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PHARMACISTS' EDITION

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COVID-19 Updates to Public Coverage

The Pharmacy Service Agreement has been amended to include two new services in response to the COVID-19 pandemic and to increase the fee for COVID-19 immunizations. The amending agreement is available online at https://novascotia.ca/dhw/pharmacare/pharmacy-guide.asp.

Increase in special service fee for COVID-19 immunization

Effective January 23, 2022, to March 31, 2022, the fee for COVID-19 immunizations will be temporarily increased to $18. The change in fee will be implemented automatically for doses administered during that timeframe and will pertain to future bottom-line adjustments for COVID-19 immunizations on each pharmacy's pay statement.

Prescription renewals for pharmacy closures

For Nova Scotia residents unable to access their usual pharmacy because it is closed due to COVID-19 impacts, effective January 21, 2022, pharmacies may bill DHW for prescription renewal services when required to ensure the continuity of care for patients. Pharmacy closure prescription renewal services must be performed in compliance with the Nova Scotia College of Pharmacists' *Standards of Practice: Prescribing Drugs* (January 2022 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.

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:

- Prescriber notification documentation is not required (pharmacy closure specific)
- 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

Prescription renewals for pharmacy closures continued…

- 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

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	Licence number
D.64.03	Special Authorization Code	91 (In Person), 92 (Telephone) or 93 (Video)
D.65.03	Intervention Code	ED
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	Licence number
D.64.03	Special Authorization Code	91 (In Person), 92 (Telephone) or 93 (Video)
D.65.03	Intervention Code	ED
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) *

Community pharmacy dispensing of oral antiviral medications for COVID-19

On January 17, 2022, nirmatrelvir/ritonavir (Paxlovid™) was approved for use by Health Canada for patients with mild to moderate disease who are at high risk for progression to severe COVID-19, including hospitalization or death. The federal government has procured a supply of this product for Canada which is being distributed to jurisdictions. Supply is however very limited at this time. With the assistance of the Pharmacy Association of Nova Scotia, specific pharmacies have been identified throughout the province to dispense this medication. Designated prescribers at the Nova Scotia Health Authority will assess and prescribe the medication to those in the highest risk categories and direct the prescription to designated pharmacies only.

Please note that all residents in Nova Scotia who have a positive COVID-19 test (PCR or rapid) should be encouraged to register their positive result and complete the online COVID-19 Report and Support screening form at https://c19hc.nshealth.ca/self-report/. This form will collect information to help identify people who are eligible for and may benefit from COVID-19 medications and treatments to reduce the risk of severe disease and hospitalization. It will also be used to identify people who may need additional support from Public Health. If patients have difficulty completing the online form, they can call 811 for assistance.

Claims submission:

Pharmacies who are part of the designated list to receive and dispense the supply of oral antivirals may claim:

- dispensing fees of up to the maximum Pharmacare dispensing fee in effect in the Pharmacare Tariff Agreement and
- a special fee of $3.50.

To be eligible for coverage, the medication must be prescribed by an NSH-authorized prescriber (a prescriber list will be provided). All persons requiring the medication in Nova Scotia are eligible for coverage, including non-residents. At this time, the only product eligible for coverage is Paxlovid™ (DIN 02524031).

Claims for patients with a Nova Scotia health card must be submitted electronically using the following CPhA Claims Standard field content:

Claims Submission Fields for COVID-19 Oral Antiviral Medications

Field Name	Content
DIN/GP#/PIN	Eligible DINs: • Paxlovid™ 02524031
Special Service Code	003 (pharmacist consultation)
Quantity	000001 (one)
Prescriber ID	Licence number
Intervention Code	ED
Drug Cost/Product Value	DDDDD (dollar value - not adjudicated)
Cost Upcharge	DDDDD (dollar value - not adjudicated)
Professional Fee	▪ To March 31, 2022: $12.39 ▪ April 1, 2022 – March 31, 2023: $12.54
Special Services Fee(s)	3500 ($3.50) *

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

Community pharmacy dispensing of oral antiviral medications for COVID-19 continued…

Delivery charges

For patients who have no options available for the pick-up of the medication, coverage for delivery services is available for patients. In such cases, pharmacies may submit a claim using a special PIN based on actual costs incurred. At this time, the only product eligible for coverage of fees is Paxlovid™ (DIN 02524031). Claims for delivery charges must be supported by a documented invoice of actual cost incurred, which must be available at the time of audit. The following must be noted by the pharmacist on the invoice to validate it was in relation to an eligible COVID-19 oral antiviral medication:

- Drug name and/or DIN of eligible antiviral product delivered
- Patient's Nova Scotia health card number
- Full name, license number and signature of dispensing pharmacist
- Full name and license number of prescriber

A copy of the associated Pharmacare claim printed and attached to the invoice would also suffice for documentation.

If delivery was provided by pharmacy staff and not an external delivery service (so there is no invoice), the maximum amount eligible for reimbursement is $10. Documentation must be available for audit purposes indicating the pharmacy provided the delivery service directly.

Claims for delivery services for patients with a Nova Scotia health card must be submitted electronically using the following CPhA Claims Standard field content**. The delivery cost must be entered in the Professional Fee field and the Prescriber ID must be the license number of the dispensing pharmacist.**

CPhA Claims Standard – COVID-19 Oral Antiviral Delivery Fee (General)

Field #	Field Name	Content
D.56.03	DIN/GP#/PIN	93899829
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)

Dispensing and delivery for non-residents

Claims for dispensing to patients who do not have a Nova Scotia health card cannot be submitted to DHW electronically. The drug dispense should be recorded in the pharmacy's software per usual practice and DHW will access dispense records for non-residents from the provincial *Drug Information System* (DIS) on a bi-weekly basis to submit bottom-line adjustments to Medavie Blue Cross for inclusion on the pharmacy's pay statement. This is similar to the process used for COVID-19 immunization payments.

Community pharmacy dispensing of oral antiviral medications for COVID-19 continued…

Should **delivery services for non-residents** be required, pharmacies must submit an electronic copy of the invoice to DHW by email to pharm.serv@novascotia.ca or by fax to 902-428-3400. The cost incurred will be added to the pharmacy's bottom-line adjustment. The following must be documented on the invoice that is submitted to DHW:

- Pharmacy license number and name
- Pharmacy MSI provider number
- Drug name and DIN of eligible antiviral product delivered
- Drug Information System (DIS) prescription number
- Full name and license number of prescriber
- Full name, license number and signature of dispensing pharmacist

If delivery was provided directly by the pharmacy (no invoice), the information above and **the date of delivery** should be submitted, and the claim will be reimbursed at the maximum non-invoice rate of $10.

Questions about billing for non-residents may be directed to pharm.serv@novascotia.ca.

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New Exception Status Benefit

The following new product has been listed with the following criteria, effective **immediately**.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Nyvepria (pegfilgrastim)	10mg/mL Prefilled Syringe	02506238	DNP	E (SFC)	PFI

Criteria

- For the prevention of febrile neutropenia in patients with non-myeloid malignancies receiving myelosuppressive chemotherapy with curative intent who:
  - are at high risk of febrile neutropenia due to chemotherapy regimen, co-morbidities or pre-existing severe neutropenia; or
  - have had an episode of febrile neutropenia, neutropenic sepsis or profound neutropenia in a previous cycle of chemotherapy; or
  - have had a dose reduction, or treatment delay greater than one week due to neutropenia.

Clinical Note:

- Patients with non-curative cancer receiving chemotherapy with palliative intent are not eligible for coverage of pegfilgrastim for prevention of febrile neutropenia.

Criteria Updates

The following criteria has been updated **effective immediately.**

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Mozobil (plerixafor)	24mg/1.2mL Single Use Vial	02377225	DNP	E (SFC)	SAV
Criteria	• For use in combination with filgrastim to mobilize hematopoietic stem cells for subsequent autologous transplantation in patients who meet one of the following criteria: o PBCD34+ count of less than 10 cells/uL after 4 days of filgrastim, or o Less than 50% of the target CD34+ yield is achieved on the first day of apheresis (after being mobilized with filgrastim alone or following chemotherapy), or o Failed a previous attempt for stem cell mobilization with filgrastim alone or following chemotherapy. **Claim Note:** • Reimbursement is limited to a maximum of 4 doses (0.24mg/kg given daily) for a single mobilization attempt and to prescriptions written by an oncologist or hematologist.				

The following indications have been added to existing criteria **effective immediately.**

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Erleada (apalutamide)	60mg Tab	02478374	DNP	E (SFC)	JAN
Criteria	• In combination with androgen deprivation therapy (ADT) for the treatment of patients with metastatic castration-sensitive prostate cancer (mCSPC). Patients must have had either no prior ADT, or are within six months of beginning ADT in the metastatic setting. **Clinical Notes:** 1. Patients should have a good performance status and no risk factors for seizures. 2. Treatment should continue until unacceptable toxicity or disease progression. **Claim Notes:** • Patients receiving apalutamide for the treatment of metastatic CSPC will be eligible for funding of abiraterone at the time of disease progression to metastatic CRPC. • Enzalutamide is not funded for patients who experience disease progression to metastatic CRPC while on apalutamide.				

Criteria Updates Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Xtandi (enzalutamide)	40mg Cap	02407329	DNP	E (SFC)	ASL
Criteria	• In combination with androgen deprivation therapy (ADT) for the treatment of patients with metastatic castration-sensitive prostate cancer (mCSPC). Patients must have had either no prior ADT or are within six months of beginning ADT in the metastatic setting. **Clinical Notes:** 1. Patients should have a good performance status and no risk factors for seizures. 2. Treatment should continue until unacceptable toxicity or disease progression. **Claim Notes:** • Patients receiving enzalutamide for the treatment of metastatic CSPC will be eligible for funding of abiraterone at the time of disease progression to metastatic CRPC.				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Zytiga and generic brands (abiraterone)	250mg Tab 500mg Tab	Various Various	DNP DNP	E (SFC) E (SFC)	VAR VAR
Criteria	• In combination with prednisone and androgen deprivation therapy (ADT) for the treatment of patients with metastatic castration-sensitive prostate cancer (mCSPC). Patients must have had either no prior ADT, or are within six months of beginning ADT in the metastatic setting **Clinical Notes:** 1. Patients should have a good performance status. 2. Treatment should be discontinued upon disease progression or unacceptable toxicity. **Claim Notes:** • Patients receiving abiraterone for the treatment of mCSPC will be eligible for funding of enzalutamide at the time of disease progression to mCRPC.				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Riximyo (rituximab)	10mg/mL Vial	02498316	DNP	E (SF)	SDZ
Criteria	• For the induction of remission in patients with severely active granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA) who have severe intolerance or other contraindication to cyclophosphamide, or who have failed an adequate trial of cyclophosphamide.				

Criteria Updates Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Erelzi (etanercept)	50mg/mL Prefilled Syringe	02462869	DNP	E (SF)	SDZ
	25mg/0.5mL Prefilled Syringe	02462877	DNP	E (SF)	SDZ
	50mg/mL Autoinjector	02462850	DNP	E (SF)	SDZ
Criteria	• For patients with severe, debilitating chronic plaque psoriasis who meet all of the following: o Body surface area (BSA) involvement of >10% and/or significant involvement of the face, hands, feet or genitals; o Failure to, contraindication to or intolerant of methotrexate and cyclosporine; o Failure to, intolerant of or unable to access phototherapy; o Written request of a dermatologist or prescriber with a specialty in dermatology. • Continued coverage is dependent on evidence of improvement, specifically: o A >75% reduction in the Psoriasis Area and Severity Index (PASI) score; or o A >50% reduction in PASI with a >5-point improvement in DLQI (Dermatology Life Quality Index); or o Significant reduction in BSA involved, with consideration of important regions such as the face, hands, feet or genitals. **Clinical Note:** • Treatment should be discontinued if a response has not been demonstrated after 12 weeks.				

New Products

Effective **immediately,** the following new products have been added to the Nova Scotia Formulary. The benefit status within the Pharmacare Programs is indicated.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Admelog	100U/mL Vial	02469901	DNP	SFD	SAV
Admelog	100U/mL Cartridge	02469898	DNP	SFD	SAV
Admelog Solostar	100U/mL Prefilled Pen	02469871	DNP	SFD	SAV
Aermony RespiClick	55mcg for Inh	02467895	DNP	SF	TEV
Aermony RespiClick	113mcg for Inh	02467909	DNP	SF	TEV
Aermony RespiClick	232mcg for Inh	02467917	DNP	SF	TEV

Delisted Products

Pharmacare currently funds Humalog cartridges (DIN 02229705), vial (DIN 02229704) and KwikPen (DIN 02403412) as Exception Status benefits.

Effective immediately, Pharmacare will begin funding the biosimilar insulin lispro - Admelog. As of March 1, 2022, Humalog cartridges, Humalog vial and Humalog KwikPen will be delisted and existing patients grandfathered for coverage until February 3, 2023.

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Change in Coverage of Biologics

Effective February 4, 2022, Nova Scotia Pharmacare is implementing a policy that requires beneficiaries to transition from an originator biologic to an eligible biosimilar version of that molecule in order for coverage to continue.

Health Canada rigorously reviews biosimilars and has deemed any differences to not be clinically significant. Biosimilars are highly similar versions of the originator biologics. Due to the complexity and nature of biologics, they have natural variability and thus an exact copy cannot be created. This is also true of different batches of the originator. Any exceptions to this policy will require an Exception Status Drug (ESD) Request Form.

During this transition period, prescribers will need to discuss biosimilar products with patients, generate new prescriptions and connect with patient support programs as needed. All patients must transition to a biosimilar version of their medication by February 3, 2023. After that date, claims for the originator will not be accepted by Pharmacare unless approved through an ESD request.

All patients will be automatically provided with biosimilar coverage if they have coverage for the originator product. This is expected to be in place by March 15, 2022. In the interim, please contact the Pharmacare office if there are any issues with billing a biosimilar for a patient who is currently being covered for an originator product – patients should not have to return to their provider for a new ESD.

The products that are currently affected by this policy are listed below. However, as more biosimilar products become available, they will also be added to this policy.

Change in Coverage of Biologics continued…

Originator Biologic	Biosimilar
Remicade	Inflectra, Renflexis, Avsola
Humira	Amgevita, Hadlima, Hyrimoz, Hulio, Idacio
Enbrel	Brenzys, Erelzi
Rituxan	Truxima, Riximyo, Ruxience
Insulin Lantus	Insulin Basaglar
Insulin Humalog	Insulin Admelog
Insulin Novorapid	Insulin Trurapi

If you have any questions please visit our website at: www. Information for Patients about the Nova Scotia Biosimilar Initiative | novascotia.ca or Information for Prescribers about the Nova Scotia Biosimilar Initiative | novascotia.ca or contact us by email at biologictherapies@novascotia.ca

Expansion of Community Pharmacist-led Anticoagulation Management Services

Through an amendment to the *Pharmacy Services Agreement*, effective December 13, 2021, pharmacies are now eligible to bill DHW a maximum of one special fee of $50 per calendar month per patient for those who are provided Community Pharmacy-led Anticoagulation Management Services (CPAMS), inclusive of all costs associated with providing the service.

The monthly fee may be billed for any resident of Nova Scotia and is not limited to Pharmacare beneficiaries. Pharmacies must be approved by Pharmacy Association of Nova Scotia (PANS) to be eligible for the fee and pharmacy enrollment in providing the service will be gradual over the next couple of years. **Interested pharmacies must contact PANS at info@pans.ns.ca for additional information.**

The services must be performed in compliance with the Nova Scotia College of Pharmacists' *Standards of Practice: Prescribing Drugs* and *the Nova Scotia College of Pharmacists' Standards of Practice: Testing* to be eligible for coverage. In addition, eligible residents enrolled in the service must meet the following criteria:

- Be a resident 18 year of age or over
- Have a valid Nova Scotia Health Card
- Must not reside in a nursing home or home for special care
- Must not have factors that based on the pharmacist's professional judgement would deem them inappropriate for the service

Service Overview

As part of this service, the pharmacist takes responsibility for appropriate testing, dosage adjustments, and communication with the patient's primary care provider, as per applicable Nova Scotia College of Pharmacists' (NSCP) Standards of Practice.

Expansion of Community Pharmacist-led Anticoagulation Management Services continued…

When a patient or healthcare provider requests that a pharmacy provide the CPAMS Service for a patient, the pharmacist will liaise as appropriate with the patient's primary prescriber and provide an initial assessment.

The pharmacist will prescribe dosage adjustments and recommend the next test interval as per clinical guidelines, and using their clinical judgement based on the information collected during the assessment.

Pharmacies will notify the patient's primary care provider of test results and pharmacist prescribing decisions, as per standards of practice. If the patient does not have a primary care provider, the patient is provided the record in addition to the one maintained at the pharmacy. Pharmacies may bill a maximum of one monthly service fee per calendar month per patient regardless of the number of tests and/or clinical assessments provided in that month. Tests may be provided as part of the recommended routine monitoring for warfarin. Additional testing may be clinically appropriate when new medications are added, doses are modified, the patient has signs of bleeding, when the most recent test result suggests more frequent monitoring is warranted and/or other clinical reasons.

If the patient has a current prescription, the pharmacist will maintain or adapt the dose as appropriate and as per the NSCP's *Standards of Practice: Prescribing Drugs*. If the patient requires a renewal of their warfarin prescription, they may obtain it from any prescriber. If a pharmacist chooses to do a renewal of a warfarin prescription, this is conducted as per standards of practice and additional requirements as identified in the Pharmacy Guide and can be billed to DHW as a separate service.

DHW is the "payer of last resort" for all services under the *Pharmacy Service Agreement*, meaning residents must first use their available insurance coverage before any portion of the professional fee can be billed to DHW. Further, the agreement covers only the pharmacist professional fees associated with the service. Residents will continue to access their usual drug coverage or method of payment for any prescriptions they have filled.

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

CPhA Claims Standard – Commmunity Pharmacist-led Anticoagulation Management Service (CPAMS)

Field #	Name	Content
D.56.03	DIN/GP#/PIN	93899872 INR Management Fee
D.57.03	Special Service Code	003 (Pharmacist consultation)
D.58.03	Quantity	000001 (one)
D.61.03	Prescriber ID	Pharmacists Prescriber ID
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 Service Fee	5000 ($50.00)

Note: Claims will be subject to audit.

RN Prescribing

Beginning February 2022, a cohort of registered nurses (RNs) will have completed the requirements to begin prescribing in Nova Scotia.

Nova Scotia Health and the IWK Health Centre, with support from the Department of Health and Wellness Nursing Strategy and in collaboration with stakeholders, are working to explore how access to health care services for Nova Scotians can be improved by enabling RNs to prescribe medications, devices, and order relevant screening or diagnostic tests within their specific area of competence and practice.

The scope of practice and role for the RN prescribers is broader than an RN, but much narrower and more restricted that that of a nurse practitioner or physician. The role of the RN prescriber is not to replace the services provided by nurse practitioners or physicians, but rather to complement those roles within interdisciplinary collaborative teams in order to improve patient access to care. RN prescribers are accountable for the decisions they make related to their nursing and prescribing practice at all times. RN prescribers may not prescribe for any client or client condition not endorsed by the employer.

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Nova Scotia Formulary Updates

New Exception Status Benefits

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

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Ajovy (fremanezumab)	225 mg/1.5 mL Prefilled Syringe	02497859	DNP	E (SF)	TEV
	225 mg/1.5 mL 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.

Initial Renewal Criteria:

- 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

Subsequent Renewal Criteria:

- 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
Ajovy (fremanezumab)	225 mg/1.5 mL Prefilled Syringe	02497859	DNP	E (SF)	TEV
	225 mg/1.5 mL Autoinjector	02509474	DNP	E (SF)	TEV
Criteria	**Claim Notes:** • Approvals: 6 months • Must be prescribed by a physician who has experience in the management of migraine headaches.				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Monoferric (ferric derisomaltose)	100 mg/mL IV Inj	02477777	DNP	E (SFC)	PFI

Criteria	• For the treatment of iron deficiency anemia in patients who:
	  ○ are intolerant to oral iron replacement products,
	  OR
	  ○ have not responded to an adequate trial of oral iron
	Notes:
	• Given the safety concerns associated with IV iron, it is expected that the patients will be carefully screened and will have tried various oral iron options before being eligible for IV iron.
	• Details regarding oral iron tried, length of therapy, and outcome must be provided.				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Opsumit (macitentan)	10mg Tab	02415690	DNP	E (SF)	JAN
Criteria	• For the treatment of patients with Group 1 pulmonary arterial hypertension (PAH) with a World Health Organization (WHO) functional class of at least II. **Clinical Note:** • The diagnosis of PAH should be confirmed by right heart catheterization. **Claim Notes:** • Must be prescribed by, or in consultation with, a physician experienced in the treatment of PAH. • Combined use of more than one endothelin receptor antagonists will not be reimbursed. • The maximum dose of macitentan that will be reimbursed is 10mg daily.				

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Riabni (rituximab)	10mg/mL Vial	02513447	DNP	E (SF)	AGA
Criteria	• For the treatment of adult patients with severe active rheumatoid arthritis who have failed to respond to an adequate trial with an anti-TNF agent. • Cannot be used concomitantly with anti-TNF agents. Written request from a rheumatologist or prescriber with a specialty in rheumatology. • Approval for re-treatment with rituximab will only be considered for patients who have achieved a response, followed by a subsequent loss of effect and, after an interval of no less than six months from the previous dose. • For the induction of remission in patients with severely active granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA) who have severe intolerance or other contraindication to cyclophosphamide, or who have failed an adequate trial of cyclophosphamide.				

Criteria Updates

The following indications have been added to existing criteria **effective immediately.**

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Androgel and generic brands (testosterone)	2.5g/pkt Top Gel 5g/pkt Top Gel	Various Various	DNP DNP	E (SFC) E (SFC)	VAR VAR
Testim (testosterone)	1% Top Gel Tube	02280248	DNP	E (SFC)	PAL
Criteria	• For use in gender affirming hormone therapy. **Claim Note:** • Maximum dose approved is 5g gel per day.				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Zofran and generic brands (ondansetron)	4mg/5mL O/L 4mg Tab 4mg OD Tab/Film 8mg Tab 8mg OD Tab/Film	Various Various Various Various Various	DNP DNP DNP DNP DNP	E (SFC) E (SFC) E (SFC) E (SFC) E (SFC)	VAR VAR VAR VAR VAR
Criteria	• For the treatment of nausea and vomiting in pediatric patients (under 18 years of age) receiving chemotherapy (e.g., methotrexate) for chronic non-oncology conditions who have experienced an episode of nausea/emesis. **[Criteria Code 04]**				

Criteria Updates Continued…

The following criteria has been updated **effective immediately.**

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Cosentyx (secukinumab)	150mg/1.0mL Prefilled Syringe / Prefilled Pen	02438070	DNP	E (SF)	NVR

Criteria	**Ankylosing Spondylitis**
	• For the treatment of patients with moderate to severe ankylosing spondylitis (e.g., Bath AS Disease Activity Index (BASDAI) score ≥ 4 on 10 point scale) who:
	  ○ Have axial symptoms and who have failed to respond to the sequential use of at least 2 NSAIDs at the optimum dose for a minimum period of 3 months or in whom NSAIDs are contraindicated, or
	  ○ Have peripheral symptoms and who have failed to respond, or have contraindications to, the sequential use of at least 2 NSAIDs at the optimum dose for a minimum period of 3 months and have had an inadequate response to an optimal dose or maximal tolerated dose of a DMARD.
	• Requests for renewal must include information demonstrating 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").
	Clinical Note:
	• Patients with recurrent uveitis (2 or more episodes within 12 months) as a complication to axial disease do not require a trial of NSAIDs alone.
	Claim Notes:
	• Must be prescribed by a rheumatologist or prescriber with a specialty in rheumatology.
	• Combined use of more than one biologic DMARD will not be reimbursed.
	• Approvals will be for 150mg given at weeks 0, 1, 2, 3, and 4, followed by monthly maintenance dosing. If a patient continues to have active ankylosing spondylitis, a monthly maintenance dosage of 300 mg may be considered.
	• Each 300 mg dose is given as two subcutaneous injections of 150 mg.
	• Initial Approval: 6 months.
	• Renewal Approval: 1 year.				

Change in Benefit Status

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

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Sublocade	100mg/0.5mL Prefilled Syringe	02483084	DNP	SF	ICL
Sublocade	300mg/1.5mL Prefilled Syringe	02483092	DNP	SF	ICL

New Products

Effective **immediately,** the following new products have been added to the Nova Scotia Formulary. The benefit status within the Pharmacare Programs is indicated.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
JAMP-Hydrocortisone Acetate/Urea	1%/10% Cr	80061501	DNP	SF	JPC
Mirtazapine	15mg Tab	02496666	DNP	SFC	SIV

Non-Insured Products

The following products will not be insured in the Pharmacare Programs; however, they will be funded through the Exception Drug Fund as per other tacrolimus products in post solid organ transplant.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Envarsus PA	0.75mg ER Tab	02485877	N/A	**Non-Insured**	PAL
Envarsus PA	1mg ER Tab	02485885	N/A	**Non-Insured**	PAL
Envarsus PA	4mg ER Tab	02485893	N/A	**Non-Insured**	PAL

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Virtual Care Update

Claims Eligibility Extended for One Year

The waiver of the in-person requirement for delivery of publicly funded assessment and prescribing services has been extended for one year to March 31, 2023. The virtual care eligibility and claims submission criteria for medication reviews for Pharmacare beneficiaries have also been extended to March 31, 2023. Provisions in the Pharmacy Guide (https://novascotia.ca/dhw/pharmacare/documents/Pharmacy-Guide.pdf) pertaining to virtual care apply until that date or until such time as a change to the date is communicated through the Pharmacare News Bulletin.

All claims for pharmacy services require criteria codes to indicate the method of service delivery. The code ED must be entered in the Intervention Code field and one of the following codes must be entered in the Special Authorization Code field for all service claims:

- 91 = In-person
- 92 = Telephone
- 93 = Video

Further, the provincial policy on Provision of Publicly Funded Virtual Health Services, which applies to public funded pharmacy professional services, remains in effect and can be viewed online at https://novascotia.ca/dhw/publications/Provision-of-Publicly-Funded-Virtual-Health-Services.pdf.

Prescription Renewals for Pharmacy Closures

With the state of emergency ending and Public Health restrictions lifting, Pharmacy Closure Prescription Renewal services will no longer be eligible for public coverage effective April 1, 2022. The PINs for these services (93899831 and 93899830) will be deactivated on that date

New Diabetic Products

The following products are new listings to the Nova Scotia Formulary, **effective immediately**. The benefit status and reimbursement price within the Nova Scotia Pharmacare Programs is indicated.

PRODUCT	DIN/PIN	PRESCRIBER	BENEFIT STATUS	MFR
Tykess Blood Glucose Test Strips (50)	97799338	DNP	SFD	TKS
Tykess Blood Glucose Test Strips (100)	97799341	DNP	SFD	TKS

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Prescription Renewals for Pharmacy Closures

With the provincial state of emergency related to the COVID-19 pandemic ended, public coverage of fees for Pharmacy Closure Prescription Renewal Services will end March 31, 2022. The PINs (93899830, 93899831) will be deactivated as of April 1.

Documentation of Patient Consent No Longer Required for Audit Purposes for Service Claims

Effective April 1, 2022, documentation of patient consent is no longer required for audit purposes for pharmacy professional services claims submitted to Pharmacare or to DHW for any resident. These include medication reviews, therapeutic substitution, prescription adaptation, assessment and prescribing services, and prescription renewals. Pharmacists are expected to continue to adhere to all relevant provisions in the Nova Scotia College of Pharmacists' Standards of Practice when providing services.

Changes to Naloxone Kit Billing

To support improved monitoring of naloxone kit usage, effective April 1, 2022, two new PINs will be in effect for billing of naloxone kits:

- Naloxone Kit - Initial or Regular Replacement: 96599960
- Naloxone Kit – Replacement when kit used: 96599961

The PIN 96599961 for "replacement when kit used" can be submitted by pharmacies when the customer voluntarily discloses that their previous kit was used. This PIN will replace the kit usage reporting form. All PINs have the same eligible fee of $25 and all other claims submission requirements remain the same. The old PIN, 93899874 THN Program Admin Fee, will remain active until April 30, 2022, to allow pharmacies time to update their systems.

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Change to Maximum Reimbursable Prices

Effective **April 29, 2022**, the Maximum Reimbursable Price (MRP) for 8 existing pan-Canadian molecules will be reduced to 15% of brand reference price:

MOLECULE	STRENGTH	CURRENT MRP	NEW MRP APRIL 29, 2022
Alendronate	70mg Tab	2.1014	1.7804
Atenolol	25mg Tab	0.0521	0.0441
Atenolol	50mg Tab	0.1107	0.0938
Atenolol	100mg Tab	0.1821	0.1543
Bisoprolol	5mg Tab	0.0715	0.0606
Bisoprolol	10mg Tab	0.1044	0.0885
Carvedilol	3.125mg Tab	0.2431	0.2060
Carvedilol	6.25mg Tab	0.2431	0.2060
Carvedilol	12.5mg Tab	0.2431	0.2060
Carvedilol	25mg Tab	0.2431	0.2060
Dutasteride	0.5mg Cap	0.3027	0.2565
Finasteride	5mg Tab	0.4138	0.3506
Risedronate	35mg Tab	1.9787	1.6764
Risperidone	0.25mg Tab	0.1036	0.0878
Risperidone	0.5mg Tab	0.1735	0.1470
Risperidone	1mg Tab	0.2397	0.2031
Risperidone	2mg Tab	0.4795	0.4062
Risperidone	3mg Tab	0.7180	0.6083
Risperidone	4mg Tab	0.9574	0.8111

Manufacturers who do not confirm prices to the new lower MRP will have impacted products removed from the Nova Scotia Formulary effective April 30, 2022.

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New Exception Status Benefits

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

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Zejula (niraparib)	100mg Cap	02489783	DNP	E (SFC)	GSK

Criteria

Newly Diagnosed Advanced Epithelial Ovarian, Fallopian Tube or Primary Peritoneal Cancer

- As monotherapy maintenance treatment of patients with newly-diagnosed ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) to at least 4 cycles of first-line platinum-based chemotherapy. Eligible patients should have high-grade serous or endometrioid tumours classified as stage III or IV according to the International Federation of Gynecology and Obstetrics (FIGO) criteria.

Clinical Notes:

- Patients should have a good performance status.
- Maintenance therapy with niraparib should begin within 12 weeks of completion of platinum- based chemotherapy and may continue for up to 3 years, or until disease progression or unacceptable toxicity, whichever occurs first.
- Patients who have stable brain metastases are eligible for treatment with niraparib.
- Patients who are unable to tolerate platinum-based chemotherapy (due to allergic reaction) and otherwise meet criteria, will be assessed on a case by case basis to determine eligibility for treatment with niraparib.
- Niraparib in combination with bevacizumab is not funded.

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Zejula (niraparib)	100mg Cap	02489783	DNP	E (SFC)	GSK
Criteria	**Relapsed, Platinum Sensitive Advanced Epithelial Ovarian, Fallopian tube or Primary Peritoneal Cancer** • As monotherapy maintenance treatment for patients with relapsed, platinum-sensitive high grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who have completed at least two previous lines of platinum-based chemotherapy, and have achieved a complete or partial response to the most recent platinum-based chemotherapy regimen. **Clinical Notes:** • Platinum-sensitive disease is defined as disease progression occurring at least six months after completion of platinum-based chemotherapy. • Patients should have a good performance status. • Patients must have received at least 4 cycles of the most recent platinum-based chemotherapy before starting treatment with niraparib. • Maintenance therapy with niraparib should begin within 12 weeks of the last chemotherapy treatment and may continue until disease progression or unacceptable toxicity, whichever occurs first. • Patients who have stable brain metastases are eligible for treatment with niraparib. • Patients who are unable to tolerate platinum-based chemotherapy (due to allergic reaction) and otherwise meet criteria, will be assessed on a case by case basis to determine eligibility for treatment with niraparib.				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Adlyxine (lixisenatide)	0.05mg/mL Prefilled Pen 0.1mg/mL Prefilled Pen	02464276 02464284	DNP DNP	E (SF) E (SF)	SAV SAV

Criteria	• For the treatment of type 2 diabetes mellitus when added to:
	  ○ basal insulin for patients who have inadequate glycemic control on basal insulin; or
	  ○ basal insulin and metformin for patients who have inadequate glycemic control on metformin and basal insulin				

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Entyvio (vedolizumab)	108mg/0.68mL Prefilled Syringe	02497875	DNP	E (SF)	TAK
	108mg/0.68mL Prefilled Pen	02497867	DNP	E (SF)	TAK
Criteria	• See *Criteria Updates* below.				

Criteria Updates

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

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Entyvio (vedolizumab)	300mg Vial	02436841	DNP	E (SF)	TAK
	108mg/0.68mL Prefilled Syringe	02497875	DNP	E (SF)	TAK
	108mg/0.68mL Prefilled Pen	02497867	DNP	E (SF)	TAK
Criteria	**Crohn's Disease** • For patients with moderate to severely active Crohn's disease and are: ○ refractory or have contraindications to an adequate course of 5-aminosalicylic acid and corticosteroids and other immunosuppressive therapy. **Clinical Notes:** • Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above. **Claim Notes:** • Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology. • Combined use of more than one biologic DMARD will not be reimbursed. • Intravenous infusion: Initial reimbursement is restricted to induction doses of 300mg at Weeks 0, 2 and 6. Clinical response to be assessed prior to the administration of the fourth dose. • Subcutaneous injection: Initial reimbursement is for at least two doses of intravenous infusions of vedolizumab. Clinical response to be assessed prior to the administration of the first subcutaneous dose. Subsequent reimbursement for maintenance dosing is 108mg subcutaneously every 2 weeks. • Initial Approval: 16 weeks • Renewal Approval: 1 year				

Criteria Updates Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Entyvio	300mg Vial	02436841	DNP	E (SF)	TAK
(vedolizumab)	108mg/0.68mL Prefilled Syringe	02497875	DNP	E (SF)	TAK
	108mg/0.68mL Prefilled Pen	02497867	DNP	E (SF)	TAK

Criteria

Ulcerative Colitis

- For the treatment of adult patients with moderately to severely active ulcerative colitis who have a partial Mayo score > 4, and a rectal bleeding subscore ≥ 2 and are:
    - refractory or intolerant to conventional therapy (i.e. 5-ASA for a minimum of 4 weeks, and prednisone ≥ 40mg daily for two weeks or IV equivalent for one week); or
    - corticosteroid dependent (i.e. cannot be tapered from corticosteroids without disease recurrence; or have relapsed within three months of stopping corticosteroids; or require two or more courses of corticosteroids within one year.)
- Renewal requests must include information demonstrating the beneficial effects of the treatment, specifically:
    - a decrease in the partial Mayo score ≥ 2 from baseline, and
    - a decrease in the rectal bleeding subscore ≥1.

Clinical Notes:

- Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above.
- Intolerant is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs. The nature of intolerance(s) must be clearly documented.
- Patients with severe disease do not require a trial of 5-ASA.

Claim Notes:

- Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology.
- Combined use of more than one biologic DMARD will not be reimbursed.
- Intravenous infusion: Initial reimbursement is restricted to induction doses of 300mg at Weeks 0, 2 and 6. Clinical response to be assessed prior to the administration of the fourth dose.
- Subcutaneous injection: Initial reimbursement is for at least two doses of intravenous infusions of vedolizumab. Clinical response to be assessed prior to the administration of the first subcutaneous dose. Subsequent reimbursement for maintenance dosing is 108mg subcutaneously every 2 weeks.
- Initial Approval: 16 weeks
- Renewal Approval: 1 year

Criteria Updates Continued…

The following criteria has been updated **effective immediately.**

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Lenvima (lenvatinib)	4mg Cap 8mg Cap 12mg Cap	02484056 02468220 02484129	DNP DNP DNP	E (SFC) E (SFC) E (SFC)	EIS EIS EIS
Criteria	• For the treatment of adult patients with unresectable or metastatic hepatocellular carcinoma as either first-line treatment, or second-line treatment following atezolizumab in combination with bevacizumab, who meet all the following criteria: ○ Child-Pugh class status of A ○ ECOG performance status of 0 or 1 ○ Less than 50% liver involvement and no invasion of the bile duct or main portal vein ○ No brain metastases or prior liver transplantation **Clinical Notes:** • Treatment should be continued until disease progression or unacceptable toxicity. • Patients who are unable to tolerate lenvatinib may be switched to sorafenib if there is no disease progression and provided all other funding criteria are met. • Patients with disease progression on lenvatinib are not eligible for reimbursement of sorafenib.				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Nexavar (sorafenib)	200mg Tab	02284227	DNP	E (SFC)	BAY
Criteria	• For the treatment of adult patients with a diagnosis of hepatocellular carcinoma (HCC) as either first line-treatment, or second-line treatment following atezolizumab in combination with bevacizumab, who meet all the following criteria: ○ Child-Pugh Class A liver dysfunction (mild hepatic impairment) ○ ECOG performance status of 0 or 1 ○ Who have either progression of disease, or who are not candidates for curative intent treatments (transplantation, hepatic resection), or other well established palliative interventions (ablation, transcatheter arterial chemo-embolization (TACE), internal radiation) **Clinical Note:** • Patients who are unable to tolerate sorafenib may be switched to lenvatinib if there is no disease progression and provided all other funding criteria are met. • Patients with disease progression on sorafenib are not eligible for reimbursement of lenvatinib.				

New Benefits

Effective **immediately,** the following products have been added to the Nova Scotia Formulary. The benefit status within the Pharmacare Programs is indicated.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Ceftazidime	1g/vial Pws Inj	02437848	DNP	SFC	STR
Ceftazidime	2g/vial Pws Inj	02437856	DNP	SFC	STR
Ceftazidime	6g/vial Pws Inj	02437864	DNP	SFC	STR

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New Exception Status Benefits

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

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Abrilada (adalimumab)	40mg/0.8mL Prefilled Pen	02511045	DNP	E (SF)	PFI
	40mg/0.8mL Prefilled Syringe	02511053	DNP	E (SF)	PFI
Simlandi (adalimumab)	40mg/0.4mL Autoinjector	02523957	DNP	E (SF)	JPC
	40mg/0.4mL Prefilled Syringe	02523949	DNP	E (SF)	JPC
	80mg/0.8mL Prefilled Syringe	02523965	DNP	E (SF)	JPC
Criteria	• Please refer to the Pharmacare Formulary (https://novascotia.ca/dhw/pharmacare/formulary.asp) for the adalimumab criteria.				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Duobrii (halobetasol propionate and tazarotene)	0.01%/0.045% Topical Lotion	02499967	DNP	E (SF)	BSL
Criteria	• Patients must have a clinical diagnosis of moderate to severe plaque psoriasis and an inadequate response to a topical high-potency corticosteroid.				

Criteria Update

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

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Ofev	100mg Capsule	02443066	DNP	E (SF)	BOE
(nintedanib)	150mg Capsule	02443074	DNP	E (SF)	BOE
Criteria	**Chronic Fibrosing Interstitial Lung Disease** **Initiation criteria** • For the treatment of chronic fibrosing interstitial lung disease with a progressive phenotype confirmed by a specialist in interstitial lung diseases, if the following criteria are met: ○ the patient has a forced vital capacity greater than or equal to 45% of predicted. **Renewal criteria** • The patient must not experience a more severe progression of disease, defined as an absolute decline in percent predicted forced vital capacity of 10% or greater over the preceding year of treatment with nintedanib. **Clinical Notes:** • The patient's clinical status should be evaluated every 12 months. **Claim Notes:** • The patient is under the care of a physician with experience in interstitial lung diseases. • Concurrent treatment of nintedanib with pirfenidone should not be reimbursed. • Approval Period: 12 months				

Public Funding of Pharmacist Assessment for COVID-19 Therapies

Through an amendment to the *Pharmacy Service Agreement*, effective May 9, 2022, pharmacies may bill DHW a specal service fee of $20 for completing assessment and, if appropriate, prescribing services for select COVID-19 therapies. There is no maximum number of services for which a resident is eligible for coverage.

At this time, only assessment for **inhaled budesonide** for patients with COVID-19 symptoms is eligible for coverage, with services performed based on the ***Inhaled Budesonide (Pulmicort Turbuhaler®) Prescribing Protocol***. The services must also be performed in compliance with the Nova Scotia College of Pharmacists' *Standards of Practice: Prescribing Drugs* (Appendix G – Prescribing for a Diagnosis Supported by a Protocol, SARS-CoV-2) to be eligible for coverage.

All residents with a valid Nova Scotia health card are eligible for coverage, except residents of nursing homes. DHW is the "payer of last resort" for all services under the *Pharmacy Service Agreement*, meaning residents must first use their available insurance coverage before any portion of the professional fee can be billed to DHW. Further, the agreement covers only the pharmacist professional fees associated with the service. Residents will continue to access their usual drug coverage or method of payment for any prescriptions they have filled.

When the service does not result in a prescription, pharmacists are expected to provide supporting documentation for why a prescription was not written by the pharmacist. All other audit requirements pertaining to existing assessment and prescribing services apply to these new services.

Public Funding of Pharmacist Assessment for COVID-19 Therapies

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

CPhA Claims Standard – Assessment for COVID-19 Therapies – Prescription Provided

Field #	Field Name	Content
D.56.03	DIN/GP#/PIN	93899825
D.57.03	Special Service Code	002 (pharmacist intervention)
D.58.03	Quantity	000001 (one)
D.61.03	Prescriber ID	Licence number
D.64.03	Special Authorization Code	91 (In Person), 92 (Telephone) or 93 (Video)
D.65.03	Intervention Code	ED
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.

CPhA Claims Standard – Assessment for COVID-19 Therapies – Prescription Not Appropriate

Field #	Field Name	Content
D.56.03	DIN/GP#/PIN	93899824
D.57.03	Special Service Code	002 (pharmacist intervention)
D.58.03	Quantity	000001 (one)
D.61.03	Prescriber ID	Licence number
D.64.03	Special Authorization Code	91 (In Person), 92 (Telephone) or 93 (Video)
D.65.03	Intervention Code	ED
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.

COVID-19 Immunizations

Effective April 1, 2022, the fee for COVID-19 immunizations was increased to $18. The $18 fee had originally been authorized on a temporary basis to March 31. The change in fee was implemented automatically and pertains to bottom-line adjustments for COVID-19 immunizations on each pharmacy's pay statement.

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New Exception Status Benefits

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

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Crysvita (burosumab)	10mg/mL Vial	02483629	DNP	E (SF)	UGX
	20mg/mL Vial	02483637	DNP	E (SF)	UGX
	30mg/mL Vial	02483645	DNP	E (SF)	UGX

Criteria

Initiation Criteria:

- For the treatment of patients with X-linked hypophosphatemia (XLH) who meet all the following criteria:
  - Initiated in a pediatric patient who is at least one year of age and in whom epiphyseal closure has not yet occurred
  - Fasting hypophosphatemia
  - Normal renal function (defined as a serum creatinine below the age-adjusted upper limit of normal)
  - Radiographic evidence of rickets with a rickets severity score (RSS) of two or greater
  - Confirmed phosphate-regulating endopeptidase homolog, X-linked (PHEX) gene variant in either the patient or in a directly related family member with appropriate X-linked inheritance

Discontinuation Criteria:

- In pediatric patients under 18 years of age in whom epiphyseal closure has not yet occurred and who met the initiation criteria, treatment should be discontinued if:
  - there is no demonstrated improvement in the 12-month RSS total score from baseline RSS total score; or

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Crysvita (burosumab)	10mg/mL Vial	02483629	DNP	E (SF)	UGX
	20mg/mL Vial	02483637	DNP	E (SF)	UGX
	30mg/mL Vial	02483645	DNP	E (SF)	UGX
Criteria					

- the patient's RSS total score achieved after the first 12 months of therapy has not been maintained subsequently.

- In adolescent patients who are 13 to 17 years of age in whom epiphyseal closure has occurred and who met the initiation criteria and initiated treatment as a pediatric patient, treatment should be discontinued if any of the following occur:
  - Hyperparathyroidism; or
  - Nephrocalcinosis; or
  - Evidence of fracture or pseudo-fracture based on radiographic assessment.
- In adult patients who met the initiation criteria and initiated treatment as a pediatric patient, treatment should be discontinued if any of the following occur:
  - Hyperparathyroidism; or
  - Nephrocalcinosis; or
  - Evidence of fracture or pseudo-fracture based on radiographic assessment.

Claim Notes:

- Requests will not be considered for treatment-naïve adults.
- Must be prescribed by a physician working in a multidisciplinary team of health care providers who are experienced in the diagnosis and management of XLH.
- Approvals for children (1-17 years of age) will be up to a maximum of 90mg every 2 weeks.
- Approvals for adults (18 years of age and older) will be up to a maximum of 90mg every 4 weeks.
- Approval period: 1 year.
- 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:
  - Crysvita Liq Inj 20mg/mL Vial
    - 00904744
    - 00904745
    - 00904746
    - 00904747
    - 00904748
  - Crysvita Liq Inj 30mg/mL Vial
    - 00904749
    - 00904750
    - 00904751
    - 00904752
    - 00904753

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Calquence (acalabrutinib)	100mg Cap	02491788	DNP	E (SFC)	AZE
Criteria	**Previously Untreated Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL)** • As a single agent treatment option for adult patients with previously untreated chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) for whom a fludarabine-based regimen is considered inappropriate due to high risk of relapse or refractory disease based on prognostic biomarkers. **Clinical Notes:** • High risk for relapse or refractory disease includes 17p deletion, TP53 mutation, 11q deletion and unmutated IGHV. • Patients should have a good performance status. • Treatment should be continued until disease progression or unacceptable toxicity. **Claim Notes:** • Requests will not be considered for patients who experience disease progression on a Bruton's tyrosine kinase (BTK) inhibitor or idelalisib. • Requests will be considered for patients who are not suitable candidates for intravenous therapy. • Venetoclax with or without rituximab is funded as a subsequent line of therapy in patients who have experienced disease progression during first-line acalabrutinib treatment, provided all other funding eligibility criteria are met. **Relapsed/ Refractory Chronic Lymphocytic Leukemia (CLL)/ Small Lymphocytic Lymphoma (SLL)** • As a single agent treatment option for adult patients with relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) who have received at least one prior therapy. **Clinical Notes:** • Patients should have a good performance status. • Treatment should be continued until disease progression or unacceptable toxicity. **Claim Notes:** • Requests will not be considered for patients who experience disease progression on a Bruton's tyrosine kinase (BTK) inhibitor or idelalisib.				

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Mayzent (siponimod)	0.25mg Tab	02496429	DNP	E (SF)	NVR
	2mg Tab	02496437	DNP	E (SF)	NVR
Criteria	**Secondary Progressive Multiple Sclerosis** **Initiation Criteria:** • For the treatment of patients with active secondary progressive multiple sclerosis, who meet all the following criteria: o a history of relapsing-remitting multiple sclerosis (RRMS) o an Expanded Disability Status Scale (EDSS) score of 3.0 to 6.5 o documented EDSS progression during the two years prior to initiating treatment with siponimod (≥ 1 point if EDSS < 6.0; ≥ 0.5 points if EDSS ≥ 6.0 at screening). **Renewal Criteria:** • Patients who do NOT exhibit evidence of disease progression since the previous assessment. Disease progression is defined as: o an increase in the EDSS score of greater than or equal to 1 point if the EDSS score was 3.0 to 5.0 at siponimod initiation *OR* o an increase of greater than or equal to 0.5 points if the EDSS score was 5.5 to 6.5 at siponimod initiation • Patients who do NOT exhibit one of the following: o progression to an EDSS score of equal to or greater than 7.0 at any time during siponimod treatment o confirmed worsening of at least 20% on the timed 25-foot walk (T25W) since initiating siponimod treatment **Clinical Notes:** • Patients should be assessed for a response to siponimod every six months. **Claims Notes:** • The patient is under the care of a neurologist with experience in the diagnosis and management of multiple sclerosis. • Siponimod should not be used in combination with other disease-modifying treatments (DMTs) used to treat multiple sclerosis. • Approval period: 1 year				

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Tegsedi (inotersen)	189 mg/mL Prefilled Syringe	02481383	DNP	E (SF)	AKT

Criteria	**Polyneuropathy in Hereditary Transthyretin-Mediated Amyloidosis**
	• For the treatment of polyneuropathy in adult patients with hereditary transthyretin-mediated amyloidosis (hATTR) who meet all of the following criteria:
	  ○ Confirmed genetic diagnosis of hATTR
	  ○ Symptomatic with early-stage neuropathy
	  ○ Does not have New York Heart Association class III or IV heart failure
	  ○ Has not previously undergone a liver transplant
	Discontinuation Criteria:
	• The patient is permanently bedridden and dependent on assistance for basic activities of daily living
	OR
	• The patient is receiving end-of-life care.
	Clinical Note:
	• Symptomatic early-stage neuropathy is defined as polyneuropathy disability stage I to IIIB or familial amyloidotic polyneuropathy stage I or II.
	Claims Note:
	• The patient must be under the care of a physician with experience in the diagnosis and management of hATTR.
	• Combination therapy with other interfering ribonucleic acid drugs or transthyretin stabilizers used to treat hATTR will not be reimbursed.
	• Initial Approval: 9 months.
	• Renewal Approval: 12 months. Confirmation of continued response is 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 PINs:
	  ○ 00904551
	  ○ 00904552
	  ○ 00904553				

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Baqsimi (glucagon)	3mg Nasal Powder	02492415	DNP	E (SFD)	LIL
Criteria	• For the emergency treatment of severe hypoglycemia (SH) reactions for patients who are receiving insulin and at high risk for SH, when impaired consciousness precludes oral carbohydrate. **Claim Notes:** • Approval duration: long term. • Quantity limit: up to two devices per year. The prescriber or pharmacist can request additional devices if clinically required.				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Entuzity (human insulin R)	500 U/mL KwikPen	02466864	DNP	E (SFD)	LIL
Criteria	• For the treatment of patients with diabetes mellitus with unacceptable glycemic control who require more than 200 units of insulin per day, with or without other therapies. **Claims Notes:** • Treatment must be initiated by an endocrinologist or prescriber with a specialty in endocrinology.				

Criteria Updates

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

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Forxiga (dapagliflozin)	5mg Tab 10mg Tab	02435462 02435470	DNP DNP	E (SF) E (SF)	AZE AZE
Criteria	**Heart Failure with Reduced Ejection Fraction** • For the treatment of adult patients with New York Heart Association (NYHA) class II or III heart failure with reduced ejection fraction (left ventricular ejection fraction ≤ 40%) as an adjunct to standard of care therapies. **Clinical note:** • Standard of care therapies include beta-blockers, angiotensin converting enzyme inhibitors (ACEIs) or angiotensin receptor blockers (ARBs), plus a mineralocorticoid receptor antagonist.				

Criteria Updates Continued…

The following criteria has been updated **effective immediately**.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Rituximab Biosimilars	10mg/mL Vial	Various	DNP	E (SF)	VAR
Criteria	**For rituximab-naïve patients whose rituximab therapy is initiated after November 1, 2020, a rituximab biosimilar will be the product approved.** • For the treatment of rheumatoid arthritis[1], vasculitis[2], or other autoimmune diseases[3]. **Clinical Notes:** 1. Severe intolerance or other contraindication to an anti-TNF agent or failed an adequate trial of an anti-TNF agent. 2. Severe intolerance or other contraindication to cyclophosphamide or failed an adequate trial of cyclophosphamide. 3. Previously failed treatments must be provided if applicable. **Claims Notes:** • Must be prescribed by a specialist. • Approval period: long term				

*Form for rituximab biosimilars available at https://novascotia.ca/dhw/pharmacare/exception-status-drugs.asp

The following criteria has been updated **effective immediately** and applies to the following new and existing indications.

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

Criteria Updates Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Venclexta (venetoclax)	10mg Tab	02458039	DNP	E (SFC)	ABV
	50mg Tab	02458047	DNP	E (SFC)	ABV
	100mg Tab	02458055	DNP	E (SFC)	ABV
	Starter Pack	02458063	DNP	E (SFC)	ABV

Criteria

Venetoclax with Azacitidine for newly diagnosed acute myeloid leukemia (AML)

- In combination with azacitidine for the treatment of patients with newly diagnosed acute myeloid leukemia (AML) who are 75 years of age or older, or who have comorbidities that preclude the use of intensive induction chemotherapy.

Clinical Notes:

- Treatment should continue until disease progression or unacceptable toxicity.
- All newly diagnosed AML patients who are ineligible for induction chemotherapy are eligible regardless of cytogenetic risk.,
- On a time-limited need, patients who are currently receiving azacitidine for newly diagnosed AML may have venetoclax added to their treatment provided there is no disease progression and patient otherwise meets criteria.

Claim Notes:

- Patients who have been previously treated with a hypomethylating agent or chemotherapy for the treatment of myelodysplastic syndromes (MDS) are not eligible for treatment with venetoclax in combination with azacitidine.
- Patients with high risk MDS are not eligible for treatment with venetoclax in combination with azacitidine.

Venetoclax monotherapy for chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) in patients who have received at least one prior therapy

- As a single agent treatment option for patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) who have received at least one prior therapy, and who have failed a B-cell receptor inhibitor (BCRi). Treatment should be continued until disease progression or unacceptable toxicity.

Clinical Notes:

- Patients who have an intolerance or a contraindication to a B-cell receptor inhibitor (BCRi) will be eligible for treatment with venetoclax. Intolerance to BCRi would be determined by the clinician.

Venetoclax with rituximab for chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) in patients who have received at least one prior therapy

- In combination with rituximab for the treatment of adult patients with chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) who have received at least one prior therapy, irrespective of their 17p deletion status. Treatment should be continued until disease progression or unacceptable toxicity up to a maximum of two years, whichever comes first.

Criteria Updates Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Venclexta (venetoclax)	10mg Tab	02458039	DNP	E (SFC)	ABV
	50mg Tab	02458047	DNP	E (SFC)	ABV
	100mg Tab	02458055	DNP	E (SFC)	ABV
	Starter Pack	02458063	DNP	E (SFC)	ABV
Criteria	**Clinical Notes:** • Patients who were previously treated with an anti-CD20 therapy (rituximab or obinutuzumab) will be eligible if they had a progression-free interval of 6 months or longer. For patients previously treated with venetoclax, the progression-free interval must be 12 months or longer. • Patients currently receiving and responding to venetoclax monotherapy, and who have not achieved an adequate response are eligible to have rituximab added to venetoclax. Note: Venetoclax therapy is funded to a maximum of two years from the time rituximab is added. • Patients will be eligible for treatment with either ibrutinib, or idelalisib with rituximab following progression on venetoclax with rituximab if they have not received before and otherwise meet eligibility criteria.				

Non-Insulin Antidiabetic Agents (SGLT-2 Inhibitors and DPP-4 Inhibitors)

Please be advised that we will now be considering additional reasons why insulin is not an option (e.g., for patients who are not amenable to taking daily injections of insulin). The form is available at:
https://novascotia.ca/dhw/pharmacare/documents/forms/Oral-Diabetes-Treatments.pdf

New Diabetic Product

The following product is a new listing to the Nova Scotia Formulary, effective immediately. The benefit status within the Nova Scotia Pharmacare Programs is indicated.

PRODUCT	DIN/PIN	PRESCRIBER	BENEFIT STATUS	MFR
BD AutoShield Duo Pen Needles	97799433	DNP	F*	BTD

* funded for children requiring administration of insulin in school

Non-Insured Products

The following products will not be insured in the Pharmacare Programs; however, they will be funded through the Exception Drug Fund as per other HIV medications.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Cabenuva	400mg/2mL/600mg/2mL Vial	02497220	N/A	**Not Insured**	VIV
Cabenuva	600mg/3mL/900mg/3mL Vial	02497247	N/A	**Not Insured**	VIV
Vocabria	30mg Tab	02497204	N/A	**Not Insured**	VIV

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:

- Updated eligible date for virtual care services to March 31, 2023.
- In the **Administration** section, further emphasis that license numbers must be accurate in CANImmunize for COVID-19 vaccination payments to be processed.
- In the **Pharmacare Programs and Benefits** section, addition of information about the Boarding, Transportation and Ostomy Program.
- In the **Exception Status Drugs** section, under Online Adjudication of Exception Status Drugs, removal of reference to Humalog, which has been de-listed.
- In the **Administration of Publicly Funded Influenza Vaccinations Provided by a Pharmacy** section, change to eligible age to six months.
- In the **Administration of Publicly Funded COVID-19 Vaccinations Provided by a Pharmacy** section, update in fee, removal of reference to standalone Provider Confirmation of Agreement, update to labelling of bottom-line adjustment on the pharmacy pay statement, and further emphasis on license numbers being correct in CANImmunize.
- In the **Prescription Renewals** section, update to reflect removal of 180-day prescribing limit.
- In the **Benefits for All Residents** section, addition of new services: dispensing of oral anti-viral medications for COVID-19, pharmacist assessment for COVID-19 therapies, and Community Pharmacy Anticoagulation Management Services (CPAMS).
- Under **Benefits for All Residents**, addition of new PINs for Take Home Naloxone Kits.
- In the **Minimum Days' Supply** section, removal of de-listed ATC codes.
- Under **Quantity Limits**, adjustment to timeframe for Biphentin.
- In the **Standardization of Package Sizes** section, adjustments to product references for package kits of more than one drug.
- In the **Adjustments** section, update to the Request for Adjustments Form.

Updates to the Nova Scotia Pharmacy Guide Continued…

- In the **Pharmacare Prescription Audit Recovery Procedures**, removal of requirement to document patient consent for services; for medication reviews delivered by telephone, addition of requirement to document reason the review was not completed in-person or by video; update to types of desk audits.
- Under **Pharmacy Service Audits**, removal of requirement to document patient consent.

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New Exception Status Benefits

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

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Alunbrig (brigatinib)	30mg Tab	02479206	DNP	E (SFC)	TAK
	90mg Tab	02479214	DNP	E (SFC)	TAK
	180mg Tab	02479222	DNP	E (SFC)	TAK
	Initiation Pack	02479230	DNP	E (SFC)	TAK

Criteria

Locally Advanced or Metastatic Non-Small Cell Lung Cancer

- For the first line treatment of patients with locally advanced or metastatic anaplastic lymphoma kinase (ALK) positive non-small cell lung cancer (NSCLC).

Clinical Notes:

- Patients should have a good performance status and treatment should be continued until disease progression or unacceptable toxicity.
- Patients are not eligible for subsequent ALK inhibitor therapy following disease progression on brigatinib.
- Patients may be switched to an alternate ALK inhibitor in the case of intolerance without disease progression.

Claim Notes:

- 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:
  - Alunbrig 30mg Tab – 00904758
  - Alunbrig 90mg Tab – 00904759
  - Alunbrig 180mg Tab – 00904760
  - Alunbrig Initiation Pack – 00904761

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Ilumya (tildrakizumab)	100 mg/mL Prefilled Syringe	02516098	DNP	E (SF)	SUN

Criteria	• For patients with severe, debilitating chronic plaque psoriasis who meet all of the following:
	  ○ Body surface area (BSA) involvement of >10% and/or significant involvement of the face, hands, feet or genitals;
	  ○ Failure to, contraindication to or intolerant of methotrexate and cyclosporine;
	  ○ Failure to, intolerant of or unable to access phototherapy;
	  ○ Written request of a dermatologist or prescriber with a specialty in dermatology.
	• Continued coverage is dependent on evidence of improvement, specifically:
	  ○ A >75% reduction in the Psoriasis Area and Severity Index (PASI) score; or
	  ○ A >50% reduction in PASI with a > 5 point improvement in DLQI (Dermatology Life Quality Index); or
	  ○ Significant reduction in BSA involved, with consideration of important regions such as the face, hands, feet or genitals.
	Clinical Note:
	• Treatment should be discontinued if a response has not been demonstrated after 16 weeks.
	Claim Notes:
	• Concurrent use of biologics not approved.
	• Approvals will be for 100 mg by subcutaneous injection at week 0, week 4, and every 12 weeks thereafter.
	• Initial approval period: 16 weeks
	• Renewal approval period: 1 year				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Yuflyma (adalimumab)	40mg/0.4mL Prefilled Pen	02523779	DNP	E (SF)	CTL
Criteria	• Please refer to the Pharmacare Formulary (https://novascotia.ca/dhw/pharmacare/formulary.asp) for the adalimumab criteria.				

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Verkazia (cyclosporine)	0.1% Ophthalmic Emulsion	02484137	DNP	E (F)	SNN

Criteria	• For the treatment of pediatric patients between the age of 4 and 18 years of age with severe vernal keratoconjunctivitis (VKC) who meet the following criteria:
	  ○ Grade 3 (severe) or 4 (very severe) on the Bonini scale, or
	  ○ Grade 4 (marked) or 5 (severe) on the modified Oxford scale.
	Discontinuation Criteria:
	• Treatment should be discontinued if no improvement in signs and symptoms of VKC is observed, or
	• Treatment should be discontinued if signs and symptoms of VKC have resolved.
	Clinical Notes:
	• Documentation of the severity of signs and symptoms of VKC at treatment initiation and renewal must be provided.
	• Patients previously treated with cyclosporine 0.1% but who discontinued treatment upon resolution of VKC signs and symptoms are eligible to reinitiate treatment if signs and symptoms of severe VKC recur and they meet the initiation criteria.
	Claim Notes:
	• The patient must be under the care of a physician experienced in the diagnosis and management of VKC.
	• Initial approval period: 6 months.
	• Renewal approval period: 1 year				

New Benefits

Effective **immediately,** the following products have been added to the Nova Scotia Formulary. The benefit status within the Pharmacare Programs is indicated. Existing criteria applies.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Skyrizi	150mg/mL Prefilled Syringe	02519283	DNP	E (SF)	ABV
Skyrizi	150mg/mL Prefilled Pen	02519291	DNP	E (SF)	ABV

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Nova Scotia Formulary Updates

New Exception Status Benefits

The following new products have been listed with the following criteria, effective **September 1, 2022**.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Vyndaqel (tafamidis meglumine)	20mg Cap	02495732	DNP	E (SF)	PFI
Vyndamax (tafamidis)	61mg Cap	02517841	DNP	E (SF)	PFI

Criteria

For the treatment of cardiomyopathy in adult patients with documented hereditary or wild-type transthyretin-mediated amyloidosis (ATTR) who meet all of the following criteria:

- New York Heart Association (NYHA) class I to III heart failure
- At least one prior hospitalization for heart failure or clinical evidence of heart failure that required treatment with a diuretic
- Has not previously undergone a heart or liver transplant
- Does not have an implanted cardiac mechanical assist device (CMAD)

Discontinuation Criteria:

The patient has:

- NYHA class IV heart failure, or
- received an implanted CMAD, or
- received a heart or liver transplant.

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Vyndaqel (tafamidis meglumine)	20mg Cap	02495732	DNP	E (SF)	PFI
Vyndamax (tafamidis)	61mg Cap	02517841	DNP	E (SF)	PFI

Criteria

Clinical Notes:

1. Wild-type ATTR-cardiomyopathy (CM) consists of all of the following:
    a. absence of a variant transthyretin (TTR) genotype
    b. TTR precursor protein identification by immunohistochemistry, scintigraphy, or mass spectrometer
    c. evidence of cardiac involvement by echocardiography with end-diastolic interventricular septal wall thickness greater than 12 mm
    d. presence of amyloid deposits in biopsy tissue (fat aspirate, salivary gland, median nerve connection tissue sheath, or cardiac tissue)
2. Hereditary ATTR-CM consists of all of the following:
    a. presence of a variant TTR genotype associated with CM and presenting with a CM phenotype
    b. evidence of cardiac involvement by echocardiography with end-diastolic interventricular septal wall thickness greater than 12 mm
    c. presence of amyloid deposits in biopsy tissue (fat aspirate, salivary gland, median nerve connective tissue sheath, or cardiac tissue)

Claim Notes:

- The patient must be under the care of a physician with experience in the diagnosis and treatment of ATTR-CM.
- Combination therapy with other interfering ribonucleic acid drugs or transthyretin stabilizers used to treat ATTR will not be reimbursed.
- Claims will be limited to a 30-day supply.
- Initial approval period: 9 months.
- Renewal approval period: 1 year.
- 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:
    - Vyndaqel 00904637
    - Vyndamax 00904778

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Kesimpta (ofatumumab)	20mg/0.4mL Prefilled Pen	02511355	DNP	E (SF)	NVR

Criteria	**Relapsing Remitting Multiple Sclerosis (RRMS)**
	• For the treatment of adult patients with relapsing remitting multiple sclerosis (RRMS) who meet all of the following criteria:
	  ○ An Expanded Disability Status Scale (EDSS) score of less than 6.0
	  ○ Evidence of active disease defined as at least one of the following:
	  ▪ One relapse during the previous year
	  ▪ Two relapses during the previous 2 years
	  ▪ A positive gadolinium (Gd)-enhancing MRI scan during the year before starting treatment with ofatumumab.
	Renewal Criteria:
	• EDSS score less than 6.0. Date and details of the most recent neurological examination and EDSS score must be provided (exam must have occurred within the last 90 days);
	AND
	• Patients must be stable or have experienced no more than 1 disabling attack/relapse in the past year.
	Claims Notes:
	• Approval: 1 year.
	• Combined use with other disease modifying therapies to treat multiple sclerosis will not be reimbursed.
	• Must be prescribed by a neurologist with experience in the diagnosis and management of multiple sclerosis.				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
MAR-Trientine (trientine hydrochloride)	250mg Cap	02504855	DNP	E (SF)	MAR
Criteria	**Wilson's Disease** • For the treatment of Wilson's disease in patients who have experienced intolerance or have a contraindication to d-penicillamine. **Clinical Notes:** • Intolerant is defined as demonstrating serious adverse effects to treatments. The nature of intolerance(s) must be clearly documented.				

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
MAR-Trientine (trientine hydrochloride)	250mg Cap	02504855	DNP	E (SF)	MAR
Criteria	**Claims Notes:** • Treatment must be initiated by clinicians experienced in the management of Wilson's disease for adult patients 18 years of age or older. • Treatment must be initiated and renewed by clinicians experienced in the management of Wilson's disease for patients less than 18 years of age. Approval: 12 months				

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

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Prometrium and generics (progesterone)	100mg Cap	Various	DNP	E (F)	VAR
Criteria	• For persons with a singleton gestation who are: ○ greater than 20 weeks gestation AND • high-risk for pre-term birth (cervix less than 25 mm or past history of pre-term birth).				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
JAMP Prasugrel	10mg Tab	02502429	DNP	E (SF)	JPC
Criteria	• In combination with ASA for patients with: ○ Unstable angina (UA) or non-ST-segment elevation myocardial infarction (NSTEMI) managed with percutaneous coronary intervention (PCI); or ○ ST-segment elevation myocardial infarction (STEMI) managed with primary or delayed PCI; or ○ Failure on clopidogrel and ASA therapy as defined by definite stent thrombosis, or recurrent STEMI, NSTEMI or UA after revascularization with PCI. **Clinical Note:** • Definite stent thrombosis, according to the Academic Research Consortium, is a total occlusion originating in or within 5 mm of the stent or is a visible thrombus within the stent or is within 5 mm of the stent in the presence of an acute ischemic clinical syndrome within 48 hours. **Claim Note:** • Approval Period: 1 year.				

Criteria Updates

The following new indication has been added to existing criteria effective **September 1, 2022**.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Lynparza	100mg Tab	02475200	DNP	E (SFC)	AZE
(olaparib)	150mg Tab	02475219	DNP	E (SFC)	AZE
Criteria	**Metastatic Castrate-Resistant Prostate Cancer** • For the treatment of patients with metastatic castration-resistant prostate cancer (mCRPC) with deleterious or suspected deleterious germline and/or somatic mutations in the homologous recombination repair (HRR) genes BRCA1, BRCA2 or ATM and who have progressed on prior treatment with androgen-receptor-axis-targeted (ARAT) therapy. **Clinical Note:** • Patients should have a good performance status and treatment should be continued until disease progression or unacceptable toxicity.				

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

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Pulmicort Nebules and generics **(budesonide)**	Various	Various	DNP	E (SF)	VAR
Criteria	• For patients who require budesonide for sinonasal irrigation when it is prescribed by, or in consultation with, a specialist (e.g., ENT, allergists, immunologists). **Claim Notes:** • Initial Approval: 1 year. • Renewal Approval: Long term				

Criteria Updates Continued…

The following criteria has been updated effective **September 1, 2022**.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Actemra (tocilizumab)	80mg/4mL Inj	02350092	DNP	E (SF)	HLR
	200mg/10mL Inj	02350106	DNP	E (SF)	HLR
	400mg/20mL Inj	02350114	DNP	E (SF)	HLR
	162mg/0.9mL SC Inj	02424770	DNP	E (SF)	HLR
	162mg/0.9mL Autoinjector	02483327	DNP	E (SF)	HLR

Criteria

Polyarticular Juvenile Idiopathic Arthritis (pJIA)

- For the treatment of children (age 2-17) with moderately to severely active polyarticular juvenile idiopathic arthritis (pJIA) who have had inadequate response to one or more disease-modifying antirheumatic drugs (DMARDs).

Notes:

- Must be prescribed by, or in consultation with, a rheumatologist who is familiar with the use of biologic DMARDs in children.
- Intravenous infusion: Approvals will be for 10mg/kg for patients <30kg or 8mg/kg for patients ≥ 30kg, to a maximum of 800mg, administered every four weeks.
- Subcutaneous injection: Approvals will be for a maximum of 162mg once every three weeks for patients weighing <30kg or 162mg once every two weeks for patients weighing ≥30kg.
- Initial approval period: 16 weeks
- Renewal Approval: 1 year. Confirmation of continued response is required.

Systemic Juvenile Idiopathic Arthritis (sJIA)

- For the treatment of active systemic juvenile idiopathic arthritis (sJIA), in patients 2 years of age or older, who have responded inadequately to non-steroidal anti-inflammatory drugs (NSAIDs) and systemic corticosteroids (with or without methotrexate) due to intolerance or lack of efficacy.

Notes:

- Must be prescribed by, or in consultation with, a rheumatologist, who is familiar with the use of biologic DMARDs in children.
- Intravenous infusion: Approvals will be for 12 mg/kg for patients < 30kg or 8 mg/kg for patients ≥ 30kg, to a maximum of 800mg, administered every two weeks.
- Subcutaneous injection: Approvals will be for a maximum of 162mg once every two weeks for patients weighing <30kg or 162mg once every week for patients weighing ≥30kg.
- Initial approval period: 16 weeks

Renewal Approval: 1 year. Confirmation of continued response is required.

Proton Pump Inhibitors

Effective **immediately** the maximum yearly quantity limit for lansoprazole, omeprazole, pantoprazole sodium and pantoprazole magnesium has been removed. Going forward special authorization requests for double dose are no longer required. The following criteria will apply.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Omeprazole and Pantoprazole Sodium	Various	Various	DNP	SFC	VAR
Criteria	• Full benefit, special authorization no longer required for double dose.				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Lansoprazole and Pantoprazole Magnesium	Various	Various	DNP	E (SFC)	VAR
Criteria	• Failure of a trial of all open benefit PPIs (omeprazole, pantoprazole sodium and rabeprazole).				

Change in Benefit Status

Effective **immediately,** cholinesterase inhibitor oral tablets and capsules have moved to full benefit status. These products will no longer require completion of an exception status request form.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Donepezil	Various Tab	Various	DNP	SF	VAR
Galantamine	Various Cap	Various	DNP	SF	VAR
Rivastigmine	Various Cap	Various	DNP	SF	VAR

Effective **immediately**, the following products have also moved to full benefit status and no longer require exception status approval.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Campral	333mg Tab	02293269	DNP	SF	MYL
Carvedilol	Various Tab	Various	DNP	SF	VAR
Lacosamide	Various Tab	Various	DNP	SF	VAR
Lurasidone	Various Tab	Various	DNP	SF	VAR
Mometasone	50mcg Nasal Spray	Various	DNP	SF	VAR
Naltrexone	50mg Tab	Various	DNP	SF	VAR
Quetiapine XR	Various Tab	Various	DNP	SF	VAR

New Benefit

Effective **immediately,** the following product has been added to the Nova Scotia Formulary. The benefit status within the Pharmacare Programs is indicated.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Trimethoprim/Polymyxin B	0.1% / 10,000 u/mL Oph Sol	Various	DNPO	SF	VAR

Temporary Benefit – US-Labelled Cortef

Pfizer Canada ULC has received approval from Health Canada for the importation and release of a limited supply of US-labelled Cortef 10mg tablets to mitigate the current market shortage.

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

The US-labelled product has the same strength, dosage form, and route of administration as the Canadian-authorized product, but the products differs with respect to the packaging.

When prescribing or dispensing this product, pharmacists are directed to consult the Pfizer Dear Healthcare Professional at the following link: DHCPL_CORTEF_06Jun2022_EN.docx.pdf (pfizer.ca)

PRODUCT	STRENGTH	PIN	PRESCRIBER	BENEFIT STATUS	MFR
Cortef (hydrocortisone) US	10mg Tab	09858155	DNP	SFC	PFI

Cystic Fibrosis Therapies Update - Trikafta

The following product is not funded in the Pharmacare Programs; however, it is funded through the Cystic Fibrosis Program with specific criteria, effective **July 18, 2022**.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Trikafta	50mg/25mg/37.5mg & 75mg Tab	02526670	N/A	**Not Insured**	VTX

New Diabetic Products

Effective **September 1, 2022,** the following products have been added to the Nova Scotia Formulary. The benefit status and reimbursement price within the Nova Scotia Pharmacare Programs is indicated.

PRODUCT	PIN	PRICE	BENEFIT STATUS	MFR
MediSure Empower Blood Glucose Test Strips (50/box)	97799054	0.6800	SFD	MSR
MediSure Empower Blood Glucose Test Strips (100/box)	97799053	0.6800	SFD	MSR

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Non-Insured Product

The following product is not funded in the Pharmacare Programs; however, it is funded through the Exception Drug Fund with specific criteria, effective **October 1, 2022.**

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Zolgensma (onasemnogene abeparvovec)	2 x 10^{13} vector genomes/mL Vial	02509695	N/A	**Not Insured**	NVR

New Exception Status Benefit

The following new product will be listed with the following criteria, effective **October 1, 2022**.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Evrysdi (risdiplam)	0.75mg/mL Pws for Sol	02514931	DNP	E (F)	HLR

Criteria

Spinal Muscular Atrophy

For patients diagnosed with 5q Spinal Muscular Atrophy (SMA) under the care of a specialist with experience in the diagnosis and management of SMA, if the following clinical criteria are met:

- Genetic documentation of 5q SMA homozygous gene deletion or compound heterozygote, AND
- Patients who:
  - are symptomatic and have genetic documentation of two or three copies of the SMN2 gene, AND

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Evrysdi (risdiplam)	0.75mg/mL Pws for Sol	02514931	DNP	E (F)	HLR
Criteria	○ aged between 2 months and 7 months (inclusive), OR ○ aged 8 months up to 25 years and are non-ambulatory • Patient is not currently requiring permanent invasive ventilation*, AND • A baseline assessment using an age-appropriate scale (the Hammersmith Infant Neurological Examination [HINE] Section 2, Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders [CHOP INTEND], or Hammersmith Functional Motor Scale-Expanded [HFMSE]) must be completed prior to initiation of risdiplam treatment. • For continued coverage, the patient must meet the following criteria: ○ There is demonstrated achievement or maintenance of motor milestone function (as assessed using age-appropriate scales: the [HINE] Section 2, CHOP INTEND, or HFMSE) after treatment initiation in patients aged between 2 months and 2 years at the time of treatment initiation; OR ○ There is demonstrated maintenance of motor milestone function (as assessed using age-appropriate scales: the HINE Section 2, CHOP INTEND, or HFMSE) after treatment initiation in patients aged between 2 years and 25 years at the time of treatment initiation; AND ○ Patient does not require permanent invasive ventilation*. The decision to discontinue reimbursement should be based on 2 assessments separated by no longer than a 12-week interval. **Claim Notes:** • Coverage for risdiplam will not be provided in combination with other SMA drug therapies or post administration of onasemnogene abeparvovec. • Approval: 12 months • 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: ○ 00904768 ○ 00904769 ○ 00904770 * Permanent invasive ventilation is defined as the use of tracheostomy and a ventilator due to progression of SMA that is not due to an identifiable and reversible cause.				

Criteria Updates

The following criteria has been updated to include criteria codes effective **October 1, 2022**.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Benzydamine Oral Rinse	0.15% Oral Rinse	Various	DNP	E (SFC)	VAR
Criteria	• For oncology patients only. **[Criteria Code 01]**				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Akynzeo (netupitant/palon-osetron)	300mg/0.5mg Capsule	02468735	DNP	E (SFC)	ELV

Criteria	• In combination with dexamethasone for the prevention of acute and delayed nausea and vomiting in patients receiving:
	  ○ highly emetogenic chemotherapy, **[Criteria Code 01]** OR
	  ○ moderately emetogenic chemotherapy who have had inadequate symptom control using a 5-HT3 antagonist and dexamethasone in a previous cycle. **[Criteria Code 02]**
	Clinical Notes:
	• Highly emetogenic chemotherapy (HEC) may include, but is not limited to: cisplatin regimens, anthracycline and cyclophosphamide combination regimens, and regimens containing carmustine, mechlorethamine, streptozocin, dacarbazine and cyclophosphamide ≥ 1500mg/m^2.
	• Patients who receive carboplatin-based regimens with AUC ≥ 4 are also eligible to receive netupitant/palonosetron in combination with dexamethasone for primary prevention of acute and delayed nausea and vomiting.				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Emend (aprepitant)	80mg Capsule	02298791	DNP	E (SFC)	FRS
	125mg Capsule	02298805	DNP	E (SFC)	FRS
	Tri-Pack Capsule	02298813	DNP	E (SFC)	FRS

Criteria	• In combination with a 5-HT3 antiemetic and dexamethasone for the prevention of acute and delayed nausea and vomiting in patients receiving:
	  ○ highly emetogenic chemotherapy, **[Criteria Code 01]** OR
	  ○ moderately emetogenic chemotherapy who have had inadequate symptom control using a 5-HT3 antagonist and dexamethasone in a previous cycle. **[Criteria Code 02]**				

Criteria Updates Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Emend (aprepitant)	80mg Capsule	02298791	DNP	E (SFC)	FRS
	125mg Capsule	02298805	DNP	E (SFC)	FRS
	Tri-Pack Capsule	02298813	DNP	E (SFC)	FRS
Criteria	**Clinical Notes:** • Highly emetogenic chemotherapy (HEC) may include, but is not limited to: cisplatin regimens, anthracycline and cyclophosphamide combination regimens, and regimens containing carmustine, mechlorethamine, streptozocin, dacarbazine and cyclophosphamide ≥ 1500mg/m^2. • Patients who receive carboplatin-based regimens with AUC ≥ 4 are also eligible to receive aprepitant in combination with a 5-HT3 antiemetic and dexamethasone for the primary prevention of acute and delayed nausea and vomiting.				

Change in Benefit Status

Effective **October 1, 2022**, the following product will move to full benefit and no longer require exception status approval.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Rexulti (brexpiprazole)	Various	Various	DNP	SF	OTS

New Benefit

Effective **October 1, 2022,** the following product has been added to 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
Xolair	150mg Prefilled Syringe	02459795	DNP	E (SF)	NVR

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New Exception Status Benefits

The following new products will be listed with the following criteria, effective **November 1, 2022**.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Inrebic (fedratinib)	100mg Cap	02502445	DNP	E (SFC)	CEL

Criteria

- For the treatment of splenomegaly and/or disease-related symptoms in adult patients with intermediate-2 or high-risk primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis, who have a contraindication or intolerance to ruxolitinib.

Clinical Notes

- Patients should have a good performance status.
- Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Note

- 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:
  - 00904799

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Kynmobi (apomorphine hydrochloride)	10mg Film	02500264	DNP	E (SF)	SNV
	15mg Film	02500272	DNP	E (SF)	SNV
	20mg Film	02500280	DNP	E (SF)	SNV
	25mg Film	02500299	DNP	E (SF)	SNV
	30mg Film	02500302	DNP	E (SF)	SNV
Criteria	• For the acute, intermittent treatment of "OFF" episodes in patients with Parkinson's Disease (PD) who meet the following criteria: ○ Apomorphine sublingual should only be used as adjunctive therapy in patients who are experiencing "OFF" episodes despite receiving optimized PD therapy (levodopa and derivatives and adjunctive therapy such as dopaminergic agonists or MAO-B inhibitors or amantadine derivatives). **Clinical Notes** • Treatment should be discontinued unless an improvement of at least 3.25 points is achieved in the Movement Disorders Society Unified Parkinson's Disease Rating Scale Part III (MDS-UPDRS III) score measured within 30 to 60 minutes after a titrated dose is administered. • This assessment should occur not more than one year after Kynmobi has been titrated to a stable and tolerated dose. **Claims Notes** • Approvals will be for a maximum of five films per day or 90 mg in total (whichever is reached first). • Patients should be under the care of a physician with experience in the diagnosis and management of PD. • Initial approval: 12 months • Renewal: long term				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Hulio (adalimumab)	20mg/0.4mL Prefilled Syringe	02502380	DNP	E (SF)	BGP
Criteria	• Please refer to the Pharmacare Formulary (https://novascotia.ca/dhw/pharmacare/formulary.asp) for the adalimumab criteria.				

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Waymade-Trientine (trientine hydrochloride)	250mg Cap	02515067	DNP	E (SF)	WMD
Criteria	**Wilson's disease** • For the treatment of Wilson's disease in patients who have experienced intolerance or have a contraindication to d-penicillamine. **Clinical Notes** • Intolerance is defined as demonstrating serious adverse effects to treatments. The nature of intolerance(s) must be clearly documented. **Claims Notes** • Treatment must be initiated by clinicians experienced in the management of Wilson's disease for adult patients 18 years of age or older. • Treatment must be initiated and renewed by clinicians experienced in the management of Wilson's disease for patients less than 18 years of age. • Approval: 12 months				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Breztri Aerosphere (budesonide/ glycopyrronium/ formoterol fumerate dihydrate)	182mcg/8.2mcg/5.8mcg Inh	02518058	DNP	E (SF)	AZE
Criteria	• For the treatment of chronic obstructive pulmonary disease (COPD), as defined by spirometry, in patients who experience inadequate control while being treated with a long-acting beta-2 agonist/long-acting muscarinic antagonist (LABA/LAMA). **Clinical Notes** • COPD is defined by spirometry as a post-bronchodilator FEV1/FVC ratio of less than 0.70. Spirometry reports from any point in time will be accepted. If spirometry cannot be obtained, reasons must be clearly explained and other evidence of COPD severity provided (i.e. MRC Dyspnea Scale Score grade). • Inadequate control while being treated with a LABA/LAMA for at least two months is defined as persistent symptoms or experiencing two or more exacerbations of COPD in the previous year requiring treatment with antibiotics and/or systemic corticosteroids or at least one exacerbation of COPD requiring hospitalization. • Patients should not be started on a LABA, LAMA and an inhaled corticosteroid (triple inhaled therapy) as initial therapy.				

Criteria Updates

The following criteria has been updated effective **November 1, 2022.**

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Vyndaqel (tafamidis meglumine)	20mg Cap	02495732	DNP	E (SF)	PFI
Vyndamax (tafamidis)	61mg Cap	02517841	DNP	E (SF)	PFI
Criteria	• For the treatment of cardiomyopathy in adult patients with documented hereditary or wild-type transthyretin-mediated amyloidosis (ATTR) who meet all of the following criteria: o New York Heart Association (NYHA) class I to III heart failure o At least one prior hospitalization for heart failure or clinical evidence of heart failure that required treatment with a diuretic o Has not previously undergone a heart or liver transplant o Does not have an implanted cardiac mechanical assist device (CMAD) **Discontinuation Criteria** • The patient has: o NYHA class IV heart failure, or o received an implanted CMAD, or o received a heart or liver transplant. **Clinical Notes** 1. Wild-type ATTR-cardiomyopathy (CM) consists of all of the following: a. absence of a variant transthyretin (TTR) genotype b. TTR precursor protein identification by immunohistochemistry, scintigraphy, or mass spectrometer c. evidence of cardiac involvement by echocardiography with end-diastolic interventricular septal wall thickness greater than 12 mm d. presence of amyloid deposits in biopsy tissue (fat aspirate, salivary gland, median nerve connection tissue sheath, or cardiac tissue) or positive findings on technetium-99m pyrophosphate (Tc-99m-PYP) scintigraphy with single-photon emission computed tomography (SPECT) scanning 2. Hereditary ATTR-CM consists of all of the following: a. presence of a variant TTR genotype associated with CM and presenting with a CM phenotype b. evidence of cardiac involvement by echocardiography with end-diastolic interventricular septal wall thickness greater than 12 mm c. presence of amyloid deposits in biopsy tissue (fat aspirate, salivary gland, median nerve connective tissue sheath, or cardiac tissue) or positive findings on Tc-99m-PYP scintigraphy with SPECT scanning				

Criteria Updates Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Vyndaqel (tafamidis meglumine)	20mg Cap	02495732	DNP	E (SF)	PFI
Vyndamax (tafamidis)	61mg Cap	02517841	DNP	E (SF)	PFI
Criteria	**Claim Notes** • The patient must be under the care of a physician with experience in the diagnosis and treatment of ATTR-CM. • Combination therapy with other interfering ribonucleic acid drugs or transthyretin stabilizers used to treat ATTR will not be reimbursed. • Claims will be limited to a 30-day supply. • Initial approval period: 9 months. • Renewal approval period: 1 year.				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Spinraza (nusinersen)	12mg/5mL Vial	02465663	DNP	E (SF)	BIG

Criteria	• For patients diagnosed with 5q Spinal Muscular Atrophy (SMA) under the care of a specialist with experience in the diagnosis and management of SMA, if the following clinical criteria are met:
	  ○ Genetic documentation of 5q SMA homozygous gene deletion, homozygous mutation, or compound heterozygote, AND
	  ○ Patients who:
	  ▪ are pre-symptomatic with two or three copies of SMN2, OR
	  ▪ have had disease duration of less than six months, two copies of SMN2, and symptom onset after the first week after birth and on or before seven months of age, OR
	  ▪ are under the age of 18 with symptom onset after six months of age,
	  ▪ AND
	  ○ Patient is not currently requiring permanent invasive ventilation*, AND
	  ○ A baseline assessment using an age-appropriate scale (the Hammersmith Infant Neurological Examination [HINE] Section 2, Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders [CHOP INTEND], or Hammersmith Functional Motor Scale-Expanded [HFMSE]) must be completed prior to initiation of nusinersen treatment.				

Criteria Updates Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Spinraza (nusinersen)	12mg/5mL Vial	02465663	DNP	E (SF)	BIG

Criteria	• For continued coverage, the patient must meet the following criteria:
	  ○ There is demonstrated achievement or maintenance of motor milestone function (as assessed using age-appropriate scales: the [HINE] Section 2), CHOP INTEND, or HFMSE) since treatment initiation in patients who were pre-symptomatic at the time of treatment initiation; OR
	  ○ There is demonstrated maintenance of motor milestone function (as assessed using age-appropriate scales: the HINE Section 2, CHOP INTEND, or HFMSE) since treatment initiation in patients who were symptomatic at the time of treatment initiation;
	  AND
	  ○ Patient does not require permanent invasive ventilation*.
	• Treatment should be discontinued if, prior to the fifth dose or every subsequent dose of nusinersen, the above renewal criteria are not met.
	Claims Notes
	• Coverage for nusinersen will not be provided in combination with other SMA drug therapies or post administration of onasemnogene abeparvovec.
	*Permanent invasive ventilation is defined as the use of tracheostomy and a ventilator due to progression of SMA that is not due to an identifiable and reversible cause.				

New Benefit

Effective **November 1, 2022,** the following product will be added as a benefit to the Nova Scotia Formulary.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
pdp-Levetiracetam	100mg/mL Sol	02490447	DNP	SF	PDP

Administration of Publicly-Funded Influenza Vaccine by Pharmacies for the 2022-2023 Influenza Season

Billing and Payment Process

With CANImmunize launching this year for influenza vaccine administration, claims submission will no longer be required. Similar to the process for COVID-19 vaccinations, 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. 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.

Administration of Publicly-Funded Influenza Vaccine by Pharmacies for the 2022-2023 Influenza Season Continued…

To ensure accurate and timely payment, all vaccines must be recorded in CANImmunize on the same day as administration. A delay in data entry may result in missed payments.

If 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.

Please note that electronic claims submission for influenza vaccines has been deactivated and the only valid method of billing will be through CANImmunize.

New: Coverage of Service Fee for Non-Residents
With the transition to the CANImmunize system, 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.

Nova Scotia Biosimilar Initiative

As a reminder, the Government of Nova Scotia is expanding the use of biosimilar medications in Nova Scotia Pharmacare programs. Starting 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. All patients who currently have funding for the originator product have also been granted funding for the biosimilar product.

This currently applies to patients on the following biologics:

Humira, Enbrel, Remicade, Rituxan, Lantus, Humalog, and NovoRapid. NovoRapid vials will remain a benefit until a biosimilar in a vial format is approved. As more biosimilar products become available, they will also be added to this policy.

Support for prescribers is available. If you are a prescriber, Pharmacare can provide you with a list of your patients who may need to switch to a biosimilar medication. To receive this list, fill out the Patient List Request form and email it to biologictherapies@novascotia.ca or fax it to 902-428-3400.

A clinical support staff member is available to help you organize, reduce administrative burden and provide education where needed. To contact the clinical support staff, email biologictherapies@novascotia.ca.

For more information you may refer to the following link: https://novascotia.ca/dhw/pharmacare/information-for-prescribers-about-biosimilars.asp

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New Exception Status Benefit

The following new product will be listed with the following criteria, effective **December 1, 2022**.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Kuvan	100mg Tablet	02350580	DNP	E (SF)	BMR
(sapropterin dihydrochloride)	100mg Sachet	02482207	DNP	E (SF)	BMR
	500mg Sachet	02482215	DNP	E (SF)	BMR
Criteria	• Ongoing funding of Kuvan will be considered for nonpregnant patients and patients actively planning pregnancy who have a diagnosis of Phenylketonuria (PKU) and who have demonstrated a response to the initial 6 month trial of sapropterin [reimbursed through the Supplier's Patient Support Program (PSP) 'BioMarin RareConnections'] **Inclusion Criteria for entry into the 6 month trial period:** • For the management of patients with the diagnosis of hyperphenylalaninemia (HPA) due to tetrahydrobiopterin (BH4)-responsive phenylketonuria (PKU) who meet ALL of the following criteria: ○ A diagnosis of Phenylketonuria (PKU) confirmed through an approved test. ○ Compliance with a low protein diet and formulas. ○ Baseline blood phenylalanine (Phe) levels > 360 µmol/L despite compliance with a low protein diet (require at least 2 baseline levels during a 3 to 6 month time frame). ○ Baseline protein intake assessment by a dietitian.				

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Kuvan	100mg Tablet	02350580	DNP	E (SF)	BMR
(sapropterin dihydrochloride)	100mg Sachet	02482207	DNP	E (SF)	BMR
	500mg Sachet	02482215	DNP	E (SF)	BMR

Criteria

- Ability to comply with medication regimen.
- Managed by a physician specialized in metabolic/biochemical diseases.

- Modified Criteria for Pregnant Patients during the 6 month trial period:
  - Patient has a diagnosis of PKU confirmed through an approved test
  - Patient's treatment is being managed by a prescriber specialized in metabolic/biochemical diseases; and
  - Patient's baseline blood Phe level is greater than 360 µmol/L despite compliance with all recommendations for dietary intervention and monitoring or compliance with a low protein diet.
- Patients will be eligible for funding through the Nova Scotia Pharmacare Programs after demonstrating a response to the 6 month trial period, as per the trial criteria.

Initial Criteria Post 6 Month Trial:

- For the management of patients with the diagnosis of hyperphenylalaninemia (HPA) due to tetrahydrobiopterin (BH4)-responsive phenylketonuria (PKU) who meet ALL of the following criteria:
  - Compliance with low protein diet, formulas, and Kuvan; AND
  - During the 6 month trial period under the patient support program BioMarin RareConnections, patient has achieved a demonstrated response to the Kuvan responsiveness test or PKU clinical protocol, based on the following information:
    - the clinic's definition for response; and
    - all relevant laboratory results used to determine that the Patient was a responder to Kuvan
  - Patient meets one of the following:
    - normal sustained Blood Phe levels [> 120 µmol/L and < 360 µmol/L] (At least 2 levels measured at least 1 month apart); OR
    - sustained blood Phe reduction of at least 30% (At least 2 levels measured at least 1 month apart) compared to baseline if the Phe baseline level is < 1200 µmol/L; OR
    - sustained blood Phe reduction of at least 50% (At least 2 levels measured at least 1 month apart) compared to baseline if the Phe baseline level is > 1200 µmol/L;
  - Demonstrated an increase in dietary protein tolerance based on targets set between the clinician and patient
  - Managed by a prescriber specialized in metabolic/ biochemical diseases.
- Dosage: Up to a maximum of 20 mg/kg per day
- Approval Duration: 1 year

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Kuvan	100mg Tablet	02350580	DNP	E (SF)	BMR
(sapropterin dihydrochloride)	100mg Sachet	02482207	DNP	E (SF)	BMR
	500mg Sachet	02482215	DNP	E (SF)	BMR
Criteria	**Renewal Criteria:** • Renewals will be considered for patients who demonstrate ongoing response to treatment. • Renewal Approval Duration: 1 year				

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 **Administration of Publicly Funded Influenza Vaccinations Provided by a Pharmacy**, updated eligibility criteria and billing and payment process to reflect implementation of CANImmunize Clinic Flow. Reference to the *Publicly Funded Seasonal Inactivated Influenza Vaccine Information for Health Care Providers 2022-23* document added for eligibility criteria and addition of reference to delegation of the technical aspect of administration as had appeared in prior versions of the Guide.
- Additional eligible DIN added under **Dispensing of oral anti-viral medications for COVID-19.**
- Under **Prescription Adaptations**, what is not insured was made more concise.

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New Exception Status Benefits

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

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Braftovi (encorafenib)	75mg Cap	02513099	DNP	E (SFC)	PFI

Criteria

Metastatic Melanoma

In combination with binimetinib for the treatment of patients with BRAF V600 mutation-positive unresectable or metastatic melanoma.

Clinical Notes:
- Patients should have a good performance status.
- If brain metastases are present, patients should be asymptomatic or have stable symptoms.
- Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Notes:
- Encorafenib in combination with binimetinib will not be reimbursed in patients who have progressed on BRAF targeted therapy.
- Requests will be considered for patients who received adjuvant BRAF targeted therapy if disease progression occurred at least 6 months following completion of therapy.

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Braftovi (encorafenib)	75mg Cap	02513099	DNP	E (SFC)	PFI
Criteria	**Metastatic Colorectal Cancer** In combination with panitumumab or cetuximab for the treatment of patients with metastatic colorectal cancer who meet all of the following criteria: • Presence of BRAF V600E mutation • Disease progression following at least one prior therapy in the metastatic setting • No previous treatment with an EGFR inhibitor **Clinical Notes:** • Patients should have a good performance status. • Treatment should be discontinued upon disease progression or unacceptable toxicity. **Claim Notes:** • Encorafenib will not be reimbursed in patients who have progressed on BRAF targeted therapy.				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Inqovi (decitabine and cedazuridine)	35mg/100mg Tab	02501600	DNP	E (SFC)	TAI
Criteria	**Myelodysplastic Syndrome** For the treatment of patients with myelodysplastic syndromes (MDS), including previously treated and untreated, who meet all of the following criteria: • De novo or secondary MDS including all French-American-British subtypes (i.e., refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, refractory anemia with excess blasts in transformation, and chronic myelomonocytic leukemia) • Intermediate-1, intermediate-2, or high-risk MDS, according to the International Prognostic Scoring System • Have not experienced disease progression on a hypomethylating agent **Clinical Notes:** • Patients should have a good performance status. • Treatment should be discontinued upon disease progression or unacceptable toxicity.				

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Mektovi (binimetinib)	15mg Cap	02513080	DNP	E (SFC)	PFI
Criteria	**Metastatic Melanoma** In combination with encorafenib for the treatment of patients with BRAF V600 mutation-positive unresectable or metastatic melanoma. **Clinical Notes:** • Patients should have a good performance status. • If brain metastases are present, patients should be asymptomatic or have stable symptoms. • Treatment should be discontinued upon disease progression or unacceptable toxicity. **Claim Notes:** • Binimetinib will not be reimbursed in patients who have progressed on BRAF targeted therapy. • Requests will be considered for patients who received adjuvant BRAF targeted therapy if disease progression occurred at least 6 months following completion of therapy.				

Criteria Update

The criteria for the following will be updated effective **January 1, 2023.**

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Stieva-A	Various	Various	DNP	FE*	GSK
Retin-A	Various	Various	DNP	FE*	BSL
Vitamin A Acid	0.05% Gel	01926489	DNP	FE*	BSL
Criteria	• Regular benefit for beneficiaries 30 years and under • For treatment of acne vulgaris in beneficiaries over the age of 30				