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PHARMACY EDITION

NOVA SCOTIA

# PharmacareNEWS

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## Nova Scotia Formulary Updates

### Nova Scotia Biosimilar Initiative

**End of Biosimilar Transition Period**

An important reminder that as of **February 3, 2023**, some original biologic medications won't be covered by Pharmacare if a biosimilar version is approved and available, unless an exemption is granted.

Where possible, to avoid any gaps in coverage, please connect with your patients who have yet to transition to a biosimilar option.

Additional services and options are outlined below with respect to patients on some original **insulins**. For patients on other original biologic medications who have not yet received a prescription for an alternative product, you can call Pharmacare at 1-800-563-8880 to determine possible options and the potential for an approval of a one-time fill.

**Biosimilar Insulins - Information for Pharmacists**

Two new options are available related specifically to biosimilar insulins for Pharmacare beneficiaries under the Biosimilar Initiative- the Therapeutic Substitution for Biosimilar Insulins and the criteria code as outlined below.

Please also note that NovoRapid vials continue to remain a benefit at this time for those using insulin pumps.

Humalog pens, cartridges, and vials will also be available as benefits during the Admelog shortage.

**Therapeutic Substitution Service – Biosimilar Insulins**

**Therapeutic substitution of an originator insulin for a biosimilar insulin for Pharmacare beneficiaries who have yet to transition from the originator insulin is eligible for coverage effective January 9, 2023 to July 9, 2023.**

**Nova Scotia Biosimilar Initiative Continued…**

Therapeutic substitution services for insulins are eligible for coverage provided all the following criteria are met:

- To provide a beneficiary of a Pharmacare Program access to a biosimilar insulin under the Biosimilar Initiative Policy (https://novascotia.ca/dhw/pharmacare/information-for-prescribers-about-biosimilars.asp)
- Pharmacists are responsible for determining the appropriateness of the therapeutic substitution before performing the service.
- The patient is a beneficiary of a Nova Scotia Pharmacare Program.
- The therapeutic substitution service is conducted by a pharmacist licensed with the Nova Scotia College of Pharmacists (NSCP).
- Pharmacists must comply with all applicable NSCP policies and standards.
- Consent is provided to authorize the pharmacist to make the therapeutic substitution

**Claims Submission**

Pharmacists must submit electronic claims for therapeutic substitution services to the Pharmacare Programs for reimbursement provided all the criteria for coverage are met.

- A claim for therapeutic substitution is submitted using PIN 93899790. This PIN is specific for therapeutic substitutions within the Biosimilar Insulin Initiative.
- All CPhA Claims Standard field content included in the table below is required on the claim.
- The record of therapeutic substitution must reference the prescription numbers for the original claim and modified claim.
- Copayments and/or deductibles are not applied to claims for therapeutic substitution services.

**CPhA Claims Standard – Therapeutic Substitution**

| Field # | Field Name | Content |
|---|---|---|
| D.56.03 | DIN/GP#/PIN | 93899790 |
| D.57.03 | Special Service Code | 002 (pharmacist intervention) |
| D.58.03 | Quantity | 000001 (one) |
| D.61.03 | Prescriber ID | Licence 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) | 2625 ($26.25)* |

*The copayment and/or deductible **will not** be applied to this claim.

**Nova Scotia Biosimilar Initiative Continued…**

The Therapeutic substitution will only apply to the originator and biosimilar insulins listed in the Biosimilar Initiative. The **current list** of originators and biosimilar insulins are listed below, but these may change as new products are funded. Please monitor the Biosimilar Initiative site and the Formulary:

- https://novascotia.ca/dhw/pharmacare/information-for-prescribers-about-biosimilars.asp.
- https://novascotia.ca/dhw/pharmacare/documents/formulary.pdf

| Drug | Originator (switch from) | Biosimilar (switch to) |
|---|---|---|
| Insulin glargine | Lantus | Basaglar |
| Insulin lispro | Humalog | Admelog |
| Insulin aspart | NovoRapid | Trurapi |

Note: NovoRapid® vials continue to remain a benefit at this time for those using insulin pumps. Humalog pens, cartridges, and vials will also be available as benefits during the Admelog shortage.

**Use of Criteria Codes for a One-time Extension of an Originator Insulin**
**Effective February 3, 2023 until April 3, 2023,** pharmacists may enter a **[criteria code 15]** for a one-time fill of an originator insulin for patients who have yet to transition from the originator insulin.

This code is intended to be used if more time is needed to arrange the therapeutic substitution, if the prescriber needs to be contacted, or if supply of the biosimilar is not on hand for example.

Please continue to refer to the Pharmacare News Bulletins and the Pharmacy Guide (www.nspharmacare.ca) for updated information regarding the use of criteria codes.

## Therapeutic Substitution Service – Paediatric Antibiotics

**Therapeutic substitution of paediatric antibiotic formulations due to shortages of the prescribed drug, is eligible for coverage for Nova Scotia residents, effective December 23, 2022 to June 23, 2023**

Therapeutic substitution services for paediatric antibiotic formulations are eligible for coverage provided all the following criteria are met:

- To allow access to an alternate antibiotic that is required due to a shortage in pediatric antibiotic formulations.
- Pharmacists are responsible for determining the appropriateness of the therapeutic substitution before performing the service.
- A different antibiotic is prescribed.
- The therapeutic substitution service is conducted by a pharmacist licensed with the Nova Scotia College of Pharmacists (NSCP).
- The resident has a valid Nova Scotia health card number.
- Pharmacists must comply with all applicable NSCP policies and standards.
- Consent is provided to authorize the pharmacist to make the therapeutic substitution.

**Therapeutic Substitution Service – Paediatric Antibiotics Continued…**

### Claims Submission

Pharmacists must submit electronic claims for therapeutic substitution services to the DHW for reimbursement provided all the criteria for coverage are met. The following steps must be completed on the same day in the following order for the pharmacy to be reimbursed for the service:

- A claim for therapeutic substitution is submitted using PIN 93899791.
- All CPhA Claims Standard field content included in the table below is required on the claim.
- A record must be available that references the original prescription and modified claim.

**CPhA Claims Standard – Therapeutic Substitution**

| Field # | Field Name | Content |
|---|---|---|
| D.56.03 | DIN/GP#/PIN | 93899791 |
| D.57.03 | Special Service Code | 002 (pharmacist intervention) |
| D.58.03 | Quantity | 000001 (one) |
| D.61.03 | Prescriber ID | Licence 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) | 2625 ($26.25) |

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## Nova Scotia Formulary Updates

### New Exception Status Benefits

The following new products will be listed with the following criteria, effective **February 1, 2023**.

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| **Onureg** | 200mg Tab | 02510197 | DNP | E (SFC) | CEL |
| **(azacitidine)** | 300mg Tab | 02510200 | DNP | E (SFC) | CEL |

Criteria

**Acute Myeloid Leukemia**

- As maintenance therapy for adult patients with acute myeloid leukemia (AML) who meet all of the following criteria:
  - Intermediate or poor risk
  - Complete remission (CR) or complete remission with incomplete blood count recovery (CRi) following induction therapy, with or without consolidation treatment.
  - Not eligible for hematopoietic stem cell transplantation (HSCT)

**Clinical Notes:**

- Newly diagnosed includes patients with AML secondary to prior myelodysplastic syndrome (MDS) or chronic myelomonocytic leukemia (CMML).
- Last dose of chemotherapy should be within 4 months of starting azacitidine maintenance.
- Treatment should be discontinued upon disease relapse (i.e., appearance of greater than 5% blasts in the bone marrow or peripheral blood), unacceptable toxicity, or if patient becomes eligible for allogeneic bone marrow or stem cell transplant during the treatment period.

**New Exception Status Benefits Continued…**

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| **Arazlo (tazarotene)** | 0.045% Lot | 02517868 | DNP | FE* | BSL |
| Criteria | • Regular benefit for beneficiaries 30 years and under<br>• For treatment of acne vulgaris in beneficiaries over the age of 30 | | | | |

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| **Enspryng (satralizumab)** | 120mg/mL Prefilled Syringe | 02499681 | DNP | E (SF) | HLR |

Criteria

**Neuromyelitis Optica Spectrum Disorder**

- For the treatment of patients 12 years of age and older with neuromyelitis optica spectrum disorder (NMOSD) who meet all of the following criteria:
  - Are anti–aquaporin 4 (AQP4) seropositive
  - Must have had at least one relapse of NMOSD in the previous 12 months:
    - despite an adequate trial of other accessible preventive treatments[1] for NMOSD, OR
    - because the patient cannot tolerate other preventive treatments[1] for NMOSD
- Patients must have an EDSS score of 6.5 points or less.
- Satralizumab should not be initiated during a NMOSD relapse episode.

**Renewal:**

- Requests for renewal will be considered for patients who maintain an EDSS score of less than 8 points.

**Clinical Notes:**

- Must be prescribed by a neurologist with expertise in treating NMOSD.

**Claim Notes:**

- Approval Period: 1 year
- Combined use of more than one biologic drug will not be reimbursed.
- Approvals will be for a maximum of 120mg at week 0, 2 and 4, then 120 mg every four weeks thereafter.

[1]Other accessible preventative treatments include, but are not limited to, monoclonal antibodies including rituximab and other immunosuppressants.

## New Benefits

Effective **February 1, 2023,** the following products will be added as benefits in the Nova Scotia Formulary.

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| Bryhali | 0.01% Lot | 02506262 | SF | DNP | BSL |
| Kirsty | 100 U/mL Prefilled Pen | 02520974 | SFD | DNP | BGP |
| Semglee | 100 U/mL Prefilled Pen | 02526441 | SFD | DNP | BGP |

## Temporary Benefit – Moxilen Forte 250mg/5mL (Amoxicillin) Oral Suspension

As a result of the shortage of amoxicillin 250mg/5mL (powder for oral suspension), Juno Pharmaceuticals Corp has received approval from Health Canada for the importation and release of a limited supply of Cyprus-labelled amoxicillin oral suspension.

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

The Cyprus-labelled amoxicillin oral suspension has the same active ingredient, strength, dosage form, route of administration and volume as some Canadian authorized products. **However, the product differs in the instructions for reconstitution, the brand name, and non-medicinal ingredients.** Pharmacists are directed to consult Health Canada's approved Risk Communication Letter, which can be found at www.junopharm.ca, when prescribing or dispensing this product.

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| Moxilen Forte | 250mg/5mL Susp | 09858237 | DNPO | SFC | JNO |

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## Nova Scotia Formulary Updates

### Pharmacists Completing and Submitting Exception Status Drug (ESD) Forms

Please note that pharmacists are among the health care providers who can complete and submit ESD forms for beneficiaries of the Pharmacare programs, provided they have the information that is required to determine whether the patient meets the established coverage criteria. The pharmacist does not have to be the prescriber of the medication.

Many products require a specialist request (biologic therapies, MS therapies, hepatitis C therapies, etc.) and in those cases, only pharmacists who work directly with that specialty group such as in a hospital or clinic setting, would be permitted to submit a coverage request. If there are extenuating circumstances, please contact the Pharmacare Office.

**IMPORTANT REMINDER**: Pharmacists who prescribe and/or submit ESD forms in Nova Scotia must register with Medavie Blue Cross to be eligible as a prescriber under the Pharmacare programs. The “Main Address” submitted with your registration will be used for all patient correspondence that Medavie sends you. **This address must be accurate and appropriate for receiving and handling private patient information**. **You are responsible under the Personal Health Information Act to ensure the patient information sent to your Main Address is protected from unauthorized disclosure or use.** If you need to change your address, please visit the site below to update your profile information and click on ‘Edit your profile’:
https://www.medaviebc.ca/en/health-professionals/register

The Department of Health and Wellness continually reviews exception status drug requirements and is continuing to explore improvements to make the ESD process as effective and efficient as possible for all providers.

ESD forms are available on the NS Pharmacare website:
https://novascotia.ca/dhw/pharmacare/exception-status-drugs.asp

Criteria for Exception Status Drugs:
https://novascotia.ca/dhw/pharmacare/documents/Criteria-for-Exception-Status-Coverage.pdf

## Pharmacy Services in Nursing Homes

Coverage for select pharmacy services has been expanded to include patients who reside in a nursing home, a home for special care and for patients insured through the Under 65 – LTC Program. Please see details below as well as the Pharmacy Guide for additional eligibility criteria.

1. Pharmacare patients in a nursing home or a home for special care are now eligible for coverage of a Medication Review Service (Basic Medication Review Service or, if the patient is enrolled in Seniors Pharmacare, Advanced Medication Review Service) upon admission to a long-term care facility.
    - The patient must meet usual eligibility criteria.
    - Reimbursement will only be provided once per year as per other beneficiaries and can only be claimed in the long term or special care setting upon admission (and if it has not already been claimed).
    - The Service will not be funded on a yearly basis unless the patient has been admitted to a new facility.
    - Medication review follow-ups are not eligible for reimbursement.
2. Prescription renewals are now eligible for coverage for patients in a nursing home.
    - Prescription renewals in nursing homes are typically provided during scheduled patient rounds or other established processes. It is expected that these processes remain in place, and that only in unique circumstances would a prescription renewal by a pharmacist be required.
    - When provided, all usual requirements apply.
3. Assessing and prescribing for herpes zoster is eligible for coverage for patients in a nursing home.
4. Patients in a nursing home or home for special care are now eligible for enrollment in the Community Pharmacy Anticoagulation Management Services (CPAMS).
    - As a reminder, pharmacies must be approved by Pharmacy Association of Nova Scotia (PANS) to be eligible for the fee. Interested pharmacies must contact PANS at info@pans.ns.ca for additional information.

Further information is available in the Pharmacy Guide which can be accessed at the following link:
https://novascotia.ca/dhw/pharmacare/documents/Pharmacy-Guide.pdf

## Change in Benefit Status

Effective **March 1, 2023,** the following products will move to full benefit and no longer require exception status approval.

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| Duloxetine | Various | Various | DNP | SF | VAR |
| Entecavir | 0.5mg Tab | Various | DNP | SF | VAR |
| Gabapentin | Various | Various | DNP | SFC | VAR |
| Lamivudine HBV | 100mg Tab | Various | DNP | SF | VAR |
| Pregabalin | Various | Various | DNP | SFC | VAR |
| Tenofovir Disoproxil Fumarate | 300mg Tab | Various | DNP | SF | VAR |

## New Exception Status Benefit

The following new product will be listed with the following criteria, effective **March 1, 2023**.

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| **Rinvoq (upadacitinib)** | 15mg Tab | 02495155 | DNP | E (SF) | ABV |

Criteria

**Rheumatoid Arthritis**

- For the treatment of severely active rheumatoid arthritis, alone or in combination with methotrexate or other disease-modifying antirheumatic drugs (DMARDs), in adult patients who are refractory or intolerant to:
    - methotrexate (oral or parenteral) at a dose of ≥ 20 mg weekly (≥15mg if patient is ≥65 years of age), or use in combination with another DMARD, for a minimum of 12 weeks;

      AND
    - methotrexate in combination with at least two other DMARDs, such as hydroxychloroquine and sulfasalazine, for a minimum of 12 weeks.

**Clinical Notes:**

- 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.
- Optimal treatment response to DMARDs may take up to 24 weeks, however coverage can be considered if no improvement is seen after 12 weeks of triple DMARD use.
- If patient factors (e.g. intolerance) prevent the use of triple DMARD therapy, these must be described and dual therapy with DMARDs must be tried.
- 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.

**Claim Notes:**

- Must be prescribed by a rheumatologist.
- Concurrent use of more than one biologic DMARD or janus kinase inhibitors will not be reimbursed.
- Approvals will be for a maximum of 15 mg daily.
- Initial Approval: 6 months

**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:

**New Exception Status Benefit Continued…**

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| **Rinvoq (upadacitinib)** | 15mg Tab | 02495155 | DNP | E (SF) | ABV |
| Criteria | ○ The sequential use of at least two NSAIDs at maximal tolerated dose for a minimum of two weeks each; AND<br>○ 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<br>○ Leflunomide for a minimum of 10 weeks or sulfasalazine for a minimum of 3 months.<br>**Clinical Notes:**<br>• 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.<br>• Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above.<br>• Intolerant is defined as demonstrating serious adverse effects to treatments. The nature of intolerance(s) must be clearly documented.<br>**Claim Notes:**<br>• Must be prescribed by a rheumatologist.<br>• Concurrent use of biologics not approved.<br>• Approvals will be for a maximum of 15mg daily.<br>• Initial coverage period: 6 months.<br>• Renewal approval: 1 year. Confirmation of continued response required. | | | | |

## Criteria Updates

The following new indication and updated criteria for existing indications are effective **March 1, 2023.**

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| **Tagrisso (osimertinib)** | 40mg Tab<br>80mg Tab | 02456214<br>02456222 | DNP<br>DNP | E (SFC)<br>E (SFC) | AZE<br>AZE |
| Criteria | **Stage IB-IIIA Non-Small Cell Lung Cancer (NSCLC)**<br>• For adjuvant therapy after tumour resection in patients with Stage IB-IIIA (AJCC 7th edition or equivalent) non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions [exon 19 del] or exon 21 [L858R] substitution mutations.<br>**Clinical Notes:**<br>• Patients should have a good performance status. | | | | |

**Criteria Updates Continued…**

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| **Tagrisso (osimertinib)** | 40mg Tab<br>80mg Tab | 02456214<br>02456222 | DNP<br>DNP | E (SFC)<br>E (SFC) | AZE<br>AZE |
| Criteria | • Treatment with osimertinib should continue for a total duration of 3 years, or until disease recurrence or unacceptable toxicity.<br>• Osimertinib treatment should be initiated within 10 weeks of complete surgical resection if adjuvant chemotherapy was not administered, or within 26 weeks if adjuvant chemotherapy was administered.<br>• Retreatment with osimertinib in the metastatic setting will be considered if disease recurrence is at least 6 months following completion of adjuvant therapy.<br>**Locally Advanced or Metastatic Non-Small Cell Lung Cancer (NSCLC)**<br>• For the first-line treatment of patients with locally advanced (not amenable to curative-intent therapy) or metastatic non-small cell lung cancer (NSCLC) whose tumors have the following epidermal growth factor receptor (EGFR) mutations: exon 19 deletions [exon 19 del] or exon 21 [L858R] mutations. Eligible patients should be previously untreated in the locally advanced or metastatic setting and have a good performance status.<br>**Clinical Notes:**<br>• Treatment may continue until clinically meaningful disease progression or unacceptable toxicity.<br>• Retreatment with osimertinib in the metastatic setting will be considered if disease recurrence is at least 6 months following completion of adjuvant therapy.<br>**Locally Advanced or Metastatic T790M Mutation-Positive Non-Small Cell Lung Cancer (NSCLC)**<br>• For the treatment of patients with locally advanced or metastatic epidermal growth factor receptor (EGFR) T790M mutation-positive non-small cell lung cancer (NSCLC) who have progressed on EGFR tyrosine kinase inhibitor (TKI) therapy, or as initial therapy in patients with a de novo EGFR T790M mutation.<br>**Clinical Notes:**<br>• Patients currently receiving alternate first-line EGFR TKI's (e.g. erlotinib, gefitinib, afatinib) whose tumors have the noted EGFR mutations (exon 19 del or L858R) may be switched to osimertinib provided they meet all other funding criteria and have not experienced disease progression.<br>• Patients who have initiated treatment with chemotherapy prior to receiving results of the EGFR mutation status may be switched to osimertinib if otherwise eligible.<br>• Osimertinib may be continued until there is evidence of disease progression or the development of unacceptable toxicity.<br>• Retreatment with osimertinib in the metastatic setting will be considered if disease recurrence is at least 6 months following completion of adjuvant therapy. | | | | |

**Criteria Updates Continued…**

The criteria for the following has been updated effective **March 1, 2023.**

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| **Adalimumab** | Various | Various | DNP | E (SF) | VAR |
| **Certolizumab pegol** | Various | Various | DNP | E (SF) | VAR |
| **Etanercept** | Various | Various | DNP | E (SF) | VAR |
| **Golimumab** | Various | Various | DNP | E (SF) | VAR |
| **Infliximab** | Various | Various | DNP | E (SF) | VAR |
| **Secukinumab** | Various | Various | DNP | E (SF) | VAR |

Criteria

**Ankylosing Spondylitis**

- For the treatment of patients with moderate to severe ankylosing spondylitis (Bath AS Disease Activity Index (BASDAI) score ≥4 on 10 point scale) who:
    - Have axial symptoms[1] and who have failed to respond to the sequential use of at least 2 NSAIDs at the optimum dose for a minimum period of 2 weeks each, or in whom NSAIDs are contraindicated;

      OR
    - Have peripheral symptoms and who have failed to respond to, or have contraindications to, the sequential use of at least 2 NSAIDs at the optimum dose for a minimum period of 2 weeks each and have had an inadequate response to an optimal dose or maximal tolerated dose of a DMARD.
- Must be prescribed by a rheumatologist or prescriber with a specialty in rheumatology.
- Requests for renewal must include information showing the beneficial effects of the treatment, specifically:
    - 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").

**Claim Notes:**

- Initial period 6 months.
- Maximum dose of 40mg every two weeks.
- Concurrent use of biologics not approved.

1. Patients with recurrent uveitis (2 or more episodes within 12 months) as a complication of axial disease, do not require a trial of 2 NSAIDs.

**Criteria Updates Continued…**

The criteria for the following has been updated effective **February 1, 2023.**

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| **Ajovy (fremanezumab)** | 225mg/1.5mL Prefilled Syringe | 02497859 | DNP | E (SF) | TEV |
| | 225mg/1.5mL Autoinjector | 02509474 | DNP | E (SF) | TEV |
| Criteria | • For the treatment of patients with episodic[1] or chronic migraine[2], who have experienced an inadequate response, intolerance, or contraindication to at least two oral prophylactic migraine medications of different classes.<br>**Initial Renewal Criteria:**<br>• 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<br>**Subsequent Renewal Criteria:**<br>• Proof that the initial 50% reduction in the average number of migraine days per month has been maintained<br>**Clinical Notes:**<br>• Baseline number of headache and migraine days per month must be provided at the time of initial request.<br>• [1] Episodic migraine: migraine headaches on atleast 4 days per month and less than 15 headache days per month for more than 3 months<br>• [2] Chronic 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.<br>**Claim Notes:**<br>• Approvals: 6 months<br>• Must be prescribed by a physician who has experience in the management of migraine headaches. | | | | |

## New Benefit

Effective **March 1, 2023,** the following product will be added as a benefit 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 |
|---|---|---|---|---|---|
| Dupixent | 175mg/mL Prefilled Pen | 02524252 | DNP | E (SF) | SAV |

## Non Insured Product

The following product will not be insured in the Pharmacare Programs; however, it will be funded through the Exception Drug Fund.

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| Luxturna | 5 Trillion vg/mL Vial | 02505851 | N/A | **Not Insured** | NVR |

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## Nova Scotia Formulary Updates

### New Exception Status Benefits

The following new products will be listed with the following criteria, effective **April 1, 2023**.

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| **Emgality (galcanezumab)** | 120mg/mL Prefilled Pen | 02491087 | DNP | E (SF) | LIL |
| | 120mg/mL Prefilled Syringe | 02491060 | DNP | E (SF) | LIL |

Criteria

**Initiation**

- For the treatment of patients with episodic[1] or chronic migraine[2], who have experienced an inadequate response, intolerance, or contraindication to at least two oral prophylactic migraine medications of different classes.

**Renewal**

- 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.

**Clinical Notes**

- Baseline number of headache and migraine days per month must be provided at the time of initial request.
- [1]Episodic migraine: migraine headaches on at least 4 days per month and less than 15 headache days per month for more than 3 months.
- [2]Chronic 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.

**New Exception Status Benefits Continued…**

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| **Emgality** | 120mg/mL Prefilled Pen | 02491087 | DNP | E (SF) | LIL |
| **(galcanezumab)** | 120mg/mL Prefilled Syringe | 02491060 | DNP | E (SF) | LIL |
| Criteria | **Claim Notes**<br>• Initial approval: 6 months<br>• Renewal approval: 1 year<br>• Must be prescribed by a physician who has experience in the management of migraine headaches. | | | | |

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| **Tukysa** | 50mg Tab | 02499827 | DNP | E (SFC) | SGC |
| **(tucatinib)** | 150mg Tab | 02499835 | DNP | E (SFC) | SGC |
| Criteria | **Locally Advanced Unresectable or Metastatic HER2-positive Breast Cancer**<br>• In combination with trastuzumab and capecitabine for the treatment of patients with locally advanced unresectable or metastatic HER2-positive breast cancer who have received prior treatment with trastuzumab, pertuzumab and a HER2-targeted antibody-drug conjugate (e.g., trastuzumab emtansine or trastuzumab deruxtecan), where at least one was given in the advanced or metastatic setting.<br>**Clinical Notes**<br>• Patients should have a good performance status.<br>• Treatment should be discontinued upon disease progression, unacceptable toxicity, or if both trastuzumab and capecitabine are discontinued.<br>**Claim Note**<br>• 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 PIN:<br>  ○ 00904820 | | | | |

## Criteria Updates

The following new indications have been added to existing criteria effective **April 1, 2023.**

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| **Levemir** | 100 U/mL Penfill | 02271842 | DNP | E (SFD) | NNO |
| **(Insulin Detemir)** | 100 U/mL FlexTouch Prefilled Pen | 02412829 | DNP | E (SFD) | NNO |
| Criteria | • For the treatment of pediatric and adolescent patients (under 18 years of age) with Type 1 diabetes.<br>• For the treatment of pregnant individuals with Type 1 or Type 2 diabetes requiring insulin. | | | | |

The following new indication and updated criteria for an existing indication is effective **April 1, 2023.**

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| **Lenalidomide** | Various | Various | DNP | E (SFC) | VAR |
| Criteria | **Multiple Myeloma Not Eligible for Autologous Stem Cell Transplant (MM-TNE)**<br>• As first-line treatment for newly diagnosed patients with multiple myeloma who are not eligible for autologous stem cell transplantation when used:<br>  ○ In combination with dexamethasone, with or without bortezomib; or<br>  ○ In combination with daratumumab and dexamethasone<br>**Multiple Myeloma Prior to Autologous Stem Cell Transplant (MM Pre-ASCT)**<br>• For the treatment of patients with multiple myeloma when used in combination with bortezomib and dexamethasone as induction therapy prior to autologous stem cell transplant.<br>**Clinical Notes:**<br>• Patients should have a good performance status.<br>• Treatment should be continued until unacceptable toxicity or disease progression. | | | | |

## New Benefit

Effective **April 1, 2023,** the following product will be added as a benefit 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 |
|---|---|---|---|---|---|
| Accel-Hyoscine | 10mg Tab | 02512335 | DNP | SF | ACC |

## Change in Benefit Status

Effective **April 1, 2023,** the following products will move to full benefit and no longer require exception status approval.

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| Pioglitazone | Various | Various | DNP | SF | VAR |
| Progesterone | 100mg Cap | Various | DNP | SF | VAR |
| Raloxifene | 60mg Tab | Various | DNP | SF | VAR |
| Ursodiol | 250mg Tab | Various | DNP | SF | VAR |
| Ursodiol DS | 500mg Tab | Various | DNP | SF | VAR |

## Update to CPAMS Criteria

Coverage for Community Pharmacy Anticoagulation Management Services (CPAMS) has been expanded to include patients who are less than 18 years old. These patients may be eligible for the service if they meet existing criteria.

## 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:

- In the **Basic Medication Review Service** and **Advanced Medication Review Service** sections, criteria that excludes patients in a nursing home, home for special care, or patients in the Under 65 - LTC Program has been removed. These patients may be eligible for the service based on new eligibility criteria.
- In the section on **Medication Review Service Follow-Up**, a sentence has been added to clarify that this service will not be funded for patients in a nursing home, a home for special needs, or for patients insured through the Under 65 – LTC Program.
- In the **Assessment and Prescribing Services** section, patients who reside in a nursing home are eligible for coverage of assessment and prescribing for herpes zoster.
- In the **Prescription Renewals section**, criteria that excludes patients in a nursing home has been removed. These patients are now eligible for the service.
- Under the section **Community Pharmacy Anticoagulation Management Services (CPAMS)**, criteria that excludes patients who reside in a nursing home or a home for special care has been removed. These patients may be eligible for the service. Additionally, criteria that stated eligible patients must be 18 years of age or older has been removed.
- In the **Requests for Coverage** section, criteria updated to allow pharmacists to submit Exception Status Drug (ESD) request forms, without requiring signature from the prescriber, provided they have the information that is required to determine whether the patient meets the established criteria.
- In the **Prescription Adaptation** and **Therapeutic Substitution** sections, the requirement to document the original prescription number was removed.
- In the section on **Therapeutic Substitutions**, pediatric antibiotics and biosimilar insulins were added as temporary services.

**Updates to the Nova Scotia Pharmacy Guide Continued…**

- Under the **Compounded Products** list, volumes were removed from the Magic Mouthwash formulations.
- In the section on **Quantity Limits**, Proton Pump Inhibitors (PPIs), duloxetine, influenza vaccines, Kalydeco and Zepatier were removed from the list; Baqsimi and Kynmobi were added to the list and Brilinta was changed to Ticagrelor to account for the generic formulations.
- In the **Online Adjudication of Exception Status Drugs** section, Nasonex was removed from the list as it is a full benefit.
- Under the section on **Dispensing of oral anti-viral medications for COVID-19**, the professional fee was updated to $12.69.

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## Nova Scotia Formulary Updates

### New Exception Status Benefits

The following new products will be listed with the following criteria, effective **May 1, 2023**.

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| **Bimzelx (bimekizumab)** | 160mg/mL Prefilled Syringe | 02525267 | DNP | E (SF) | UCB |
| | 160 mg/mL Autoinjector | 02525275 | DNP | E (SF) | UCB |
| Criteria | • For patients with severe, debilitating chronic plaque psoriasis who meet all of the following:<br>○ Body surface area (BSA) involvement of >10% and/or significant involvement of the face, hands, feet or genitals;<br>○ Failure to, contraindication to or intolerant of methotrexate and cyclosporine;<br>○ Failure to, intolerant of or unable to access phototherapy;<br>○ Written request of a dermatologist or prescriber with a specialty in dermatology.<br>• Continued coverage is dependent on evidence of improvement, specifically:<br>○ A >75% reduction in the Psoriasis Area and Severity Index (PASI) score; or<br>○ A >50% reduction in PASI with a > 5 point improvement in DLQI (Dermatology Life Quality Index); or<br>○ Significant reduction in BSA involved, with consideration of important regions such as the face, hands, feet or genitals. | | | | |

**New Exception Status Benefits Continued…**

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| **Bimzelx (bimekizumab)** | 160mg/mL Prefilled Syringe | 02525267 | DNP | E (SF) | UCB |
| | 160 mg/mL Autoinjector | 02525275 | DNP | E (SF) | UCB |
| Criteria | **Clinical Note:**<br>• Treatment should be discontinued if a response has not been demonstrated after 16 weeks.<br>**Claim Notes:**<br>• Concurrent use of biologics not approved.<br>• Approvals will be for 320mg by subcutaneous injection at weeks 0, 4, 8, 12, and 16, followed by maintenance dosing of 320mg every 8 weeks. Maintenance dosing every 4 weeks may be considered for patients >120kg.<br>• Initial approval period: 16 weeks<br>• Renewal approval period: 1 year | | | | |

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| **Reblozyl (luspatercept)** | 25mg Vial | 02505541 | DNP | E (SF) | CEL |
| | 75mg Vial | 02505568 | DNP | E (SF) | CEL |
| Criteria | **Beta-Thalassemia Anemia**<br>• For the treatment of adult patients with RBC transfusion-dependent anemia associated with beta-thalassemia. Patients must be receiving regular transfusions, defined as:<br>  ○ 6 to 20 RBC units in the 24 weeks prior to initiating treatment with luspatercept, AND<br>  ○ No transfusion-free period greater than 35 days in the 24 weeks prior to initiating treatment with luspatercept.<br>**Renewal Criteria:**<br>• Patients must demonstrate an initial response, defined as a ≥33% reduction in transfusion burden (RBC units/time) compared to the pre-treatment baseline RBC transfusion burden, measured over 24 weeks prior to initiating treatment with luspatercept.<br>• For continued coverage, patients should maintain a reduction in transfusion burden of ≥33% compared to the pre-luspatercept transfusion burden.<br>• Luspatercept should be discontinued if a patient does not respond after nine weeks of treatment (three doses) at the maximum dose.<br>**Claim Notes:**<br>• The patient should be under the care of a specialist with experience in managing patients with beta-thalassemia.<br>• The maximum dose of luspatercept should not exceed 1.25mg/kg (or 120mg total dose) once every three weeks. | | | | |

**New Exception Status Benefits Continued…**

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| **Reblozyl (luspatercept)** | 25mg Vial<br>75mg Vial | 02505541<br>02505568 | DNP<br>DNP | E (SF)<br>E (SF) | CEL<br>CEL |
| Criteria | **Claim Notes Continued:**<br>• Initial Approval: 6 months<br>• Renewal Approval: 1 year<br>**Myelodysplastic Syndromes**<br>• For the treatment of adult patients with red blood cell (RBC) transfusion–dependent anemia associated with very low- to intermediate-risk MDS who have ring sideroblasts and who have failed or are not suitable for erythropoietin-based therapy.<br>**Renewal Criteria:**<br>• Patients should be RBC transfusion independent over a minimum of 16 consecutive weeks within the first 24 weeks of treatment initiation.<br>• For continued coverage, patients should be RBC transfusion independent over a minimum of 16 consecutive weeks within the previous approval period.<br>**Claims Notes:**<br>• Treatment should be initiated by a specialist with expertise in managing and treating patients with MDS.<br>• The maximum dose of luspatercept should not exceed 1.75mg/kg (or 168mg total dose) once every three weeks.<br>• Approval: 6 months | | | | |

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| **Ruzurgi (amifampridine)** | 10mg Tab | 02503034 | DNP | E (SF) | MDU |
| Criteria | • For the treatment of patients with Lambert-Eaton myasthenic syndrome (LEMS) who are 6 years of age and older.<br>**Renewal Criteria:**<br>• Patients should be assessed for a response to treatment within 3 months of initiating amifampridine.<br>  ○ A response to treatment is defined as an improvement of at least 30% on the 3TUG test.<br>**Claims Notes:**<br>• The patient should be under the care of a neurologist with expertise in managing LEMS.<br>• Initial approval: 6 months<br>• Renewal approval: Long term | | | | |

## New Benefits

Effective **May 1, 2023,** 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 |
|---|---|---|---|---|---|
| Abrilada | 20mg/0.4mL Prefilled Syringe | 02511061 | DNP | E (SF) | PFI |
| Clasteon | 400mg Tab | 02245828 | DNP | SFC | SNV |
| Elonox | 30mg/0.3mL Prefilled Syringe | 02532247 | DNP | SFC | FKB |
| Elonox | 40mg/0.4mL Prefilled Syringe | 02532255 | DNP | SFC | FKB |
| Elonox | 60mg/0.6mL Prefilled Syringe | 02532263 | DNP | SFC | FKB |
| Elonox | 80mg/0.8mL Prefilled Syringe | 02532271 | DNP | SFC | FKB |
| Elonox | 100mg/mL Prefilled Syringe | 02532298 | DNP | SFC | FKB |
| Elonox HP | 120mg/0.8mL Prefilled Syringe | 02532301 | DNP | SFC | FKB |
| Elonox HP | 150mg/mL Prefilled Syringe | 02532328 | DNP | SFC | FKB |

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## Nova Scotia Formulary Updates

### New Exception Status Benefits

The following new products will be listed with the following criteria, effective **June 1, 2023**.

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| **Brukinsa (zanubrutinib)** | 80mg Cap | 02512963 | DNP | E (SFC) | BGN |
| Criteria | **Relapsed or Refractory Waldenström Macroglobulinemia**<br>• For the treatment of adult patients with relapsed or refractory Waldenström macroglobulinemia who have received at least one prior therapy and have not experienced disease progression on a Bruton's tyrosine kinase inhibitor.<br>**Clinical Notes:**<br>• Patients should have a good performance status and no evidence of disease transformation.<br>• Treatment should be discontinued upon disease progression or unacceptable toxicity. | | | | |

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| **Increlex (mecasermin)** | 10mg/mL Vial | 02509733 | DNP | E (F) | IPS |
| Criteria | • For the treatment of growth failure in children and adolescents from 2 to 18 years with confirmed severe primary insulin-like growth factor-1 deficiency (SPIGFD) who meet the following criteria:<br>○ Epiphyseal closure has not yet occurred; AND | | | | |

**New Exception Status Benefits Continued…**

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| **Increlex (mecasermin)** | 10mg/mL Vial | 02509733 | DNP | E (F) | IPS |
| Criteria | ○ Have a confirmed diagnosis of SPIGFD, defined by:<br>▪ a known genetic mutation recognized as a cause of SPIGFD, AND/OR<br>▪ has clinical and biochemical features of SPIGFD<br><br>**Renewal Criteria:**<br>• Treatment with mecasermin must be discontinued upon the occurrence of any of the following:<br>○ Height velocity is less than 1cm per 6 months or less than 2cm per year, OR<br>○ Bone age is more than 16 years in boys and 14 years in girls<br><br>**Claim Notes:**<br>• The patient must be under the care of a pediatric endocrinologist<br>• Mecasermin must not be prescribed concomitantly with recombinant GH treatment<br>• Approvals: 1 year<br>• 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:<br>○ 00900015<br>○ 00900016 | | | | |

## Change in Benefit Status

Effective **June 1, 2023,** the following product will move to full benefit and no longer require exception status approval.

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| Baqsimi | 3mg Nasal Powder | 02492415 | DNP | SFD* | LIL |

* Quantity limit of two (2) devices per fiscal year. Prescribers can submit a request for consideration or contact the Pharmacare Office should beneficiaries require more than two (2) devices per fiscal year (e.g., need for frequent use).

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## Nova Scotia Formulary Updates

### Prescription Renewals for Emergency Pharmacy Closures

For Nova Scotia residents unable to access their usual pharmacy because it is closed due to emergencies, effective June 1, 2023, until September 30, 2024, pharmacies may bill DHW for prescription renewal services when required to ensure the continuity of care for patients during an emergency pharmacy closure. Emergency pharmacy closure prescription renewal services must be performed in compliance with the Nova Scotia College of Pharmacists' *Standards of Practice: Prescribing Drugs* (April 2023 update, section 4.3 Pharmacy Closures). A special service fee of $12 is in effect for renewal of three prescriptions or less and $20 for renewals of four prescriptions or more. There is no maximum number of services for which a resident is eligible for coverage and claims will not affect the resident's annual maximum of regular prescription renewal services. Pharmacists must comply with all applicable NSCP policies and standards.

Pharmacy closure prescription renewals will be subject to audit and must comply with the requirements in Pharmacy Guide for prescription renewals except for the following:

- Duration of therapy prescribed must be consistent with the number of refills remaining on the patient's prescription unless a documented clinical reason is provided.
- Documentation must include the name and license number of the pharmacy that was closed and the reason why the prescription had to be refilled prior to the pharmacy reopening.

**Prescription Renewals for Emergency Pharmacy Closures Continued…**

Claims must be submitted electronically using the following CPhA Claims Standard field content:

**CPhA Claims Standard – Pharmacy Closure Prescription Renewal for 3 or Less Prescriptions Renewed**

| Field # | Field Name | Content |
|---|---|---|
| D.56.03 | DIN/GP#/PIN | 93899831 |
| 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) | 1200($12.00) * |

* The copayment and/or deductible ***will not*** be applied to this claim.

**CPhA Claims Standard – Pharmacy Closure Prescription Renewal for 4 or More Prescriptions Renewed**

| Field # | Field Name | Content |
|---|---|---|
| D.56.03 | DIN/GP#/PIN | 93899830 |
| 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) * |

* The copayment and/or deductible ***will not*** be applied to this claim.

## Change in Benefit Status

Effective **June 12, 2023,** the following products will move to full benefit and no longer require exception status approval.

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| Dapagliflozin | 5mg Tab | Various | DNP | SFD | VAR |
| Dapagliflozin | 10mg Tab | Various | DNP | SFD | VAR |

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## Nova Scotia Formulary Updates

### New Exception Status Benefits

The following new products will be listed with the following criteria, effective **July 1, 2023**.

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| **Dojolvi (triheptanoin)** | 100% O/L | 02512556 | DNP | E (SF) | UGX |

**Criteria**

- For the treatment of adult and pediatric patients with an acute life-threatening long-chain fatty acid oxidation disorders (LC-FAOD) who meet the following criteria:
  - patients with a confirmed diagnosis of LC-FAOD and acute life-threatening events who require alternative therapy to conventional even-chain medium-chain triglyceride (MCT) supplementation, OR
  - patients without a confirmed diagnosis of LC-FAOD presenting with acute life-threatening events consistent with LC-FAOD who require alternative therapy to conventional even-chain MCT supplementation.

**Claims Notes:**

- Triheptanoin should only be prescribed by clinicians experienced in the management of LC-FAOD.
- Approval: 1 year. Confirmation of continued response required.
- 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 PIN:
  - 00900021

**New Exception Status Benefits Continued…**

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| **Scemblix** | 20mg Tab | 02528320 | DNP | E (SFC) | NVR |
| **(asciminib)** | 40mg Tab | 02528339 | DNP | E (SFC) | NVR |
| Criteria | **Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML)**<br>• For the treatment of adult patients with Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in the chronic phase who meet the following criteria:<br>  ○ Treatment failure on or intolerance to a minimum of two prior tyrosine kinase inhibitor (TKI) therapies.<br>  ○ No evidence of a T315I or V299L mutation.<br>**Clinical Notes:**<br>• Patients should have a good performance status.<br>• Not for use in the acute phase or blast phase. | | | | |

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| **Vitrakvi** | 25mg Cap | 02490315 | DNP | E (SFC) | BAY |
| **(larotrectinib)** | 100mg Cap | 02490323 | DNP | E (SFC) | BAY |
| | 20mg/mL O/L | 02490331 | DNP | E (SFC) | BAY |
| Criteria | **Locally advanced unresectable or metastatic solid tumors with a neurotrophic tyrosine receptor kinase (NTRK) gene fusion**<br>• For the treatment of adult and pediatric patients with locally advanced unresectable or metastatic solid tumors with NTRK gene fusion without a known acquired resistance mutation. Patient is not a candidate for surgery and/or radiation due to risk of substantial morbidity and have no satisfactory treatment options.<br>**Clinical Notes:**<br>• Patients should have a good performance status.<br>• Treatment should be discontinued upon disease progression or unacceptable toxicity.<br>• Brain metastases are stable, if present.<br>• Patients with prior progression on an NTRK inhibitor are not eligible.<br>**Claim Note:**<br>• 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:<br>  ○ Vitrakvi 100mg Cap - 00900013<br>  ○ Vitrakvi 20mg/mL O/L - 00900014 | | | | |

## Updates to the Department of Health and Wellness' Provincial Clozapine Program

The Dartmouth General Hospital Pharmacy staff have started transitioning clozapine from being dispensed and monitored by hospital pharmacy to community pharmacy. This is in keeping with most other Canadian provinces. This will allow for entry into the patient's NS Drug Information System Medication Profile.

Clinicians will continue to enrol patients in the Provincial Clozapine Program via the same application to the Dartmouth General Hospital Pharmacy.

Clozapine used in community pharmacies will be ordered through the Provincial Drug Distribution Program. Pharmacy team members at the Dartmouth General Hospital, currently involved in the Clozapine Program will contact community pharmacies who have existing patients on the Provincial Clozapine Program to provide support and education. This transition period will continue into July.

Additional information will be available in the *Pharmacy Guide* (https://novascotia.ca/dhw/pharmacare/documents/Pharmacy-Guide.pdf). If you have other questions regarding the transition, please contact Karen Leyte or Kelly MacIsaac at 902-465-8556. Questions related to ordering, please contact the Provincial Drug Distribution Program at the following email address: ClozapineOPP@nshealth.ca.

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## Nova Scotia Formulary Updates

### Expansion of Public Coverage for Pharmacy Services: Therapeutic Substitution and Prescription Adaptation

Effective immediately, two additional pharmacy professional services will now be funded for **all Nova Scotia residents** with a valid health card number: *Therapeutic Substitution Services and Prescription Adaptations.*

**Therapeutic substitution** involves substituting one drug for another and is funded for the following situations:

- drug shortages,
- better patient outcomes,
- intolerance or allergy, or
- to reduce the financial impact on patients (e.g. formulary coverage).

**Prescription adaptation** involves adapting a prescription written by another provider and is funded for the following situations only when done to improve clinical effectiveness/outcomes:

- changes in dose and duration, or
- refusal to fill a drug monitored by the Prescription Monitoring Program.

All the following criteria must be met:

- Pharmacists are responsible for determining the appropriateness of the therapeutic substitution or prescription adaptation before performing the service.
- The service is conducted by a pharmacist licensed with the Nova Scotia College of Pharmacists (NSCP).
- The resident has a valid Nova Scotia health card number.
- Pharmacists must comply with all applicable NSCP policies and standards.

**Expansion of Public Coverage for Pharmacy Services: Therapeutic Substitution and Prescription Adaptation Continued…**

- A record must be available that references the original written or scanned prescription and modified prescription.
- Consent is provided to authorize the pharmacist to do the therapeutic substitution or prescription adaptation.

As with previous Pharmacare coverage, **prescription adaptation is not a funded service** in the following types of situations:

- A change in prescription quantity unrelated to a dose change or duration change, for example:
    - Replacing a 5mg tablet with one-half of a 10mg tablet, or using multiples of a lower strength (e.g., Synthroid® 0.2mg changed to 2 Synthroid® 0.1mg).
    - Changing quantities for compliance packaging must be authorized by the original prescriber, so it is not a prescription adaptation service and is not insured.
    - Changes made to match the quantity prescribed to a commercially available package size.
    - Any change in formulation (e.g., tablet to liquid).
    - Any change in regimen (e.g., changing therapy from morning to bedtime dosing).
- Verification and completion of a prescription element is not an insured prescription adaptation service.

Claim submission information is included below:

- There is no annual frequency limit for any individual with a valid Nova Scotia health card number.
- Three PINS are assigned to each service for situations when an individual requires more than one service on the same day. Only one PIN can be used per prescription.
- PINS associated with coverage that was provided for Pharmacare beneficiaries will be terminated on August 7, 2023.

Claims must be submitted electronically using the following CPhA Claims Standard field content:

**CPhA Claims Standard – Therapeutic Substitutions (All NS)**

| Field # | Field Name | Content |
|---|---|---|
| D.56.03 | DIN/GP#/PIN | 93899773<br>93899737<br>93899738 |
| 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) | 2625 ($26.25) |

**Expansion of Public Coverage for Pharmacy Services: Therapeutic Substitution and Prescription Adaptation Continued…**

**CPhA Claims Standard – Refusal to Fill (Adaptation) (All NS): Refusal to Fill a Prescription for a Drug Monitored by the NSPMP**

| Field # | Field Name | Content |
|---|---|---|
| D.56.03 | DIN/GP#/PIN | 93899772<br>93899735<br>93899736 |
| 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) | 1400 ($14.00) |

**CPhA Claims Standard – Prescription Adaptation (All NS): Changing a Prescription for a Clinical Reason to Enhance Patient Outcomes Related to a Change in Dose or Duration**

| Field # | Field Name | Content |
|---|---|---|
| D.56.03 | DIN/GP#/PIN | 93899771<br>93899733<br>93899734 |
| 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) | 1400 ($14.00) |

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## Nova Scotia Formulary Updates

### New Exception Status Benefit

The following new product will be listed with the following criteria, effective **August 1, 2023**.

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| **Givlaari (givosiran)** | 189mg/mL Vial | 02506343 | DNP | E (SF) | ALN |
| Criteria | • For the treatment of acute hepatic porphyria (AHP) in adults:<br>**Initiation**<br>• Reimbursement of givosiran should be restricted to patients with 4 or more attacks requiring either hospitalization, an urgent health care visit, or IV hemin in the year before the prescribing date.<br>**Renewal**<br>• A reduction in the annualized attack rate after 12 months of therapy compared to baseline.<br>**Claim Notes**<br>• Prescription should be restricted to a clinician experienced in the management of AHP.<br>• Should not be used in combination with prophylactic hemin.<br>• 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 PINs. Please refer to Appendix III of the Nova Scotia Formulary for additional PINs. | | | | |

## Criteria Update

The following new indication has been added to existing criteria effective **August 1, 2023**.

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| Norfloxacin | 400mg Tab | 02229524 | DNPO | E (SFC) | AAP |
| Criteria | • For prevention of recurrent spontaneous bacterial peritonitis. **[Criteria Code 07]** | | | | |

## Product Updates

Effective **August 1, 2023**, the 50 U/vial will be assigned a unique DIN, as indicated below.

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| Botox | 50 U/vial Inj | 02531577 | DNP | E (SFC) | ABV |

Effective **August 1, 2023,** the following products will move to full benefit and no longer require exception status approval.

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| Cabergoline | 0.5mg Tab | Various | DNP | SF | VAR |

Effective **August 1, 2023**, the following products will be delisted and existing beneficiaries grandfathered for coverage.

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| Chloral Hydrate | 100mg/mL Syr | 02247621 | N/A | **Not Insured** | ODN |
| Erdol | 8,288IU/mL Sol | 80003615 | N/A | **Not Insured** | ODN |
| Placebo | 100mg Tab | 00501190 | N/A | **Not Insured** | ODN |

## New Benefits

Effective **August 1, 2023,** 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 |
|---|---|---|---|---|---|
| Halycil | 50mg Tab | 02521059 | DNP | SF | ARN |
| Propylthiouracil | 50mg Tab | 02523019 | DNP | SF | PCI |

## Reminder: Drugs that Are No Longer Exception Status

As a reminder, over the past number of months, the following drugs have moved to full benefit status and no longer require exception status approval.

- Acamprosate (Campral) tablets
- Brexpiprazole (Rexulti) tablets
- Buprenorphine (Sublocade) prefilled syringes
- Carvedilol tablets
- Cholinesterase inhibitors (donepezil tablets, galantamine capsules, rivastigmine capsules)
- Dapagliflozin tablets
- Duloxetine capsules
- Entecavir tablets
- Gabapentin capsules
- Glucagon (Baqsimi) nasal device
- Lacosamide tablets
- Lamivudine HBV tablets
- Lurasidone tablets
- Mometasone nasal spray
- Naltrexone tablets
- Pioglitazone tablets
- Pregabalin capsules
- Progesterone capsules
- Quetiapine XR tablets
- Raloxifene tablets
- Tenofovir disoproxil fumarate tablets
- Ursodiol tablets

## 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:

- Under the Prescription Renewals section, criteria that allows Prescription Renewals for Emergency Pharmacy Closures has been added.
- In the Pharmacare Programs and Benefits section, new direction has been added on the Provincial Clozapine Program: Adjudication of Clams.

## Standardization of Package Sizes

Providers are reminded that claims to the Pharmacare Programs must be billed according to the following standardized package sizes.

| FORM | QUANTITY | FORM | QUANTITY |
|---|---|---|---|
| Aerosols | Per dose | Methadone oral compound solution** | Per mg |
| Capsules | Per capsule | Nasal sprays | Per dose |
| Creams* | Per gram | Nebules | Per ml |
| Enemas | Per ml | Ointments | Per gram |
| Foam*** | Per gram | Oral contraceptives | As 21 or 28 |
| Gels | Per gram | Ostomy supplies | Per item (e.g., 20 pouches) |
| Inhalers | Per actuation | Patches | Per patch |
| Insulins (vials, penfills, cartridges) | Per ml | Powders | Per gram |
| Kits | Per kit | Powder Injectables | Per vial |
| Lancets | Per lancet | Suppositories | Per suppository |
| Liquids Injectables**** | Per ml | Tablets | Per tablet |
| Liquids (except methadone) | Per ml | Testing strips | Per testing strip |

**Other:**

| FORM | QUANTITY |
|---|---|
| Package/Kits of more than one drug | Per Package<br>(e.g., Invega Sustenna®, HP-Pac®, Monistat 3 Dual-Pack, Didrocal®) |
| Packages of blood glucose testing strips with built-in meter | Per test strip<br>(e.g., Sidekick® Blood Glucose Testing System) |
| Methadone Oral Compound Solution** | Per milligram methadone, regardless of the product used to prepare the oral liquid |

*imiquimod 5% cream – Effective April 15, 2019, claims should be billed per gram and not by packet or mg.

**compounded according to NSCP standards

***claims for foam – Claims should be billed per gram and not per dose

****adalimumab biosimilars should be billed per pen/syringe/autoinjector; Somatuline Autogel should be billed as 0.5mL syringe

**Standardization of Package Sizes Continued…**

**Common Products with Incorrect Quantities Adjudicated**

| PRODUCT | FORM | CORRECT QUANTITY | ADJUDICATION NOTE |
|---|---|---|---|
| Actemra | Liquid Injectable | Per mL | • Adjudicate total volume by mL<br>• Do not adjudicate per syringe or Autoinjector |
| Kesimpta | Liquid Injectable | Per mL | • Adjudicate total volume by mL<br>• Do not adjudicate per Pen |
| Lenvima | Compliance pack | Per Cap | • Adjudicate total number of capsules in pack<br>• Do not adjudicate per Pack |
| methotrexate SC | Liquid Injectable | Per mL | • Adjudicate total volume by mL<br>• Do not adjudicate per syringe |
| Ozempic | Liquid Injectable | Per mL | • Adjudicate total volume by mL<br>• Do not adjudicate per Pen |
| Radicava | Powder Injectable | Per vial | • Adjudicate total number of vials<br>• Do not adjudicate per milligram |
| Skyrizi | Liquid Injectable | Per mL | • Adjudicate total volume by mL<br>• Do not adjudicate per Pen or syringe |
| Takhzyro | Liquid Injectable | Per mL | • Adjudicate total volume by mL<br>• Do not adjudicate per Prefilled Syringe or Vial |
| Taltz | Liquid Injectable | Per mL | • Adjudicate total volume by mL<br>• Do not adjudicate per milligram |

## Product Shortages

As a reminder, a product may be considered short when it has been confirmed to be in short supply by both the manufacturer and the wholesaler.

In the event of a shortage, prescribers are encouraged to investigate other insured options for Pharmacare beneficiaries that may be available on the NS Pharmacare Formulary. If no other insured options are available, you may wish to contact the Pharmacare office to discuss if alternatives can be considered for coverage.

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## Nova Scotia Formulary Updates

### New Exception Status Benefit

The following new product will be listed with the following criteria, **effective immediately**.

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| **Albrioza (sodium phenylbutyrate and ursodoxi-coltaurine)** | 3g/1g Sachet | 02527707 | DNP | E (SF) | ALY |
| Criteria | • For the treatment of amyotrophic lateral sclerosis (ALS), if the following criteria are met:<br>**Initiation:**<br>• Patient with a diagnosis of definite ALS; AND<br>• Patient who meets all of the following:<br>o have had ALS symptoms for 18 months or less<br>o have a forced vital capacity of at least 60% of predicted value<br>o not require permanent non-invasive ventilation or invasive ventilation<br>**Renewal:**<br>• Reimbursement of treatment should be discontinued in patients who meet any one of the following criteria:<br>o the patient becomes non-ambulatory and is unable to cut food and feed themselves without assistance, irrespective of wheather a gastrostomy is in place; OR<br>o patient requires permanent non-invasive ventilation | | | | |

**New Exception Status Benefit Continued…**

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| **Albrioza**<br>**(sodium phenylbutyrate and ursodoxi-coltaurine)** | 3g/1g Sachet | 02527707 | DNP | E (SF) | ALY |
| Criteria | **Claim Notes:**<br>• Patient must be under the care of a specialist with experience in the diagnosis and management of ALS.<br>• 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 PIN:<br>○ 00904825 | | | | |

## New Benefit

Effective **immediately,** the following product will be added as a benefit 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 |
|---|---|---|---|---|---|
| Radicava | 105mg/5mL Susp | 02532611 | DNP | E (SF) | MBT |

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## Nova Scotia Formulary Updates

### New Exception Status Benefits

The following new products will be listed with the following criteria, **effective September 1, 2023**.

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| **Vimizim (elosulfase alfa)** | 1mg/mL IV Sol | 02427184 | DNP | E (SF) | BMR |

Criteria

**Mucopolysaccharidosis Type IVA**
**Initiation Criteria:**

For the treatment of mucopolysaccharidosis type IVA (MPS IVA) in patients meeting all the following criteria:

- Diagnosis is confirmed by enzymatic assay for N-acetylgalactosamine-6-sulfate sulfatase (GALNS) activity in peripheral blood leukocytes or fibroblasts (excluding multiple sulfatase deficiency) AND mutational analysis of GALNS[1]; AND
- Patient is under the care of a specialist with experience in the diagnosis and management of MPS IVA; AND

The following baseline evaluations prior to initiation of elosulfase alfa must be provided with the request for coverage:

- Detailed medical history documenting surgeries, medical admissions, subspecialty assessments
- Orthopedic evaluation including spinal and cranial MRI, skeletal x-rays, pain symptoms from bone and joints as appropriate to age and clinical disease
- Mobility measure: 6MWT and stair climb (if appropriate for age and disease status)
- Respiratory function testing including sleep study testing (if appropriate for age)

**New Exception Status Benefits Continued…**

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| **Vimizim (elosulfase alfa)** | 1mg/mL IV Sol | 02427184 | DNP | E (SF) | BMR |
| Criteria | • Age-appropriate quality of life measure (such as HAQ, PODCI, EQ5D5L or SF36)[2]<br>• Documentation of mobility aide requirement, such as a walker or cane<br>• Documentation of requirement for respiratory aides, including ventilation status and changes in respiratory support requirements<br>• Ophthalmologic and ear, nose and throat (ENT) assessment (if appropriate)<br>• Urine keratin sulfate (KS) determination: specific KS determination is preferred over total glycosaminoglycans (GAGs)<br>• Cardiac echocardiogram<br>[1]Note: not all MPS IVA patients will have two known pathogenic alleles identified and parental mutation analysis to establish the phase of mutations should be performed.<br>[2]Note that academic goals (e.g. attendance or participation in school) may be considered case-by-case in pediatric patients.<br>**Exclusion Criteria:**<br>• The patient is diagnosed with an additional progressive life limiting condition where treatment would not provide long term benefit (such as cancer or multiple sclerosis).<br>• The patient has a forced vital capacity (FVC) of less than 0.3 liters and requires continuous ventilator assistance.<br>• The patient/family is unwilling to comply with the associated monitoring criteria.<br>• The patient/family is unwilling to attend clinics for assessment and treatment purposes.<br>Approval duration of initial approval: 1 year<br>Recommended dose: 2mg/kg IV infusion once a week.<br>**Renewal criteria:**<br>Patients must demonstrate at least 3 of the 5 following treatment effects for continuation of coverage of treatment with elosulfase alfa:<br>• 6 MWT or Stair Climb test stabilized at or improved by at least 5% of baseline measure<br>• FVC or forced expiratory volume in one second (FEV-1) stabilized at or improved by at least 5% of baseline measure or remaining within 2 standard deviations of normal for the patient's age<br>• Improvement or no change (if minimal effect) in age-appropriate quality of life measure[3]<br>• Reduction of urine KSs of 20%<br>• Stability of cardiac ejection fraction reduction (within 5% of baseline)<br>[3]Note that academic goals (e.g. attendance or participation in school) may be considered case-by-case in pediatric patients. | | | | |

**New Exception Status Benefits Continued…**

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| **Vimizim (elosulfase alfa)** | 1mg/mL IV Sol | 02427184 | DNP | E (SF) | BMR |
| Criteria | **Discontinuation criteria:**<br>Patients will not be eligible for coverage of treatment if they:<br>• Fail to meet 3 of the 5 renewal criteria<br>• Are unable to tolerate infusions due to infusion related adverse events that cannot be resolved<br>• Require permanent invasive ventilation<br>• Miss more than 6 infusions in a 12-month interval, unless for medically related issues<br>• Meet any one of the Exclusion Criteria<br>Approval duration of renewals: 1 year<br>Recommended dose: 2mg/kg IV infusion once a week. | | | | |

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| **Vyepti (eptinezumab)** | 100mg/1mL IV | 02510839 | DNP | E (SF) | LBK |
| Criteria | • For the treatment of patients with episodic[1] or chronic migraine[2], who have experienced an inadequate response, intolerance, or contraindication to at least two oral prophylactic migraine medications of different classes.<br>**Renewal:**<br>• 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.<br>• For subsequent renewals, proof that the initial 50% reduction in the average number of migraine days per month has been maintained.<br>**Clinical Notes:**<br>• Baseline number of headache and migraine days per month must be provided at the time of initial request.<br>• [1]Episodic migraine: migraine headaches on at least 4 days per month and less than 15 headache days per month for more than 3 months.<br>• [2]Chronic 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.<br>**Claim Notes:**<br>• Initial approval: 6 months<br>• Renewal approval: 1 year<br>• Must be prescribed by a physician who has experience in the management of migraine headaches. | | | | |

## Criteria Updates

The following new indications have been added to existing criteria **effective September 1, 2023**.

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| **Jakavi (ruxolitinib)** | 5mg Tab | 02388006 | DNP | E (SFC) | NVR |
| | 10mg Tab | 02434814 | DNP | E (SFC) | NVR |
| | 15mg Tab | 02388014 | DNP | E (SFC) | NVR |
| | 20mg Tab | 02388022 | DNP | E (SFC) | NVR |

Criteria

**Acute Graft-Versus-Host Disease**

For the treatment of steroid-refractory or steroid-dependent acute graft-versus-host disease (aGvHD) in adult and pediatric patients aged 12 years and older who meet all the following criteria:

- Clinically diagnosed grade II to IV aGvHD according to the NIH criteria (Harris et al. [2016]).
- Confirmed diagnosis of corticosteroid-refractory or corticosteroid-dependent aGvHD.

**Renewal criteria:**

- Achieved an overall response (i.e., CR, VGPR, PR, or stable disease with significant reduction in steroid doses), according to standard NIH criteria at day 28.
- For subsequent renewals, patients should be assessed for treatment response every 2 to 3 months, until the occurrence of any of the discontinuation criteria listed below.

**Clinical Notes:**

- Treatment should be discontinued upon the occurrence of any of the following:
    - progression of aGvHD, defined as worsening of aGvHD symptoms or occurrence of new aGvHD symptoms
    - unacceptable toxicity
    - addition of systemic therapies (other than calcineurin inhibitors) for aGvHD after day 28
    - recurrence or relapse of underlying hematological malignancy.

**Claim Notes:**

- Must be prescribed by clinicians who have experience in the diagnosis and management of patients with aGvHD.
- Must not be added to patients' concurrent treatment of systemic therapies for the treatment of aGvHD other than steroids with or without calcineurin inhibitors.
- Approval: 6 months

**Chronic Graft-Versus-Host Disease**

For the treatment of chronic graft-versus-host disease (cGvHD) in adults and pediatric patients aged 12 years and older who have inadequate response to corticosteroids or other systemic therapies who meet all the following criteria:

- Clinically diagnosed cGvHD staging of moderate to severe based on NIH consensus criteria

**Criteria Updates Continued…**

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| **Jakavi (ruxolitinib)** | 5mg Tab | 02388006 | DNP | E (SFC) | NVR |
| | 10mg Tab | 02434814 | DNP | E (SFC) | NVR |
| | 15mg Tab | 02388014 | DNP | E (SFC) | NVR |
| | 20mg Tab | 02388022 | DNP | E (SFC) | NVR |
| Criteria | • Confirmed diagnosis cGvHD with inadequate response to corticosteroids or other systemic therapies<br>**Renewal criteria:**<br>• Achieved an overall response (i.e., CR or PR, or stable disease with significant reduction in steroid doses), according to NIH criteria, after 24 weeks of therapy<br>**Clinical Notes:**<br>• Treatment should be discontinued upon the occurrence of any of the following:<br>o Progression of cGvHD, defined as worsening of cGvHD symptoms or occurrence of new cGvHD symptoms<br>o recurrence or relapse of underlying hematological malignancy<br>**Claim Notes:**<br>• Must be prescribed by clinicians who have experience in the diagnosis and management of patients with cGvHD.<br>• Must not be added to patients' concurrent treatment of systemic therapies other than steroids with or without calcineurin inhibitors.<br>• Initial Approval: 6 months<br>• Renewal Approval: 1 year | | | | |

The criteria for the following has been updated **effective September 1, 2023**

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| **Tykerb (lapatinib)** | 250mg Tab | 02326442 | DNP | E (SFC) | NVR |
| Criteria | For the treatment of patients with unresectable locally advanced or metastatic HER2-positive breast cancer in combination with capecitabine for use as:<br>• First line therapy following disease relapse during or within six months of completing adjuvant treatment with trastuzumab or trastuzumab emtansine; or<br>• Second line therapy following disease progression during treatment with trastuzumab, with or without pertuzumab, in the advanced setting.<br>**Clinical Notes:**<br>• Patients should have a good performance status. | | | | |

## New Benefits

Effective **September 1, 2023,** 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 |
|---|---|---|---|---|---|
| Norditropin FlexPro | 5mg/1.5mL Prefilled Pen | 02529181 | DNP | E (SF) | NNO |
| Norditropin FlexPro | 10mg/1.5mL Prefilled Pen | 02529203 | DNP | E (SF) | NNO |
| Norditropin FlexPro | 15mg/1.5mL Prefilled Pen | 02529211 | DNP | E (SF) | NNO |

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## Nova Scotia Formulary Updates

### Criteria Update

The following new indication has been added to existing criteria **effective immediately**.

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| **Lynparza (olaparib)** | 100 mg Tab | 02475200 | DNP | E (SFC) | AZE |
| | 150 mg Tab | 02475219 | DNP | E (SFC) | AZE |

Criteria

**High-Risk Early Breast Cancer**

For the treatment of adult patients with germline BRCA-mutated (gBRCAm) HER2-negative high-risk early breast cancer who meet one of the following criteria:

- For patients who underwent upfront surgery followed by adjuvant chemotherapy:
  - If TNBC: must have node-positive disease or pT ≥ 2cm, or
  - If HR-positive, HER2-negative: must have ≥ 4 involved pathologically confirmed lymph nodes

  OR
- For patients who received neoadjuvant chemotherapy followed by surgery:
  - If TNBC: must have residual invasive disease, or
  - If HR-positive, HER2-negative: must have residual invasive disease and deemed high-risk using a risk assessment tool.

**Clinical Notes:**

- Patients should have a good performance status.
- Treatment should continue until disease recurrence, unacceptable toxicity, or to a maximum of one year, whichever occurs first.

**Criteria Updates Continued…**

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| **Lynparza (olaparib)** | 100 mg Tab<br>150 mg Tab | 02475200<br>02475219 | DNP<br>DNP | E (SFC)<br>E (SFC) | AZE<br>AZE |
| Criteria | • Must have confirmed gBRCAm prior to starting therapy.<br>• Patients must have completed chemotherapy containing anthracyclines and/or taxanes. Patients who stop chemotherapy early for toxicity are eligible. | | | | |

## New Benefit

Effective **immediately,** 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 |
|---|---|---|---|---|---|
| Tresiba | 100 U/mL Penfill Cartridge | 02467860 | DNP | SFD | NNO |

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## Nova Scotia Formulary Updates

### New Exception Status Benefits

The following new products have been listed with the following criteria, **effective October 1, 2023**.

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| **Firdapse (amifampridine)** | 10mg Tab | 02502984 | DNP | E (SF) | KYE |

**Criteria**

- For the treatment of patients with Lambert-Eaton myasthenic syndrome (LEMS) who are 18 years of age and older.

**Renewal Criteria:**

- Patients should be assessed for a response to treatment within 3 months of initiating amifampridine.
  - A response to treatment is defined as an improvement of at least 30% on the 3TUG test.

**Claims Notes:**

- The patient should be under the care of a neurologist with expertise in managing LEMS.
- Initial Approval: 6 months
- Renewal Approval: long term

**New Exception Status Benefits Continued…**

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| **Lorbrena (lorlatinib)** | 25mg Tab<br>100mg Tab | 02485966<br>02485974 | DNP<br>DNP | E (SFC)<br>E (SFC) | PFI<br>PFI |
| Criteria | • As monotherapy for the first-line treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive locally advanced (not amenable to curative therapy) or metastatic non-small cell lung cancer (NSCLC).<br><br>**Clinical Notes:**<br>• Patients should have a good performance status.<br>• Treatment should continue until disease progression or unacceptable toxicity.<br>• Patients must not have had any prior systemic treatment for advanced or metastatic disease.<br>• Patients are not eligible for subsequent ALK inhibitor therapy following disease progression on lorlatinib.<br>• Patients may be switched to an alternate ALK inhibitor in the case of intolerance without disease progression. | | | | |

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| **Xpovio (selinexor)** | 20mg Tab | 02527677 | DNP | E (SFC) | FTI |
| Criteria | • In combination with bortezomib and dexamethasone for the treatment of adult patients with multiple myeloma and who have received at least one prior therapy.<br><br>**Clinical Notes:**<br>1. Prior treatment with bortezomib/proteasome inhibitor is permitted if all the following criteria are met:<br>  ○ Best response achieved with bortezomib/proteasome inhibitor was at least a partial response<br>  ○ Bortezomib/proteasome inhibitor not discontinued for grade 3 or higher toxicity<br>  ○ Bortezomib/proteasome inhibitor treatment-free interval has been at least six months.<br>2. Treatment should continue until disease progression or unacceptable toxicity. | | | | |

**New Exception Status Benefits Continued…**

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| **Qinlock (ripretinib)** | 50mg Tab | 02500833 | DNP | E (SFC) | MDP |
| Criteria | • For the treatment of adult patients with advanced gastrointestinal stromal tumors (GIST) who have progression on or intolerance to imatinib, sunitinib and regorafenib.<br><br>**Clinical Notes:**<br>• Patients should have a good performance status.<br>• Treatment should continue until disease progression or unacceptable toxicity.<br>• Patients must not have active CNS metastases. | | | | |

## Criteria Updates

The following new indications have been added to existing criteria **effective October 1, 2023**.

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| **Lenvima (lenvatinib)** | 4mg Cap | 02484056 | DNP | E (SFC) | EIS |
| | 8mg Cap | 02468220 | DNP | E (SFC) | EIS |
| | 10mg Cap | 02450321 | DNP | E (SFC) | EIS |
| | 12mg Cap | 02484129 | DNP | E (SFC) | EIS |
| | 14mg Cap | 02450313 | DNP | E (SFC) | EIS |
| | 20mg Cap | 02450305 | DNP | E (SFC) | EIS |
| | 24mg Cap | 02450291 | DNP | E (SFC) | EIS |
| Criteria | **Advanced and Metastatic Renal Cell Carcinoma**<br>• In combination with pembrolizumab for the treatment of adult patients with advanced (not amenable to curative surgery or radiation) or metastatic renal cell carcinoma who have not had prior systemic therapy for metastatic disease.<br><br>**Clinical Notes:**<br>• Patients should have a good performance status.<br>• Treatment should continue until disease progression or unacceptable toxicity (can be continued as monotherapy after completing 2 years of combination therapy with pembrolizumab).<br>• If pembrolizumab or lenvatinib is discontinued for toxicity, the other agent can be continued at the discretion of the physician. | | | | |

**Criteria Updates Continued…**

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| **Lenvima (lenvatinib)** | 4mg Cap | 02484056 | DNP | E (SFC) | EIS |
| | 8mg Cap | 02468220 | DNP | E (SFC) | EIS |
| | 10mg Cap | 02450321 | DNP | E (SFC) | EIS |
| | 12mg Cap | 02484129 | DNP | E (SFC) | EIS |
| | 14mg Cap | 02450313 | DNP | E (SFC) | EIS |
| | 20mg Cap | 02450305 | DNP | E (SFC) | EIS |
| | 24mg Cap | 02450291 | DNP | E (SFC) | EIS |

Criteria

- Patients are eligible for one of pembrolizumab with lenvatinib or pembrolizumab with axitinib in this setting. If intolerant to one tyrosine kinase inhibitor (TKI), patient may be switched to an alternate TKI, provided there has been no progression.
- Patients who received pembrolizumab in the adjuvant setting are eligible for treatment provided there was a disease-free interval of at least six months.
- If patient requires and qualifies for re-treatment with pembrolizumab, lenvatinib may also be given at the discretion of the treating physician.

**Advanced Endometrial Carcinoma**

- In combination with pembrolizumab for the treatment of adult patients with advanced endometrial carcinoma that is not microsatellite instability high (MSI-H) or mismatch repair deficient (dMMR), who have disease progression following prior platinum-based systemic therapy are and are not candidates for curative surgery or radiation.

**Clinical Notes:**

- 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).
- Confirmation that patient does not have MSI-H or dMMR disease must be done prior to initiating treatment.
- No active CNS metastases (eligible if treated/stable).
- If pembrolizumab or lenvatinib is discontinued for toxicity, the other agent can be continued at the discretion of the physician.
- If patient requires and qualifies for re-treatment with pembrolizumab, lenvatinib can also be given at the discretion of the treating physician.

**Criteria Updates Continued…**

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| **Rozlytrek (entrectinib)** | 100mg Cap<br>200mg Cap | 02495007<br>02495015 | DNP<br>DNP | E (SFC)<br>E (SFC) | HLR<br>HLR |
| Criteria | • For the treatment of adult patients with unresectable locally advanced or metastatic extracranial solid tumors with NTRK gene fusion without a known acquired resistance mutation. Eligible patients are not candidates for surgery and/or radiation due to risk of substantial morbidity and have no satisfactory treatment options.<br>**Clinical Notes:**<br>• Patients should have a good performance status.<br>• Treatment should be discontinued upon disease progression or unacceptable toxicity.<br>• CNS metastases are stable if present.<br>• Patients with prior progression on an NTRK inhibitor are not eligible. | | | | |

The criteria for the following has been updated **effective October 1, 2023**

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| **Aranesp (darbepoetin)** | Various | Various | DNP | E (SFC) | AGA |
| Criteria | • For the treatment of transfusion dependent patients with hematologic malignancies who have a baseline anemia of ≤ 90g/L and whose transfusion requirements are ≥ 2 units of packed red blood cells per month over 3 months.<br>• Initial approval for 6 months with the documentation of dose, hemoglobin and therapeutic outcome (number of transfusions).<br>• Subsequent 6-month approvals are dependent on evidence of satisfactory clinical response or reduced treatment requirement to less than 2 units of PRBC monthly. | | | | |

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| **Sprycel and generic brands (dasatinib)** | Various | Various | DNP | E (SFC) | VAR |
| Criteria | • For the treatment of adult patients with Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic, accelerated, or blast phase.<br>• For the treatment of patients with Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL). | | | | |

**Criteria Updates Continued…**

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| **Eprex (erythropoietin)** | Various | Various | DNP | E (SFC) | JAN |
| Criteria | • For the treatment of transfusion dependent patients with hematologic malignancies who have a baseline anemia of ≤ 90g/L and whose transfusion requirements are ≥ 2 units of packed red blood cells per month over 3 months<br>• Initial approval for 6 months with the documentation of dose, hemoglobin and therapeutic outcome (number of transfusions).<br>• Subsequent 6-month approvals are dependent on evidence of satisfactory clinical response or reduced treatment requirement to less than 2 units of PRBC monthly.<br>• If transfusion requirements increase to ≥ 2 units/ month (over a 3-montheriod), one dose increase may be attempted (maximum dose 60,000iu per week). | | | | |

## Change in Benefit Status

Effective **October 1, 2023,** the following products have moved to full benefit and no longer require exception status approval.

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| Imatinib | 100mg Tab | Various | DNP | SFC | VAR |
| Imatinib | 400mg Tab | Various | DNP | SFC | VAR |

## New Benefits

Effective **October 1, 2023,** the following products have been added as benefits in the Nova Scotia Formulary. The benefit status within the Pharmacare Programs is indicated.

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| Lapelga | 10mg/mL Prefilled Autoinjector | 02529343 | DNP | E (SFC) | APO |
| Yuflyma | 80mg/0.8mL Prefilled Pen | 02535084 | DNP | E (SF) | CTL |
| Yuflyma | 80mg/0.8mL Prefilled Syringe | 02535076 | DNP | E (SF) | CTL |

## Renewed Three-Year Generics Initiative

The pan-Canadian Pharmaceutical Alliance (pCPA) and the Canadian Generic Pharmaceutical Association (CGPA) reached an agreement, effective October 1, 2023, on a renewed three-year pricing initiative for generic medicines. For more information, please visit https://www.pcpacanada.ca/generic-drug-framework.

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## Nova Scotia Formulary Updates

### New Exception Status Benefits

The following new products have been listed with the following criteria, **effective November 1, 2023**.

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| **Cibinqo (abrocitinib)** | 50mg Tab | 02528363 | DNP | E (SF) | PFI |
| | 100mg Tab | 02528371 | DNP | E (SF) | PFI |
| | 200mg Tab | 02528398 | DNP | E (SF) | PFI |

Criteria

- For the treatment of moderate to severe atopic dermatitis (AD) in patients 12 years of age and older who meet all the following criteria:
  - Patients must have had an adequate trial (with a documented refractory disease, including the relief of pruritis), or were intolerant (with documented intolerance), or are ineligible for each of the following therapies:
    - Maximally tolerated medical topical therapies for AD combined with phototherapy (where available), and
    - Maximally tolerated medical topical therapies for AD combined with at least 1 of the 4 systemic immunomodulators (methotrexate, cyclosporine, mycophenolate mofetil, or azathioprine)
  - Baseline Physician Global Assessment score of 3 or greater and Eczema Area and Severity Index (EASI) of 7.1 or greater.

**Renewal Criteria:**

- Requests for renewal must provide proof of beneficial clinical effect defined as a 75% or greater improvement from baseline in the EASI score (EASI-75) six months after treatment initiation.

**New Exception Status Benefits Continued…**

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| **Cibinqo (abrocitinib)** | 50mg Tab | 02528363 | DNP | E (SF) | PFI |
| | 100mg Tab | 02528371 | DNP | E (SF) | PFI |
| | 200mg Tab | 02528398 | DNP | E (SF) | PFI |
| Criteria | • Proof of maintenance of EASI-75 response from baseline must be provided for subsequent authorizations.<br><br>**Clinical Note:**<br>• Not to be used in combination with phototherapy or any immunomodulatory agents (including biologics or other janus kinase inhibitor treatment) for moderate to severe AD.Treatment should continue until disease progression or unacceptable toxicity.<br><br>**Claim Notes:**<br>• The patient must be under the care of a dermatologist, allergist, clinical immunologist, or pediatrician who has expertise in the management of moderate to severe AD.<br>• Approvals will be for a maximum of 200 mg once daily.<br>• Initial approval period: 6 months.<br>• Renewal approval period: 1 year. | | | | |

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| **Retevmo (selpercatinib)** | 40mg Cap | 02516918 | DNP | E (SFC) | LIL |
| | 80mg Cap | 02516926 | DNP | E (SFC) | LIL |
| Criteria | **Medullary Thyroid Cancer**<br>• For the treatment of patients 12 years and older with unresectable locally advanced or metastatic RET-mutant medullary thyroid cancer (MTC) who have progressed on, are intolerant to, or have a contraindication to first-line therapy.<br><br>**Clinical Notes:**<br>• Discontinuation for unacceptable toxicity or loss of clinical benefit.<br>• Patients should have a good performance status.<br>• Monotherapy only.<br>• Confirm RET mutation prior to initiating therapy.<br>• Patients with prior progression on a RET inhibitor are ineligible.<br><br>**Differentiated Thyroid Carcinoma**<br>• For the treatment of adult patients with locally advanced or metastatic RET fusion-positive differentiated thyroid carcinoma (DTC) not amenable to surgery or radioactive iodine therapy following prior Lenvatinib and/or Sorafenib. | | | | |

**New Exception Status Benefits Continued…**

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| **Retevmo** | 40mg Cap | 02516918 | DNP | E (SFC) | LIL |
| **(selpercatinib)** | 80mg Cap | 02516926 | DNP | E (SFC) | LIL |
| Criteria | **Clinical Notes:**<br>• Discontinuation for unacceptable toxicity or loss of clinical benefit.<br>• Patients should have a good performance status.<br>• Monotherapy only.<br>• Confirm RET mutation prior to initiating therapy.<br>• Patients with prior progression on a RET inhibitor are ineligible.<br><br>**Non-Small Cell Lung Cancer**<br>• For the treatment of adult patients with metastatic RET fusion-positive non-small cell lung cancer (NSCLC) as first-line treatment or after prior systemic therapy.<br><br>**Clinical Notes:**<br>• Discontinuation for unacceptable toxicity or loss of clinical benefit.<br>• Patients should have a good performance status.<br>• Monotherapy only.<br>• Confirm RET mutation prior to initiating therapy.<br>• Patients with prior progression on a RET inhibitor are ineligible. | | | | |

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| **Tremfya** | 100mg/mL Autoinjector | 02487314 | DNP | E (SF) | JAN |
| **(guselkumab)** | 100mg/mL Prefilled Syringe | 02469758 | DNP | E (SF) | JAN |
| Criteria | **Psoriasis**<br>• For patients with severe, debilitating chronic plaque psoriasis who meet all of the following:<br>  ○ Body surface area (BSA) involvement of >10% and/or significant involvement of the face, hands, feet or genitals;<br>  ○ Failure to, contraindication to or intolerant of methotrexate and cyclosporine;<br>  ○ Failure to, intolerant of or unable to access phototherapy;<br>  ○ Written request of a dermatologist or prescriber with a specialty in dermatology.<br>• Continued coverage is dependent on evidence of improvement, specifically:<br>  ○ A >75% reduction in the Psoriasis Area and Severity Index (PASI) score; or<br>  ○ A >50% reduction in PASI with a > 5 point improvement in DLQI (Dermatology Life Quality Index); or<br>  ○ Significant reduction in BSA involved, with consideration of important regions such as the face, hands, feet or genitals. | | | | |

**New Exception Status Benefits Continued…**

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| **Tremfya** | 100mg/mL AutoInjector | 02487314 | DNP | E (SF) | JAN |
| **(guselkumab)** | 100mg/mL Prefilled Syringe | 02469758 | DNP | E (SF) | JAN |
| Criteria | **Clinical Note:**<br>• Treatment should be discontinued if a response has not been demonstrated after 16 weeks.<br>**Claim Notes:**<br>• Concurrent use of biologics not approved.<br>• Approvals will be for 100mg by subcutaneous injection at weeks 0, 4, followed by maintenance dosing of 100mg every 8 weeks.<br>• Initial approval period: 16 weeks<br>• Renewal approval period: 1 year<br>**Psoriatic Arthritis**<br>• 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.<br>• For the treatment of patients with predominantly peripheral psoriatic arthritis who are refractory, intolerant or have contraindications to:<br>o The sequential use of at least two NSAIDs at maximal tolerated dose for a minimum of two weeks each; AND<br>o 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<br>o Leflunomide for a minimum of 10 weeks or sulfasalazine for a minimum of 3 months.<br>**Clinical Notes:**<br>• 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.<br>• Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above.<br>• Intolerant is defined as demonstrating serious adverse effects to treatments. The nature of intolerance(s) must be clearly documented.<br>**Claim Notes:**<br>• Must be prescribed by a rheumatologist.<br>• Combined use of more than one biologic DMARD will not be reimbursed.<br>• Initial approval:12 weeks, loading dose of 100mg at weeks 0, 4, and 8 weeks<br>• Maximum dose of 100mg every 8 weeks<br>• Renewal approval: 1 year. Confirmation of continued response required. | | | | |

## Criteria Update

The following new indications and updated criteria for an existing indication is effective **November 1, 2023**.

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| **Dupixent (dupilumab)** | 200mg/1.14mL Prefilled Syringe | 02492504 | DNP | E (SF) | SAV |
| | 200 mg/1.14mL Prefilled Pen | 02524252 | DNP | E (SF) | SAV |
| | 300mg/2mL Prefilled Pen | 02510049 | DNP | E (SF) | SAV |
| | 300mg/2mL Prefilled Syringe | 02470365 | DNP | E (SF) | SAV |

Criteria

**Atopic Dermatitis**

- For the treatment of moderate to severe atopic dermatitis (AD) in patients 12 years of age and older who meet all of the following criteria:
    - Patients must have had an adequate trial (with a documented refractory disease), or were intolerant (with documented intolerance), or are ineligible for each of the following therapies:
        - maximally tolerated medical topical therapies for AD combined with phototherapy (where available), and;
        - maximally tolerated medical topical therapies for AD combined with at least 1 of the 4 systemic immunomodulators (methotrexate, cyclosporine, mycophenolate mofetil, or azathioprine).
    - Baseline Physician Global Assessment score of 3 or greater and Eczema Area and Severity Index (EASI) of 7.1 or greater.

Renewal criteria:

- Requests for renewal must provide proof of beneficial clinical effect defined as a 75% or greater improvement from baseline in the Eczema Area and Severity Index (EASI-75) score six months after treatment initiation.
- Proof of maintenance of EASI-75 response from baseline must be provided for subsequent authorizations.

**Clinical Note:**

- Not to be used in combination with phototherapy or any immunomodulatory drugs (including biologics) or a Janus kinase inhibitor treatment for moderate-to-severe AD.

**Claim Notes:**

- The patient must be under the care of a dermatologist, allergist, clinical immunologist, or pediatrician who has expertise in the management of moderate to severe AD.
- Approvals will be for a maximum of 600 mg at week 0, then 300 mg every two weeks thereafter.
- Initial approval period: 6 months.
- Renewal approval period: 1 year.

**Severe Asthma (Pediatric)**

- For the adjunctive treatment of severe asthma with a type 2 or eosinophilic phenotype in patients aged 6 to 11 years of age who are inadequately controlled with medium-to high-dose inhaled corticosteroids (ICS) plus one or more additional asthma controller(s) (e.g., long-acting beta-agonist) or high-dose ICS alone and meet the following criteria:
    - blood eosinophil count ≥ 0.15 × $10^9$/L within the past 12 months; and

**Criteria Update Continued…**

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| **Dupixent (dupilumab)** | 200mg/1.14mL Prefilled Syringe | 02492504 | DNP | E (SF) | SAV |
| | 200 mg/1.14mL Prefilled Pen | 02524252 | DNP | E (SF) | SAV |
| | 300mg/2mL Prefilled Pen | 02510049 | DNP | E (SF) | SAV |
| | 300mg/2mL Prefilled Syringe | 02470365 | DNP | E (SF) | SAV |

Criteria

- uncontrolled asthma with at least one clinically significant asthma exacerbation in the past 12 months.

Initial Discontinuation Criteria:

- Baseline asthma control questionnaire score has not improved at 12 months since initiation of treatment, or
- The number of clinically significant asthma exacerbations has increased within the previous 12 months

Subsequent Discontinuation Criteria:

- Asthma control questionnaire score achieved after the first 12 months of therapy has not been maintained subsequently, or
- The number of clinically significant asthma exacerbations has increased within the previous 12 months.

**Clinical Notes:**

- A baseline and annual assessment of asthma symptom control using a validated asthma control questionnaire must be provided.
- Medium dose ICS is defined as between 200 mcg and 400 mcg of fluticasone propionate or equivalent daily dose and high-dose ICS is defined as greater than 400 mcg of fluticasone propionate or equivalent daily dose.
- A significant clinical exacerbation is defined as worsening of asthma such that the treating physician elected to administer systemic glucocorticoids for at least 3 days or the patient visited an emergency department or was hospitalized.

**Claim Notes:**

- Must be prescribed by a pediatric respirologist or allergist experienced in the treatment of severe asthma.
- Combined use of dupilumab with other biologics used to treat asthma will not be reimbursed.
- Approvals will be for a maximum of 200 mg every two weeks or 300 mg every four weeks.
- Approval period: 1 year.

**Severe Asthma**

- For the adjunctive treatment of severe asthma with a type 2 or eosinophilic phenotype or oral corticosteroid (OCS) dependent severe asthma in patients 12 years of age and older who are inadequately controlled with high-dose inhaled corticosteroids (ICS) and one or more additional asthma controller(s) (e.g., long-acting beta-agonist) and meets one of the following criteria:
  - blood eosinophil count ≥ 0.15 × $10^9$/L within the past 12 months, or
  - have OCS dependent asthma.

**Criteria Update Continued…**

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| **Dupixent (dupilumab)** | 200mg/1.14mL Prefilled Syringe | 02492504 | DNP | E (SF) | SAV |
| | 200 mg/1.14mL Prefilled Pen | 02524252 | DNP | E (SF) | SAV |
| | 300mg/2mL Prefilled Pen | 02510049 | DNP | E (SF) | SAV |
| | 300mg/2mL Prefilled Syringe | 02470365 | DNP | E (SF) | SAV |

Criteria

Initial Discontinuation Criteria:

- Baseline asthma control questionnaire score has not improved at 12 months since initiation of treatment, or
- No decrease in the daily maintenance OCS dose in the first 12 months of treatment, or
- Number of clinically significant asthma exacerbations has increased within the previous 12 months.

Subsequent Discontinuation Criteria:

- Asthma control questionnaire score achieved after the first 12 months of therapy has not been maintained subsequently, or
- Reduction in the daily maintenance OCS dose achieved after the first 12 months of treatment is not maintained subsequently, or
- Number of clinically significant asthma exacerbations has increased within the previous 12 months.

**Clinical Notes:**

- A baseline and annual assessment of asthma symptom control using a validated asthma control questionnaire must be provided.
- A baseline and annual number of clinically significant asthma exacerbations must be provided.
- High-dose ICS is defined as greater than or equal to 500 mcg of fluticasone propionate or equivalent daily dose.
- A significant clinical exacerbation is defined as worsening of asthma such that the treating physician elected to administer systemic glucocorticoids for at least 3 days or the patient visited an emergency department or was hospitalized.

**Claim Notes:**

- Must be prescribed by a respirologist, clinical immunologist, allergist or internist experienced in the treatment of severe asthma.
- Combined use of dupilumab with other biologics used to treat asthma will not be reimbursed.
- Approvals will be for a maximum of 600 mg at week 0, then 300 mg every two weeks thereafter.
- Approval period: 1 year.

## Change in Benefit Status

Effective **November 1, 2023,** the following products will move to full benefit and no longer require exception status approval.

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| Erlotinib | 25mg Tab | Various | DNP | SFC | VAR |
| Erlotinib | 100mg Tab | Various | DNP | SFC | VAR |
| Erlotinib | 150mg Tab | Various | DNP | SFC | VAR |

## New Benefits

Effective **October 1, 2023,** the following product has been added as a benefit 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 |
|---|---|---|---|---|---|
| Zejula | 100mg Tab | 02530031 | DNP | E (SFC) | GSK |

Effective **November 1, 2023,** the following product has been added as a benefit 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 |
|---|---|---|---|---|---|
| Yuflyma | 40mg/0.4mL Prefilled Syringe | 02523760 | DNP | E (SF) | CTL |

## Product Update

Effective **November 1, 2023**, the 200 U/vial will be assigned a unique DIN, as indicated below.

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| Botox | 200 U/vial Inj | 02531585 | DNP | E (SF) | ABV |

## Administration of Publicly Funded Influenza Vaccine by Pharmacies for the 2023-2024 Influenza Season

### Eligibility

All individuals 6 months of age and over can have publicly funded influenza vaccine provided by a pharmacy. Eligibility for publicly funded influenza vaccine is defined in the document https://novascotia.ca/dhw/cdpc/documents/Publicly-Funded-Seasonal-Inactivated-Influenza-Vaccine-Information.pdf

**New for the 2023-2024 Influenza Season**

Everyone in Nova Scotia who is 65 years and older is eligible to receive High Dose influenza vaccine. High Dose influenza vaccine has four times the amount of antigen and offers better protection for this age group.

**Administration of Publicly Funded Influenza Vaccine by Pharmacies for the 2023-2024 Influenza Season Continued…**

### Coadministration of COVID-19 and Influenza Vaccines

Administration of COVID-19 vaccines may occur concurrently with (i.e., same day), or at any time before or after seasonal influenza immunization for those aged 6 months and older. Health care providers should consult the Canadian Immunization Guide COVID-19 chapter for updated NACI guidance on the concurrent administration of influenza and COVID-19.

https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-4-active-vaccines/page-26-covid-19-vaccine.html#a8.3

### Billing and Payment Process

Pharmacies are to use Clinic Flow for appointment booking and to document administration of influenza vaccine. As the publicly funded influenza vaccine is available free of charge, no individual is to be charged for the vaccine.

The Department of Health and Wellness (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. DHW will submit these reports to Medavie and payments will be processed on a bi-weekly basis within two pay periods of report submission. The payments will appear as a bottom-line adjustment on each pharmacy's pay statement, labelled as "FLU" 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.

In line with the Pharmacy Practice Regulations effective October 5, 2020, claims for seasonal influenza vaccine will be accepted when the technical aspect of the administration has been delegated to a pharmacy technician or when administered by any self-regulated health professional under a pharmacist's direction and supervision, when performed in compliance with the regulations and standards of practice.

**Coverage of Service Fee for Non-Residents:** The pharmacy professional fee will be covered for all persons receiving a pharmacy-administered influenza vaccine when recorded in CANImmunize, including those who do not have a valid Nova Scotia health card. This is consistent with the policy for COVID-19 vaccinations.

**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 a pharmacy has changed license numbers, this information must be updated in Clinic Flow to ensure accurate payment processing. Inactive or incorrect license numbers will result in payments not being processed. To update your license in Clinic Flow, please refer to the information provided by the NS College of Pharmacists when you were issued your license.

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## Nova Scotia Formulary Updates

### New Exception Status Benefits

The following new products have been listed with the following criteria, effective **December 1, 2023**.

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| **Foquest (methylphenidate hydrochloride)** | 25mg Cap | 02470292 | DNP | E (SF) | ELV |
| | 35mg Cap | 02470306 | DNP | E (SF) | ELV |
| | 45mg Cap | 02470314 | DNP | E (SF) | ELV |
| | 55mg Cap | 02470322 | DNP | E (SF) | ELV |
| | 70mg Cap | 02470330 | DNP | E (SF) | ELV |
| | 85mg Cap | 02470349 | DNP | E (SF) | ELV |
| | 100mg Cap | 02470357 | DNP | E (SF) | ELV |
| Criteria | • For the treatment of patients with attention deficit hyperactivity disorder (ADHD) who have tried other forms of extended-release methylphenidate with unsatisfactory results.<br><br>**Claim Note:**<br>• The maximum dose reimbursed is 100mg daily. | | | | |

**New Exception Status Benefits Continued…**

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| **Tezspire (tezepelumab)** | 210mg/1.91mL Prefilled Syringe | 02529548 | DNP | E (SF) | AZE |
| | 210mg/1.91mL Prefilled Pen | 02529556 | DNP | E (SF) | AZE |
| Criteria | • For the treatment of severe asthma in patients 12 years and older who are inadequately controlled with high-dose inhaled corticosteroids (ICS), and one or more additional asthma controller(s) (e.g., long-acting beta-agonist), and have experienced 2 or more clinically significant asthma exacerbations in the past 12 months.<br>**Initial Discontinuation Criteria:**<br>• Baseline asthma control questionnaire score has not improved at 12 months since initiation of treatment, or<br>• No decrease in the daily maintenance OCS dose in the first 12 months of treatment, or<br>• The number of clinically significant asthma exacerbations has increased within the previous 12 months.<br>**Subsequent Discontinuation Criteria:**<br>• Asthma control questionnaire score achieved after the first 12 months of therapy has not been maintained subsequently, or<br>• The reduction in the daily maintenance dose of OCS achieved after the first 12 months of treatment is not maintained or improved subsequently, or<br>• The number of clinically significant asthma exacerbations has increased within the previous 12 months.<br>**Clinical Notes:**<br>• A baseline assessment of asthma symptom control using a validated asthma control questionnaire must be provided.<br>• A baseline and annual number of clinically significant asthma exacerbations must be provided.<br>• High dose ICS is defined as ≥ 500 mcg of fluticasone propionate or equivalent daily dose.<br>• A significant clinical exacerbation is defined as worsening of asthma such that the treating physician elected to administer systemic glucocorticoids for at least 3 days or the patient visited an emergency department or was hospitalized.<br>**Claim Notes:**<br>• Must be prescribed by a respirologist, clinical immunologist, allergist or internist experienced in the treatment of severe asthma.<br>• Combined us of tezepelumab with other biologics used to treat asthma will not be reimbursed.<br>• Approvals will be for a maximum of 210mg subcutaneous injection every 4 weeks.<br>• Approval period: 1 year. | | | | |

**New Exception Status Benefits Continued…**

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| **Verzenio (abemaciclib)** | 50mg Tab | 02487098 | DNP | E (SFC) | LIL |
| | 100mg Tab | 02487101 | DNP | E (SFC) | LIL |
| | 150mg Tab | 02487128 | DNP | E (SFC) | LIL |
| Criteria | • In combination with endocrine therapy (ET) for the adjuvant treatment of adult patients with hormone receptor (HR) positive, human epidermal growth factor receptor 2 (HER2) negative, node-positive early breast cancer at high risk of disease recurrence and a Ki-67 score of at least 20%.<br>**Clinical Notes:**<br>• Patients should have a good performance status.<br>• Treatment should continue until disease progression, unacceptable toxicity, or completion of 2 years of adjuvant therapy. ET may be continued after abemaciclib is completed.<br>• Patients are not eligible if they have inflammatory breast cancer, or prior treatment with a cyclin-dependent kinases 4 and 6 (CDK4/6) inhibitor.<br>• Retreatment with a CDK4/6 inhibitor may be reasonable in the metastatic setting if disease recurrence occurs greater than or equal to 6 months after completion of adjuvant abemaciclib. | | | | |

## Criteria Updates

The criteria for the following has been updated effective **December 1, 2023.**

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| **Tasigna** | 150mg Tab | 02368250 | DNP | E (SFC) | NVR |
| **(nilotinib)** | 200mg Tab | 02315874 | DNP | E (SFC) | NVR |
| Criteria | **First Line:**<br>• For the first-line treatment of adult patients with Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase.<br>**Second Line:**<br>• For the treatment of chronic phase and accelerated phase Philadelphia chromosome positive (Ph+) chronic myeloid leukemia (CML) in adult patients who:<br>  ○ Are resistant to imatinib;<br>  ○ Have progressed to accelerated phase while on imatinib;<br>  ○ Are intolerant to previous oral tyrosine kinase inhibitors (TKIs) (i.e. imatinib or dasatinib or both). Sequential use of nilotinib and dasatinib is not permitted except in cases of intolerance (i.e. grade 3 or 4 toxicity). | | | | |

**Criteria Update Continued…**

The following new indication and strength has been added to existing criteria, effective **December 1, 2023.**

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| **Rinvoq** | 15mg Tab | 02495155 | DNP | E (SF) | ABV |
| **(upadacitinib)** | 30mg Tab | 02520893 | DNP | E (SF) | ABV |

Criteria

- For the treatment of moderate to severe atopic dermatitis in patients 12 years of age and older who meet all of the following criteria:
    - Patients must have had an adequate trial (with a documented refractory disease), or were intolerant (with documented intolerance), or are ineligible for each of the following therapies:
        - maximally tolerated medical topical therapies for AD combined with phototherapy (where available), and;
        - maximally tolerated medical topical therapies for AD combined with at least 1 of the 4 systemic immunomodulators (methotrexate, cyclosporine, mycophenolate mofetil, or azathioprine)
    - Baseline Physician Global Assessment score of 3 or greater and Eczema Area and Severity Index (EASI) of 7.1 or greater.

**Renewal Criteria:**

- Requests for renewal must provide proof of beneficial clinical effect when defined as a 75% or greater improvement from baseline in the EASI score (EASI-75) 6 months after treatment initiation.
- Proof of maintenance of EASI-75 response from baseline must be provided for subsequent authorizations.

**Clinical Note:**

- Not to be used in combination with phototherapy, any immunomodulatory agents (including biologics or other janus kinase inhibitor treatment) for moderate to severe AD.

**Claim Notes:**

- The patient must be under the care of a dermatologist, allergist, clinical immunologist, or pediatrician who has expertise in the management of moderate to severe AD.
- Approvals will be for a maximum of 30mg once daily.
- Initial approval period: 6 months
- Renewal approval period: 1 year

## Change in Benefit Status

Effective **December 1, 2023,** the following product will move to full benefit and no longer require exception status approval.

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| Abiraterone | Various | Various | DNP | SFC | VAR |

## New Benefits

Effective **December 1, 2023,** 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 |
|---|---|---|---|---|---|
| Depo-Provera | 150mg/mL Inj | 02523493 | DNP | SFC | PFI |
| Hadlima | 40mg/0.4mL Syringe | 02533472 | DNP | E (SF) | ORG |
| Hadlima PushTouch | 40mg/0.4mL Autoinjector | 02533480 | DNP | E (SF) | ORG |

## Temporary Benefit – US-Labelled Prazosin

SteriMax Inc. has received approval from Health Canada for the import and release of US-labelled prazosin hydrochloride capsules. This is to mitigate shortages of prazosin tablets in Canada.

The Nova Scotia Pharmacare Programs will be adding this product as a temporary benefit effective **December 1, 2023**.

The US-labelled product has the same active ingredient, strengths (1 mg, 2 mg, and 5 mg) and route of administration (oral) as the Canadian marketed products. The US-labelled product, however, differs in the following ways:

- The US-labelled product is available as capsules while the Canadian marketed products are available as tablets. The US 1 mg capsule cannot be split into a 0.5 mg starting or titration dose.
- The US-labelled capsules have a different product composition (non-medicinal ingredients) than the Canadian marketed products.

When prescribing or dispensing these products, pharmacists are directed to consult Sterimax Inc. Dear Healthcare Professional at the following link: https://sterimaxinc.com/wp-content/uploads/2023/10/SteriMax-HPRC-Letter_Prazosin_English_Exceptional-Importation_09112023-3.pdf

| PRODUCT | STRENGTH | PIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| Prazosin Hydrochloride | 1mg Cap | 09858281 | DNP | SFC | STR |
| Prazosin Hydrochloride | 2mg Cap | 09858282 | DNP | SFC | STR |
| Prazosin Hydrochloride | 5mg Cap | 09858283 | DNP | SFC | STR |

## Temporary Benefit – US-Labelled Vigabatrin Sachets

Dr. Reddy's Laboratories has received approval from Health Canada for the import and release of US-labelled Vigabatrin for Oral Solution. This is to mitigate shortages of vigabatrin sachets in Canada.

The Nova Scotia Pharmacare Programs will be adding this product as a temporary benefit effective **December 1, 2023**.

The US-labelled drug product has the identical active ingredient, strength (500 mg vigabatrin), dosage form (powder for solution), route of administration (oral), and non-medicinal ingredients as the Canadian-authorized product.

The US-labelled product, however, differs with respect to the reconstitution instructions. The instructions for the US-labelled product state that the product should be reconstituted only with cold or room temperature water prior to

**Temporary Benefits Continued…**

administration while the instructions for the Canadian-authorized product state that the product should be reconstituted with cold or room temperature water, fruit juice, milk, or infant formula prior to administration.

For the reconstitution instructions, healthcare professionals should refer to the United States Prescribing Information (USPI) for Dr. Reddy's Vigabatrin for Oral Solution, USP (500 mg vigabatrin) available at the following link: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=f6be436e-46c7-e9ab-0fcf-e8d04dc12b72

| PRODUCT | STRENGTH | PIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| Vigabatrin | 0.5g Sachets | 09858315 | DNP | E (SF) | RCH |

## Expansion of Chemoprophylaxis Coverage through Pharmacies for Close Contacts of Invasive Group A Streptococcus (iGAS), Pertussis or Invasive Meningococcal Disease (IMD) Infections

Effective November 30, 2023 new pharmacy service PINs will be eligible for assessment and prescribing of antibiotics (chemoprophylaxis) to prevent:

- iGAS
- pertussis
- IMD infections

This coverage will apply when Public Health, Nova Scotia Health (NSH) recommends that Nova Scotia residents receive it because they were a close contact of a case of iGAS, pertussis or IMD. Non-residents may still be referred for treatment, but the billing for non-residents is outlined below.

Following a report of a notifiable disease, Public Health nurses will identify close contacts and assess their eligibility for preventative antibiotics.

- Once eligibility is confirmed, Public Health completes a request for chemoprophylaxis for the specific disease and sends it to the community pharmacy. This letter provides patient information and the recommendation for an antibiotic to be prescribed following direction from the NSH Medical Officer of Health.
- The community pharmacy will prescribe the appropriate drug, dose, and formulation, depending on patient's age, weight, allergies, and any health conditions that may be relevant for prescribing.
- If a contact requires chemoprophylaxis, then the first choice of payment for the drug is through their private plan. Pharmacare is the payer of last resort. If there is no coverage either privately or through Pharmacare, then Public Health will pay for the drug via an invoice from the pharmacy.
- Public Health will also pay for the drug and pharmacy service fee via an invoice from the pharmacy for non-Nova Scotia residents.

Further information, and final copies of the documents to be used by pharmacists, will be available at a webinar scheduled for November 29, 2023.

PANS has posted the prescribing protocols and sample fax notifications that will be sent to pharmacists to the Member Lounge Portal. Please login to the Member Lounge to access these resources here, under the tag "Public Health

**Expansion of Chemoprophylaxis Coverage through Pharmacies for Close Contacts of Invasive Group A Streptococcus (iGAS), Pertussis or Invasive Meningococcal Disease (IMD) Infections Continued…**

Protocols" https://pans.memberlounge.app/. Non-members will be able to create a profile in the PANS member lounge to access a small list of resources that are required to be available to all pharmacy professionals in the province.

These new service PINs will be eligible for electronic claims submission at a rate of $20.00 per service, with no annual frequency limit for any individual.

Claims must be submitted electronically using the following CPhA Claims Standard field content:

**CPhA Claims Standard – CPhA Claims Standard – Fee to Prescribe antibiotic prophylaxis to prevent Invasive group A streptococcus (iGAS)**

| Field # | Field Name | Content |
|---|---|---|
| D.56.03 | DIN/GP#/PIN | 93899732 |
| 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 Prescribe antibiotic prophylaxis to prevent pertussis**

| Field # | Field Name | Content |
|---|---|---|
| D.56.03 | DIN/GP#/PIN | 93899731 |
| 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) |

**Expansion of Chemoprophylaxis Coverage through Pharmacies for Close Contacts of Invasive Group A Streptococcus (iGAS), Pertussis or Invasive Meningococcal Disease (IMD) Infections Continued…**

**CPhA Claims Standard – Fee to Prescribe antibiotic prophylaxis to prevent invasive meningococcal disease (IMD) infection**

| Field # | Field Name | Content |
|---|---|---|
| D.56.03 | DIN/GP#/PIN | 93899730 |
| 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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NOVA SCOTIA

# PharmacareNEWS

inside

**Nova Scotia Formulary Updates**



## Nova Scotia Formulary Updates

### Short-Term Funding of Victoza and Trulicity During Ozempic Shortage

The manufacturer's Ozempic supply shortage continues. As a result, Pharmacare will provide temporary short-term funding for two other GLP-1 agonists (Trulicity and Victoza), should these be appropriate options for a beneficiary.

For beneficiaries with Ozempic coverage, short term approvals for the alternatives listed above will be added to their profile automatically. No additional exception status drug form is required for these beneficiaries.

### Changes in Benefit Status

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

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| Dabigatran | 110mg Cap | VAR | DNP | SFC | VAR |
| Dabigatran | 150mg Cap | VAR | DNP | SFC | VAR |
| Apixaban | 2.5mg Tab | VAR | DNP | SFC | VAR |
| Apixaban | 5mg Tab | VAR | DNP | SFC | VAR |
| Rivaroxaban | 2.5mg Tab | VAR | DNP | SFC | VAR |
| Rivaroxaban | 10mg Tab | VAR | DNP | SFC | VAR |
| Rivaroxaban | 15mg Tab | VAR | DNP | SFC | VAR |
| Rivaroxaban | 20mg Tab | VAR | DNP | SFC | VAR |
| Lixiana | 15mg Tab | 02458640 | DNP | SFC | SEV |
| Lixiana | 30mg Tab | 02458659 | DNP | SFC | SEV |
| Lixiana | 60mg Tab | 02458667 | DNP | SFC | SEV |

## Criteria Updates

The criteria for the following has been updated effective **January 1, 2024.**

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| **Tamiflu and generics (oseltamivir)** | 30mg Cap | VAR | DNP | E (SFC) | VAR |
| | 45mg Cap | VAR | DNP | E (SFC) | VAR |
| | 75mg Cap | VAR | DNP | E (SFC) | VAR |
| | 6mg/mL Oral Susp | VAR | DNP | E (SFC) | VAR |

Criteria

**Treatment: [Criteria Code 40]**

For patients who test negative for COVID-19 and meet one of the following:

1. have suspected[1] or test confirmed severe, complicated, or progressive[2] influenza OR
2. are hospitalized[2] with suspected[1] or test confirmed influenza OR
3. have suspected[1] or test confirmed influenza and are at higher risk of complications, which include the following age groups, chronic medical conditions, and persons:

- Asthma and other chronic pulmonary disease, including asthma, bronchopulmonary dysplasia, cystic fibrosis, chronic bronchitis, and emphysema
- Cardiovascular disease (excluding isolated hypertension; including congenital and acquired heart disease, such as congestive heart failure and symptomatic coronary artery disease)
- Renal disease
- Chronic liver disease
- Diabetes mellitus and other metabolic diseases
- Anemia and hemoglobinopathies, such as sickle cell disease
- Cancer, immunosuppression, or immunodeficiency due to disease (e.g.: HIV infection, especially if CD4 is <200) or management of underlying condition (solid organ transplant or hematopoietic stem cell transplant recipients)
- Neurological disease and neurodevelopmental disorders that compromise handling of respiratory secretions (cognitive dysfunction; spinal cord injury; neuromuscular, neurovascular, neurodegenerative, and seizure disorders; cerebral palsy; metabolic disorders)
- Children aged younger than 5 years[2]
- Individuals aged 65 years or older
- People of any age who are residents of nursing homes or other chronic care facilities
- Pregnancy and up to 4 weeks postpartum regardless of how the pregnancy ended[3]
- Obesity with a BMI ≥40 or a BMI >3 z-scores above the mean for age and gender
- Children and adolescents aged younger than 18 years undergoing treatment for long periods with acetylsalicylic acid because of the potential increase in Reye's syndrome associated with influenza
- Indigenous peoples

For the treatment of long-term care and eligible[4] residential care residents with clinically suspected or lab confirmed influenza A or B upon advice of the Medical Officer of Health. A clinically suspected case is one in which the patient meets the criteria of influenza-like illness and there is confirmation of influenza A or B circulating within the facility or surrounding community.

**Criteria Updates Continued…**

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| **Tamiflu and generics (oseltamivir)** | 30mg Cap | VAR | DNP | E (SFC) | VAR |
| | 45mg Cap | VAR | DNP | E (SFC) | VAR |
| | 75mg Cap | VAR | DNP | E (SFC) | VAR |
| | 6mg/mL Oral Susp | VAR | DNP | E (SFC) | VAR |
| Criteria | **Prophylaxis: [Criteria Code 41]**<br>• For the prophylaxis of influenza A or B in long-term care and eligible[4] residential care residents where the facility has an outbreak upon advice of the Medical Officer of Health.<br>• A protocol has been developed by Public Health for the treatment of residents in long-term care facilities and eligible[4] residential care residents. The facility must contact the Medical Officer of Health or local Public Health Office who will notify the Pharmacare office (or dispensing pharmacy after office hours) if coverage is required.<br>**Notes:**<br>1. For suspected cases, discontinue oseltamivir if the lab test is negative<br>2. Among healthy children aged younger than 5 years, the risk of hospitalization is further increased among those aged younger than 2 years<br>3. The risk of influenza-related hospitalization increases with length of gestation (i.e., it is higher in the third trimester than in the second)<br>4. Eligible residents are people of any age who are residents of nursing homes or other chronic care facilities. | | | | |

**NS Health and IWK Resources:**

1. NS Health Firstline: https://app.firstline.org/en/clients/78-nova-scotia-health-authority/steps/31838?show_draft=true
2. NS Health Antimicrobial Handbook chapter: https://library.nshealth.ca/ld.php?content_id=35150942
3. IWK Health Firstline: https://app.firstline.org/en/clients/7-iwk-health-centre/steps/17384?show_draft=true (pediatrics)
4. IWK Health Firstline: https://app.firstline.org/en/clients/7-iwk-health-centre/steps/19740?show_draft=true

**Criteria Updates Continued…**

The following new indication will be added to existing criteria effective **January 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 | **Locally Advanced or Metastatic Differentiated Thyroid Carcinoma (DTC)**<br><br>For the treatment of adult patients with locally advanced or metastatic differentiated thyroid carcinoma (DTC) who have progressed on at least one prior line of vascular endothelial growth factor receptor (VEGFR)-targeted tyrosine kinase inhibitor (TKI) therapy.<br><br>**Clinical Notes:**<br>1. Patients should have a good performance status.<br>2. Patients should be refractory to radioactive iodine therapy (RAI-R) or not eligible for radioactive iodine therapy.<br>3. Treatment should continue until disease progression or unacceptable toxicity.<br>4. Patients will be eligible for funding if intolerant to the prior line of VEGFR-targeted TKI therapy.<br>5. Cabozantinib may be used in the third line setting for RET fusion positive patients after progression on or intolerance to selpercatinib. | | | | |

## New Exception Status Benefits

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

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| **Evenity (romosozu-mab)** | 90mg/mL (105mg/1.17mL) Prefilled Syringe | 02489597 | DNP | E (SF) | AGA |
| Criteria | For the treatment of osteoporosis in postmenopausal women who meet all the following criteria:<br>• Have a history of osteoporotic fracture; and<br>• Are at high risk for future fracture, defined as a 10-year fracture risk ≥ 20% as per the Fracture Risk Assessment (FRAX) tool; and<br>• Are treatment naive to osteoporosis medications, except for calcium and/or vitamin D.<br><br>**Claim Notes:**<br>• Maximum approval period: 12 months per lifetime.<br>• Concurrent use with other osteoporosis medications, except for calcium and/or vitamin D, will not be reimbursed. | | | | |

**New Exception Status Benefits Continued…**

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| **Qulipta** | 10mg Tab | 02533979 | DNP | E (SF) | ABV |
| **(atogepant)** | 30mg Tab | 02533987 | DNP | E (SF) | ABV |
| | 60mg Tab | 02533995 | DNP | E (SF) | ABV |
| Criteria | For the treatment of patients with episodic[1] migraine who have experienced an inadequate response, intolerance, or contraindication to at least two oral prophylactic migraine medications of different classes.<br><br>**Renewal:**<br>• 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.<br>• For subsequent renewals, proof that the initial 50% reduction in the average number of migraine days per month has been maintained.<br><br>**Clinical Notes:**<br>• Baseline number of headache and migraine days per month must be provided at the time of initial request.<br>• [1]Episodic migraine: migraine headaches on at least 4 days per month and less than 15 headache days per month for more than 3 months.<br><br>**Claim Notes:**<br>• Initial approval: 6 months<br>• Renewal approval: 1 year<br>• Concurrent use of more than one calcitonin gene-related peptide (CGRP) inhibitor will not be reimbursed.<br>• Must be prescribed by a physician who has experience in the management of migraine headaches. | | | | |

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| **Jadenu and generics** | Various | VAR | DNP | E (SFC) | VAR |
| **(deferasirox)** | | | | | |
| Criteria | • For the treatment of patients who require iron chelation and deferoxamine is contraindicated. | | | | |

## Temporary Benefit – UK-Authorized Nitroglycerin 0.4mg/dose Pumpspray

Juno Pharmaceuticals Corp. has received approval from Health Canada for the import and release of UK-Authorized nitroglycerin 0.4mg/metered dose spray. This is to mitigate shortages of nitroglycerin spray in Canada.

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

The UK-authorized drug product and Canadian-marketed Nitroglycerin Sublingual Spray drug products have the **same active ingredient, strength (0.4 mg per metered dose), and route of administration; however, the products differ in the following ways:**

- **Nomenclature used for the active ingredient:** "Glyceryl trinitrate" is used in the UK product labelling whereas "Nitroglycerin" is used in the labelling of the Canadian-marketed products.
- **Product composition:**
    - The Canadian-marketed products are aromatized oily solutions containing peppermint oil as a flavouring agent while the **UK-authorized product does not contain peppermint oil and thus does not have the same peppermint aroma.**
    - The **UK-authorized product contains propylene glycol as an excipient,** which is not present in the Canadian-marketed products. **Due to its propylene glycol content, the UK-authorized product can cause skin irritation.**
- **Number of metered doses in each container:** The UK-authorized drug product contains 180 metered doses while the Canadian-marketed products contain 200 metered doses.
- **Expression of strength:** The UK-authorized products states "400 mcg per metered dose" whereas the Canadian format for expressing the equivalent strength is "0.4 mg per metered dose".

When prescribing or dispensing these products, pharmacists are directed to consult Juno Pharmaceuticals Corp Dear Healthcare Professional at the following link:
https://irp.cdn-website.com/bbcdb0d5/files/uploaded/Company%20led%20risk%20communications%20-%20Nitroglycerin%20-%20Final.pdf

| PRODUCT | STRENGTH | PIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| Nitroglycerin | 0.4mg/Dose Spray | 09858317 | DNPM | SF | JNO |

## Temporary Benefit – US-Authorized Vigabatrin Tablets

Dr. Reddy's Laboratories has received approval from Health Canada for the import and release of US-authorized Vigabatrin tablets, 500mg USP. This is to mitigate shortages of vigabatrin tablets in Canada.

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

The US-authorized drug product has the identical active ingredient, strength (500 mg vigabatrin), dosage form (tablet), and route of administration (oral) as the Canadian-authorized drug product but differs with respect to the non-medicinal ingredients. The US-authorized drug product contains colloidal silicon dioxide, which is not present in the Canadian-authorized drug product; however, this difference is considered minor and is not expected to have significant clinical impact. There are also differences in tablet engraving.

**Criteria:**

- For the treatment of epilepsy in those patients who respond inadequately to alternative treatment combinations, or in whom other drug combinations have not been tolerated, and in whom the potential benefits conferred by its use outweigh the risk of ophthalmologic abnormalities.
- For the management of infantile spasms.

| PRODUCT | STRENGTH | PIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| Vigabatrin | 500mg Tab | 09858318 | DNP | E (SF) | RCH |

## New Benefits

Effective **December 1, 2023,** the following product has been added as a benefit 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 |
|---|---|---|---|---|---|
| Calquence | 100mg Tab | 02535696 | DNP | E (SFC) | AZE |

Effective **January 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 |
|---|---|---|---|---|---|
| Imvexxy | 4mcg Vag Insert | 02503689 | DNP | SF | KNI |
| Imvexxy | 10mcg Vag Insert | 02503697 | DNP | SF | KNI |
| Glycopyrrolate | 0.2mg/1mL Inj | 02473879 | DNP | SFC | STR |
| Glycopyrrolate | 0.4mg/2mL Inj | 02473895 | DNP | SFC | STR |
| Glycopyrrolate | 4mg/20mL Inj | 02473887 | DNP | SFC | STR |
| PMS-Lactulose-Pharma | 667mg/mL O/L | 02469391 | DNP | E (SFC) | PMS |