter.</td> </tr> </tbody> </table> <ul style="list-style-type: none"> Initial Approval: 6 months Renewals: 12 months 					Body Weight Range (kg)	Loading Dose	Maintenance Dose	Less than 10 kg	6mg/kg once monthly for 3 doses	3 mg/kg once monthly, beginning 1 month after the last loading dose.	10 kg to less than 20 kg	6mg/kg once monthly for 3 doses	6 mg/kg once every 3 months: give the first maintenance dose 1 month after the last loading dose and quarterly thereafter	20 kg and above	3mg/kg once monthly for 3 doses	3 mg/kg once every 3 months: give the first maintenance dose 1 month after the last loading dose and quarterly thereafter.
Body Weight Range (kg)	Loading Dose	Maintenance Dose															
Less than 10 kg	6mg/kg once monthly for 3 doses	3 mg/kg once monthly, beginning 1 month after the last loading dose.															
10 kg to less than 20 kg	6mg/kg once monthly for 3 doses	6 mg/kg once every 3 months: give the first maintenance dose 1 month after the last loading dose and quarterly thereafter															
20 kg and above	3mg/kg once monthly for 3 doses	3 mg/kg once every 3 months: give the first maintenance dose 1 month after the last loading dose and quarterly thereafter.															

New Exception Status Benefits Continued...

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Posaconazole (Posanol)	100mg DR Tab	Various	DNP	E (SFC)	VAR
Criteria	<p>For the prevention of invasive fungal infection (IFI) in allogeneic stem cell transplant recipients with a contraindication or intolerance to voriconazole.</p> <ul style="list-style-type: none"> From time of engraftment until day +90 <p>OR</p> <ul style="list-style-type: none"> With graft versus host disease (GVHD) taking prednisone 1 mg/kg/day or more, until dose is less than 20 mg/day. 				

Criteria Updates

The following new indications have been added to existing criteria effective **September 1, 2024**.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Lonsurf (trifluridine/tipiracil)	15mg/6.14mg Tab	02472104	DNP	E (SFC)	TAI
Criteria	<p>20mg/8.19mg Tab</p> <p>02472112</p> <p>DNP</p> <p>E (SFC)</p> <p>TAI</p> <p>In combination with bevacizumab for the treatment of adult patients with unresectable or metastatic colorectal cancer who:</p> <ul style="list-style-type: none"> Have previously been treated with, or are not candidates for, available therapies including fluoropyrimidine-, oxaliplatin, and irinotecan-based chemotherapies, anti-VEGF biological agents, and, if RAS wild-type, anti-EGFR agents; and Have disease progression or demonstrated intolerance to a maximum of 2 prior chemotherapy regimens for the treatment of unresectable or metastatic colorectal cancer. <p>Clinical Notes:</p> <ul style="list-style-type: none"> 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. Patients who were unable to receive bevacizumab in a prior line of therapy due to a contraindication will be eligible. Patients who have received adjuvant/neoadjuvant chemotherapy and had recurrence during or within 6 months of completion can count the adjuvant/neoadjuvant therapy as 1 of the maximum of 2 required prior chemotherapy regimens. <p>If bevacizumab is discontinued due to intolerance or contraindication, trifluridine-tipiracil can be continued at the discretion of the physician</p>				

Criteria Updates Continued...

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Lynparza (olaparib)	100mg Tab	02475200	DNP	E (SFC)	AZE
	150mg Tab	02475219	DNP	E (SFC)	AZE
Criteria	<p>In combination with abiraterone and prednisone for the first-line treatment of adult patients with deleterious or suspected deleterious germline and/or somatic BRCA-mutated metastatic castration-resistant prostate cancer (mCRPC) in whom chemotherapy is not clinically indicated.</p> <p>Clinical Notes:</p> <ul style="list-style-type: none"> • Patients should have a good performance status. • Treatment should continue until disease progression or unacceptable toxicity. • Eligible patients must have a confirmed germline and/or somatic BRCA1 or BRCA2 gene alteration prior to starting treatment. • Patients should not have received prior treatment with a poly - (ADP ribose) polymerase (PARP) inhibitor, or with androgen-receptor-axis-targeted (ARAT) therapy (e.g., apalutamide, darolutamide, enzalutamide). • Patients should not have received prior treatment with abiraterone, or are within 4 months of initiating abiraterone in the mCRPC setting with no disease progression. 				

The following new indications and strength have been added to existing criteria, effective **September 1, 2024**.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Rinvoq (upadacitinib)	15mg Tab	02495155	DNP	E (SF)	ABV
	30mg Tab	02520893	DNP	E (SF)	ABV
	45mg Tab	02539721	DNP	E (SF)	ABV
Criteria	<p>Crohn Disease</p> <ul style="list-style-type: none"> • For the treatment of patients with moderately to severely active Crohn's disease who are refractory to, intolerant or have contraindications to corticosteroids and other immunosuppressive therapy. <p>Clinical Notes:</p> <ul style="list-style-type: none"> • 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 to treatments. The nature of intolerance(s) must be clearly documented. <p>Claim Notes:</p> <ul style="list-style-type: none"> • Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology. • Combined use with other biologic drugs or janus kinase (JAK) inhibitors will not be reimbursed. 				

Criteria Updates Continued...

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Rinvoq (upadacitinib)	15mg Tab	02495155	DNP	E (SF)	ABV
	30mg Tab	02520893	DNP	E (SF)	ABV
	45mg Tab	02539721	DNP	E (SF)	ABV
Criteria	<ul style="list-style-type: none"> Initial reimbursement will be for an induction dose of 45mg once daily, with a clinical response to be assessed prior to week 12. Subsequent reimbursement for maintenance dosing will be for a maximum dose of up to 30mg once daily. Initial Approval: 12 weeks Renewal Approval: 1 year <p>Ulcerative Colitis</p> <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> a decrease in the partial Mayo score ≥ 2 from baseline, AND a decrease in the rectal bleeding subscore ≥ 1. <p>Clinical Notes:</p> <ul style="list-style-type: none"> 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. <p>Claim Notes:</p> <ul style="list-style-type: none"> Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology. Combined use with biologic drugs or other JAK inhibitors will not be reimbursed. Initial Approval: 8 weeks at a maximum dose of 45mg once daily Renewal Approval: 1 year at a maximum dose of 30mg once daily. 				

Criteria Updates Continued...

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Rinvoq (upadacitinib)	15mg Tab	02495155	DNP	E (SF)	ABV
	30mg Tab	02520893	DNP	E (SF)	ABV
	45mg Tab	02539721	DNP	E (SF)	ABV
Criteria	<p>Ankylosing Spondylitis</p> <ul style="list-style-type: none"> For treatment of patients with moderate to severe ankylosing spondylitis (Bath AS Disease Activity Index (BASDAI) score ≥ 4 on 10 point scale) who are refractory to, intolerant or have contraindications to a biologic disease-modifying antirheumatic drug (bDMARD). <p>Renewal Criteria:</p> <ul style="list-style-type: none"> A decrease of at least 2 points on the BASDAI scale, compared with the pre-treatment score; OR Patient and expert opinion of an adequate clinical response as indicated by a significant functional improvement (measured by outcomes such as HAQ or "ability to return to work"). <p>Clinical Notes:</p> <ul style="list-style-type: none"> 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 to treatments. The nature of intolerance(s) must be clearly documented. <p>Claim Notes:</p> <ul style="list-style-type: none"> Must be prescribed by a rheumatologist or prescriber with a specialty in rheumatology. Combined use with biologic drugs or other JAK inhibitors will not be reimbursed. Approvals will be for a maximum of 15 mg daily. Initial Approval: 6 months Renewal Approval Period: 1 year. 				

Change in Benefit Status

Effective **September 1, 2024**, the following products will move to full benefit and no longer require exception status approval.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Almotriptan	12.5mg Tab	Various	DNP	SF	VAR

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Nova Scotia Formulary Updates

New Exception Status Benefits

- Jubbonti (denosumab)
- Wyost (denosumab)
- Camzyos (mavacamten)
- Verquvo (vericiguat)

Criteria Update

- Cosentyx (secukinumab)

Change in Benefit Status

New Benefits

Nova Scotia Formulary Updates

New Exception Status Benefits

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

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Jubbonti (denosumab)	60mg/mL Prefilled Syringe	02545411	DNP	E (SFC)	SDZ
Criteria	<p>Effective October 1, 2024, patients currently taking the originator drug product Prolia, are required to switch to a biosimilar version by October 1, 2025.</p> <p>For denosumab-naïve patients whose therapy is initiated after October 1, 2024, a denosumab biosimilar will be the product approved.</p> <p>For the treatment of osteoporosis in postmenopausal women and in men who meet the following criteria:</p> <ul style="list-style-type: none"> • Have a contraindication to oral bisphosphonates; and • High risk for fracture, or refractory or intolerant to other available osteoporosis therapies. <p>Clinical Notes:</p> <ul style="list-style-type: none"> • Refractory is defined as a fragility fracture or evidence of a decline in bone mineral density below pre-treatment baseline levels, despite adherence for one year to other available osteoporosis therapies. • High fracture risk is defined as: <ul style="list-style-type: none"> ○ Moderate 10-year fracture risk (10% to 20%) as defined by the Canadian Association of Radiologists and Osteoporosis Canada (CAROC) tool or the World Health Organization's Fracture Risk Assessment (FRAX) tool with a prior fragility fracture; or ○ High 10-year fracture risk ($\geq 20\%$) as defined by the CAROC or FRAX tool. 				

New Exception Status Benefits Continued...

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Wyost (denosumab)	120mg/1.7mL Vial	02545764	DNP	E (SFC)	SDZ
Criteria	<p>Effective October 1, 2024, patients currently taking the originator drug product Xgeva, are required to switch to a biosimilar version by April 1, 2025.</p> <p>For denosumab-naïve patients whose therapy is initiated after October 1, 2024, a denosumab biosimilar will be the product approved.</p> <p>As a single agent for the prevention of skeletal related events (SREs) for metastatic castrate resistant prostate cancer (CRPC) patients with one or more documented bone metastases and ECOG performance status (PS) 0-2.</p>				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Camzyos (mavacamten)	2.5mg Cap	02532549	DNP	E (SF)	BRI
	5mg Cap	02532557	DNP	E (SF)	BRI
	10mg Cap	02532565	DNP	E (SF)	BRI
	15mg Cap	02532573	DNP	E (SF)	BRI
Criteria	<p>For the treatment of patients with of symptomatic obstructive hypertrophic cardiomyopathy (oHCM) of New York Heart Association (NYHA) class II to III who meet all of the following criteria:</p> <ul style="list-style-type: none"> documented left ventricular ejection fraction (LVEF) \geq 55% at rest determined by echocardiography. left ventricular (LV) wall thickness \geq15 mm (or \geq13 mm with a family history of hypertrophic cardiomyopathy). left ventricular outflow tract (LVOT) peak gradient \geq 50 mm Hg at rest, after Valsalva maneuver, or post exercise, as confirmed by echocardiography. must be receiving beta-blocker or calcium channel blocker therapy and experience clinical deterioration in symptoms or echocardiography while receiving either of these treatments or for patients who have an intolerance or contraindication to treatments, details must be provided. <p>Renewal Criteria:</p> <p>Patients must not have any of the following:</p> <ul style="list-style-type: none"> a LVEF \leq 30% received septal reduction therapy. <p>Claim Notes:</p> <ul style="list-style-type: none"> Must be prescribed by, or in consultation with a specialist in cardiology. Approvals will be for a maximum of up to 5mg daily for 12 weeks, then up to 15mg daily thereafter. Initial Approval: 12 weeks. Renewal Approval: 1 year. 				

New Exception Status Benefits Continued...

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Verquvo (vericiguat)	2.5mg Tab	02537044	DNP	E (SF)	BAY
	5mg Tab	02537060	DNP	E (SF)	BAY
	10mg Tab	02537052	DNP	E (SF)	BAY
Criteria	<p>For the treatment of patients with symptomatic chronic heart failure (HF) as an adjunct to standard-of-care (SOC) therapy with reduced ejection fraction who are stabilized after a recent HF decompensation who meet all of the following criteria:</p> <ul style="list-style-type: none"> patients with symptomatic chronic HF with reduced ejection fraction (i.e., left ventricular ejection fraction <45%) AND patients must have a recent HF decompensation event requiring hospitalization and/or IV diuretic therapy. <p>Clinical Notes:</p> <ul style="list-style-type: none"> SOC includes beta blockers, angiotensin-converting enzyme inhibitors (ACEis), angiotensin receptor blockers (ARBs), angiotensin receptor-neprilysin inhibitor (ARNI), sodium-glucose co-transporter 2 inhibitor (SGLT2i), and a mineralocorticoid receptor antagonist (MRA) unless these therapies are contraindicated or not tolerated. 				

Criteria Update

The following criteria has been updated effective **October 1, 2024** and applies to the following new and existing products.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Cosentyx (secukinumab)	75mg/0.5mL Prefilled Syringe	02525569	DNP	E (SF)	NVR
	150mg/mL Prefilled Pen	02438070	DNP	E (SF)	NVR
	150mg/mL Prefilled Syringe	02547724	DNP	E (SF)	NVR
	300mg/dose Kit (two 150mg/mL Prefilled Pens)	02438070	DNP	E (SF)	NVR
	300mg/dose Kit (two 150mg/mL Prefilled Syringes)	02547724	DNP	E (SF)	NVR
Criteria	<p>Psoriasis</p> <p>For the treatment of patients 6 years of age or older with chronic moderate to severe plaque psoriasis who meet all of the following:</p> <ul style="list-style-type: none"> Psoriasis Area Severity Index (PASI) greater than 10 and Dermatology Life Quality Index (DLQI) greater than 10, OR major involvement of visible areas, scalp, genitals, or nails; Refractory, intolerant to or unable to access phototherapy; Refractory, intolerant to or have contraindications to methotrexate (oral or parenteral) at a dose of greater than or equal to 20 mg weekly (greater than or equal to 15 mg if patient is 65 years of age or older) for a minimum of 12 weeks. 				

Criteria Update Continued...

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Cosentyx (secukinumab)	75mg/0.5mL Prefilled Syringe	02525569	DNP	E (SF)	NVR
	150mg/mL Prefilled Pen	02438070	DNP	E (SF)	NVR
	150mg/mL Prefilled Syringe	02547724	DNP	E (SF)	NVR
	300mg/dose Kit (two 150mg/mL Prefilled Pens)	02438070	DNP	E (SF)	NVR
	300mg/dose Kit (two 150mg/mL Prefilled Syringes)	02547724	DNP	E (SF)	NVR
Criteria	<p>Clinical Notes:</p> <ul style="list-style-type: none"> For patients who do not demonstrate a clinical response to oral methotrexate, or who experience gastrointestinal intolerance, a trial of parenteral methotrexate may be considered if clinically appropriate. 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 to treatments. The nature of intolerance(s) must be clearly documented. For patients aged 6 to 16, a Children's Dermatology Life Quality Index (CDLQI) greater than 7 will be considered. For pediatric patients an adequate trial of a weight-based appropriate dose of methotrexate will be considered. <p>Claim Notes:</p> <ul style="list-style-type: none"> Must be prescribed by a dermatologist or prescriber with a specialty in dermatology. Combined use of more than one biologic will not be reimbursed. For pediatric patients weighing less than 50 kg, approvals will be for a maximum of 75mg given at weeks 0, 1, 2, 3, and 4, then monthly. Approvals will be for a maximum of 300 mg given at weeks 0, 1, 2, 3, and 4, then monthly. Initial Approval: 16 weeks. Renewal Approval: 1 year. 				

Change in Benefit Status

Effective **October 1, 2024**, the following product will move to full benefit and no longer require exception status approval.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Fosfomycin	3g Sachet	Various	DNP	SFC*	VAR

* Quantity limit of 3 doses annually without special authorization. Prescribers may submit a request for consideration should beneficiaries require more than 3 doses annually.

Change in Benefit Status Continued...

Effective **October 1, 2024**, the following product will be delisted.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Albrioza	3g/1g Sachet	02527707	N/A	Not Insured	ALY

New Benefits

Effective **October 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
Amlodipine	2.5 Tab	02478587	DNP	SF	SAS
Lactulose	667mg/mL O/L	02412268	DNP	E (SFC)	SAS
PRZ-K8	600mg Tab	80108882	DNP	SFC	PRZ
PRZ K20	1500mg Tab	80107649	DNP	SFC	PRZ
Vyepti	300mg/3mL IV	02542269	DNP	E (SF)	LBK

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Criteria Updates

- Maviret (glecaprevir/pibrentasvir)
- Cabometyx (cabozantinib)
- Inlyta (axitinib)
- Lenvima (lenvatinib)
- Qulipta (atogepant)

Change in Benefit Status

Nova Scotia Formulary Updates

Criteria Updates

The following criteria has been updated effective **November 1, 2024** and applies to the following new and existing products.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Maviret	100mg/40mg Tab	02467550	DNP	E (SF)	ABV
(glecaprevir/pibrentasvir)	50mg/20mg Sachet	02522470	DNP	E (F)	ABV
Criteria	<ul style="list-style-type: none"> • For treatment-naïve or treatment-experienced patients aged 3 and older with chronic hepatitis C virus (HCV) with a confirmed quantitative HCV RNA value within the last 12 months. 				
	Genotypes 1, 2, 3, 4, 5 or 6 <ul style="list-style-type: none"> • Treatment-naïve 		8 weeks		
	Genotypes 1, 2, 4, 5 or 6 <ul style="list-style-type: none"> • Treatment-experienced with regimens containing peginterferon/ribavirin (PR) and/or sofosbuvir (SOF) 		8 weeks (12 weeks with cirrhosis)		
	Genotype 1 <ul style="list-style-type: none"> • NS5A inhibitor treatment-naïve and treatment-experienced with regimens containing: <ul style="list-style-type: none"> - Boceprevir/PR; or - Simeprevir (SMV)/SOF; or - SMV/PR; or - Telaprevir/PR 		12 weeks		

Criteria Updates Continued...

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Maviret (glecaprevir/ pibrentasvir)	100mg/40mg Tab	02467550	DNP	E (SF)	ABV
	50mg/20mg Sachet	02522470	DNP	E (F)	ABV
Criteria	<p>Genotype 1</p> <ul style="list-style-type: none"> NS3/4A inhibitor treatment-naïve and treatment-experienced with regimens containing: <ul style="list-style-type: none"> - Daclatasvir (DCV)/SOF; or - DCV/PR; or - Ledipasvir/SOF 		16 weeks		
	<p>Genotype 3</p> <ul style="list-style-type: none"> Treatment-experienced with regimens containing PR and/or SOF 		16 weeks		
<p>The following information is also required:</p> <ul style="list-style-type: none"> Lab-confirmed hepatitis C genotype 1, 2, 3, 4, 5 or 6 Quantitative HCV RNA value within the last 6 months <p>Claim Notes:</p> <ul style="list-style-type: none"> Must be prescribed by a hepatologist, gastroenterologist, or infectious disease specialist (or other physician experienced in treating a patient with hepatitis C infection). Sachets will only be considered for pediatric patients 3 years of age and older weighing between 12 kg and 45 kg. Claims that exceed the maximum claim amount of \$9,999.99 must be divided and submitted as separate transactions using the following PINs: <ul style="list-style-type: none"> 100mg/40mg Tablet <ul style="list-style-type: none"> 00904394 00904395 50mg/20mg Sachet <ul style="list-style-type: none"> 00904885 Claims will be limited to a 28-day supply. [Criteria Code 34] has been added to allow payment of a patient's initial 28 day supply only. Criteria code 34 should be provided by the prescribing physician only. 					

Criteria Updates Continued...

The following criteria has been updated and will replace existing criteria effective **November 1, 2024**.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Cabometyx (cabozantinib)	20mg Tab	02480824	DNP	E (SFC)	IPS
	40mg Tab	02480832	DNP	E (SFC)	IPS
	60mg Tab	02480840	DNP	E (SFC)	IPS
Criteria	<p>Advanced or Metastatic Renal Cell Carcinoma</p> <p>For the treatment of patients with advanced (not amenable to curative surgery or radiation therapy) or metastatic renal cell carcinoma when used as:</p> <ul style="list-style-type: none"> • First-line therapy in combination with nivolumab • Second-line monotherapy following disease progression on: <ul style="list-style-type: none"> ○ vascular endothelial growth factor receptor (VEGFR) tyrosine kinase inhibitor (TKI) (i.e., sunitinib or pazopanib); or ○ pembrolizumab in combination with either axitinib or lenvatinib • Third-line monotherapy following disease progression on: <ul style="list-style-type: none"> ○ first-line VEGFR TKI (i.e., sunitinib or pazopanib) and second-line nivolumab monotherapy; or ○ first-line nivolumab in combination with ipilimumab and second-line VEGFR TKI (i.e., sunitinib or pazopanib) <p>Clinical Notes:</p> <ul style="list-style-type: none"> • 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 treated with immunotherapy in the adjuvant setting will be eligible for nivolumab in combination with cabozantinib provided that there has been a 6-month interval between the completion of immunotherapy and metastatic disease. • Sequential use of axitinib (as monotherapy) and cabozantinib is not permitted except in the case of intolerance or contraindication. 				

Criteria Updates Continued...

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Inlyta (axitinib)	1mg Tab	02389630	DNP	E (SFC)	PFI
	5mg Tab	02389649	DNP	E (SFC)	PFI
Criteria	<p>Advanced or Metastatic Renal Cell Carcinoma</p> <p>For the treatment of patients with advanced (not amenable to curative surgery or radiation therapy) or metastatic renal cell carcinoma when used as:</p> <ul style="list-style-type: none"> • First-line therapy in combination with pembrolizumab • Second-line monotherapy following disease progression on: <ul style="list-style-type: none"> ○ vascular endothelial growth factor receptor (VEGFR) tyrosine kinase inhibitor (TKI) (i.e., sunitinib or pazopanib); or ○ pembrolizumab in combination with lenvatinib or nivolumab in combination with cabozantinib • Third-line monotherapy following disease progression on: <ul style="list-style-type: none"> ○ first-line nivolumab in combination with ipilimumab and second-line VEGFR TKI (i.e., sunitinib or pazopanib) <p>Clinical Notes:</p> <ul style="list-style-type: none"> • Patients should have a good performance status. • Treatment should continue until disease progression or unacceptable toxicity. • Patients treated with immunotherapy in the adjuvant setting will be eligible for pembrolizumab in combination with axitinib provided that there has been a 6-month interval between the completion of immunotherapy and metastatic disease. • Requests for axitinib will not be considered for patients who experience disease progression on cabozantinib monotherapy, nivolumab monotherapy, or everolimus. 				

Criteria Updates Continued...

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Lenvima (lenvatinib)	Various	Various	DNP	E (SFC)	EIS
Criteria	<p>Advanced or Metastatic Renal Cell Carcinoma</p> <p>In combination with pembrolizumab for the treatment of adult patients with advanced (not amenable to curative surgery or radiation therapy) or metastatic renal cell carcinoma who have not had prior systemic therapy for metastatic disease.</p> <p>Clinical Notes:</p> <ul style="list-style-type: none"> • Patients should have a good performance status. • Treatment should continue until disease progression or unacceptable toxicity (can be continued as monotherapy after completing 2 years of combination therapy with pembrolizumab). • If pembrolizumab or lenvatinib is discontinued for toxicity, the other agent can be continued at the discretion of the physician. • Patients treated with immunotherapy in the adjuvant setting will be eligible provided that there has been a 6-month interval between the completion of immunotherapy and metastatic disease. • If patient requires and qualifies for re-treatment with pembrolizumab, lenvatinib may also be given at the discretion of the treating physician. • Funding is limited to one line of immunotherapy for patients with advanced or metastatic RCC. 				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Qulipta (atogepant)	10mg Tab	02533979	DNP	E (SF)	ABV
	30mg Tab	02533987	DNP	E (SF)	ABV
	60mg Tab	02533995	DNP	E (SF)	ABV
Criteria	<p>Initiation:</p> <p>For the treatment of patients with episodic¹ or chronic migraine², who have experienced an inadequate response, intolerance, or contraindication to at least two oral prophylactic migraine medications of different classes.</p> <p>Renewal:</p> <ul style="list-style-type: none"> • Proof of beneficial clinical effect, defined as a reduction of at least 50% in the average number of migraine days per month at the time of first renewal compared with baseline. • For subsequent renewals, proof that the initial 50% reduction in the average number of migraine days per month has been maintained. 				

Criteria Updates Continued...

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Qulipta (atogepant)	10mg Tab	02533979	DNP	E (SF)	ABV
	30mg Tab	02533987	DNP	E (SF)	ABV
	60mg Tab	02533995	DNP	E (SF)	ABV
Criteria	<p>Clinical Notes:</p> <ul style="list-style-type: none"> Baseline number of headache and migraine days per month must be provided at the time of initial request. ¹Episodic migraine: migraine headaches on at least 4 days per month and less than 15 headache days per month for more than 3 months. ²Chronic migraine: headaches for at least 15 days per month for more than 3 months of which at least eight days per month are with migraine. <p>Claim Notes:</p> <ul style="list-style-type: none"> Initial approval: 6 months Renewal approval: 1 year Must be prescribed by a physician who has experience in the management of migraine headaches. 				

Change in Benefit Status

Effective **November 1, 2024**, the following products will move to full benefit and no longer require exception status approval.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Azithromycin	250mg Tab	Various	DNP	SFC	VAR
Azithromycin	100mg/5mL Susp	Various	DNP	SFC	VAR
Azithromycin	200 mg/5mL Susp	Various	DNP	SFC	VAR

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- Omvoh (mirikizumab)

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New Benefit

Change in Benefit Status

Nova Scotia Formulary Updates

New Exception Status Products

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

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Omvoh (mirikizumab)	20mg/mL Vial	02539861	DNP	E (SF)	LIL
	100mg/mL Prefilled Syringe	02539853	DNP	E (SF)	LIL
	100mg/mL Prefilled Pen	02539845	DNP	E (SF)	LIL

Criteria

- For the treatment of adult 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
 - 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.

New Exception Status Products Continued...

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
OmvoH (mirikizumab)	20mg/mL Vial	02539861	DNP	E (SF)	LIL
	100mg/mL Prefilled Syringe	02539853	DNP	E (SF)	LIL
	100mg/mL Prefilled Pen	02539845	DNP	E (SF)	LIL
Criteria	<ul style="list-style-type: none"> 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. <p>Claim Notes:</p> <ul style="list-style-type: none"> Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology. Combination therapy with biologic therapies or JAK inhibitors for UC will not be reimbursed. Initial Approval: 6 months Renewal Approval: 1 year. Confirmation of continued response is required. Initial reimbursement will be 300mg at Weeks 0, 4 and 8. If patients do not have adequate therapeutic response at Week 12, 300mg will be reimbursed at Weeks 12, 16 and 20. Subsequent reimbursement for maintenance dosing is 200mg every 4 weeks. 				

Coverage Period Updates for Multiple Sclerosis Medications

Effective December 1, 2024:

Dimethyl fumarate (Tecfidera), fingolimod (Gilenya), Tysabri, Ocrevus, Kesmipta, Mayzant & teriflunomide (Aubagio)

- Initial approval period: 2 years
- Renewal approval period: 5 years

Glatiramer (Copaxone), Avonex, Rebif & Betaseron

- Initial approval period: 2 years
- Renewal approval period: Long term

Nova Scotia Biosimilar Initiative Reminder: Lantus

Lantus cartridges will be covered for those 17 or younger who require ½ unit dosing.

Cystic Fibrosis Program Updates

The following product is not funded in the Pharmacare Programs; however, it is funded through the Cystic Fibrosis Program with specific criteria, effective **November 8, 2024**.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Orkambi	94mg/75mg Sachet	02537087	N/A	Non Insured	VTX

Trikafta Criteria Update

Effective **November 8, 2024**, funding for Trikafta has been expanded to include patients with at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to Trikafta based on clinical and/or in vitro data.

New Benefit

Effective **December 1, 2024**, the following product will be added as a benefit in the Nova Scotia Formulary. The benefit status within the Pharmacare Programs is indicated.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Slynd	4mg Tab	02522802	DNP	F	DUI

Change in Benefit Status

Effective **December 1, 2024**, the following product will be delisted as a benefit under the Pharmacare Programs.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Jamp-Prasugrel	10mg Tab	02502429	N/A	Non Insured	JPC



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- Akeega (niraparib and abiraterone acetate)
- Steqeyma (ustekinumab)
- Vraylar (cariprazine)

New Benefits

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New Exception Status Products

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

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Akeega (niraparib and abiraterone acetate)	50mg/500mg Tablet	02538555	DNP	E (SFC)	JAN
	100mg/500mg Tablet	02538563	DNP	E (SFC)	JAN

Criteria

In combination with prednisone for the first-line treatment of adult patients with deleterious or suspected deleterious germline and/or somatic BRCA-mutated metastatic castration-resistant prostate cancer (mCRPC) in whom chemotherapy is not clinically indicated.

Clinical Notes:

- Patients should have a good performance status.
- Treatment should continue until disease progression or unacceptable toxicity.
- Eligible patients must have a confirmed germline and/or somatic BRCA1 or BRCA2 gene alteration prior to starting treatment.
- Patients should not have received prior treatment with a poly-(ADP ribose) polymerase (PARP) inhibitor, or with androgen-receptor-axis-targeted (ARAT) therapy (e.g., apalutamide, darolutamide, enzalutamide).
- Patients should not have received prior treatment with abiraterone or are within 4 months of initiating abiraterone in the mCRPC setting with no disease progression.

New Exception Status Products Continued...

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Steqeyma (ustekinumab)	45mg/0.5mL Prefilled Syringe	02550245	DNP	E (SF)	CLT
	90mg/1.0mL Prefilled Syringe	02550253	DNP	E (SF)	CLT
	130mg/26mL Vial	02550261	DNP	E (SF)	CLT
Criteria	<p>Plaque Psoriasis</p> <p>For the treatment of patients with chronic moderate to severe plaque psoriasis who meet all of the following:</p> <ul style="list-style-type: none"> • Psoriasis Area Severity Index (PASI) greater than 10 and Dermatology Life Quality Index (DLQI) greater than 10, OR major involvement of visible areas, scalp, genitals, or nails; • Refractory, intolerant to or unable to access phototherapy; • Refractory, intolerant to or have contraindications to methotrexate (oral or parenteral) at a dose of greater than or equal to 20 mg weekly (greater than or equal to 15 mg if patient is 65 years of age or older) for a minimum of 12 weeks OR cyclosporine (6 weeks treatment). <p>For continued coverage, patients must meet the following criteria:</p> <ul style="list-style-type: none"> • Greater than or equal to 75% reduction in PASI score, OR • Greater than or equal to 50% reduction in PASI and greater than or equal to 5 points in the DLQI OR • Significant reduction in BSA involved, with consideration of specific regions such as face, hands, feet or genital region and situations such as itch and recalcitrant plaques. <p>Clinical Notes:</p> <ul style="list-style-type: none"> • For patients who do not demonstrate a clinical response to oral methotrexate, or who experience gastrointestinal intolerance, a trial of parenteral methotrexate may be considered if clinically appropriate • 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 to treatments. The nature of intolerance(s) must be clearly documented. <p>Claim Notes:</p> <ul style="list-style-type: none"> • Must be prescribed by a dermatologist or prescriber with a specialty in dermatology. • Combined use of more than one biologic will not be reimbursed. • Approvals will be for a maximum of 45mg subcutaneously at Week 0, 4 and 16 weeks, followed by a maintenance dose of 45mg subcutaneously every 12 weeks. Response must be assessed prior to fourth dose. • Initial Approval: 16 weeks • Renewal Approval: 1 year 				

New Exception Status Products Continued...

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Steqeyma (ustekinumab)	45mg/0.5mL Prefilled Syringe	02550245	DNP	E (SF)	CLT
	90mg/1.0mL Prefilled Syringe	02550253	DNP	E (SF)	CLT
	130mg/26mL Vial	02550261	DNP	E (SF)	CLT
Criteria	<p><u>Psoriatic Arthritis</u></p> <p>For the treatment of patients with predominantly axial psoriatic arthritis who are refractory, intolerant or have contraindications to the sequential use of at least two NSAIDs at maximal tolerated dose for a minimum of two weeks each.</p> <p>For the treatment of patients with predominantly peripheral psoriatic arthritis who are refractory, intolerant or have contraindications to:</p> <ul style="list-style-type: none"> • The sequential use of at least two NSAIDs at maximal tolerated dose for a minimum of two weeks each; AND • Methotrexate (oral or parenteral) at a dose of ≥ 20mg weekly (≥ 15mg if patient is ≥ 65 years of age) for a minimum of 8 weeks; AND • Leflunomide for a minimum of 10 weeks or sulfasalazine for a minimum of 3 months. <p>Clinical Notes:</p> <ul style="list-style-type: none"> • For patients who do not demonstrate a clinical response to oral methotrexate, or who experience gastrointestinal intolerance, a trial of parenteral methotrexate must be considered. • 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 to treatments. The nature of intolerance(s) must be clearly documented. <p>Claim Notes:</p> <ul style="list-style-type: none"> • Must be prescribed by a rheumatologist. • Concurrent use of biologics not approved. • Initial period 6 months. • Approvals will be for a maximum of 45mg subcutaneously at Weeks 0 and 4, and maintenance dosing of 45mg subcutaneously every 12 weeks. For patients >100kg, doses of 90mg may be considered. • Renewal approval: 1 year. Confirmation of continued response required. 				

New Exception Status Products Continued...

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Steqeyma (ustekinumab)	45mg/0.5mL Prefilled Syringe	02550245	DNP	E (SF)	CLT
	90mg/1.0mL Prefilled Syringe	02550253	DNP	E (SF)	CLT
	130mg/26mL Vial	02550261	DNP	E (SF)	CLT
Criteria	<p><u>Crohn's Disease</u></p> <p>For the treatment of patients with moderately to severely active Crohn's disease who are refractory to, intolerant or have contraindications to corticosteroids and other immunosuppressive therapy.</p> <p>Clinical Notes:</p> <ul style="list-style-type: none"> 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 to treatments. The nature of intolerance(s) must be clearly documented. <p>Claim Notes:</p> <ul style="list-style-type: none"> Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology. Combined use of more than one biologic disease-modifying antirheumatic drugs (DMARD) or janus kinase inhibitors (JAK) 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: 16 weeks Renewal Approval: 1 year 				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Vraylar (cariprazine)	1.5mg Cap	02526794	DNP	E (SF)	ABV
	3mg Cap	02526808	DNP	E (SF)	ABV
	4.5mg Cap	02526816	DNP	E (SF)	ABV
	6mg Cap	02526824	DNP	E (SF)	ABV
Criteria	<p>For the treatment of schizophrenia in adults [Criteria Code 01].</p> <p>Clinical Notes:</p> <ul style="list-style-type: none"> Cariprazine should not be used in combination with other atypical antipsychotics. Cariprazine should not be used in patients with treatment resistant schizophrenia or used as add-on therapy to clozapine. 				

New Benefits

Effective **January 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	PRESCRIBER	BENEFIT STATUS	MFR
Atenolol	25mg Tab	02541564	DNP	SF	SIV
Bisoprolol	1.25mg Tab	02544245	DNP	SF	SDZ
Bisoprolol	2.5mg Tab	02544253	DNP	SF	SDZ
Cetirizine	10mg Tab	02517566	DNP	E (SF)	JPC
PRZ-Metformin	1000mg Tab	02534673	DNP	SFD	PRZ
pms-Methotrexate	7.5mg/0.3mL Prefilled Syringe	02422166	DNP	SFC	PMS
pms-Methotrexate	10mg/0.4mL Prefilled Syringe	02422174	DNP	SFC	PMS
pms-Methotrexate	15mg/0.6mL Prefilled Syringe	02422182	DNP	SFC	PMS
pms-Methotrexate	20mg/0.8mL Prefilled Syringe	02422190	DNP	SFC	PMS
pms-Methotrexate	25mg/1.0mL Prefilled Syringe	02422204	DNP	SFC	PMS
M-Hydrocortisone/ Urea	1%/10% Cr	80073645	DNP	SF	MRA
Glycopyrrolate	0.2mg/mL Inj	02532379	DNP	SFC	JPC
Glycopyrrolate	0.2mg/mL Inj	02513749	DNP	SFC	JPC
AeroChamber2go	N/A	96899950	DNP	SFC	TMI