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Nova Scotia Formulary Updates

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	<ul style="list-style-type: none"> For use in combination with filgrastim to mobilize hematopoietic stem cells for subsequent autologous transplantation in patients who meet one of the following criteria: <ul style="list-style-type: none"> PBCD34+ count of less than 10 cells/uL after 4 days of filgrastim, or 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 Failed a previous attempt for stem cell mobilization with filgrastim alone or following chemotherapy. <p>Claim Note:</p> <ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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. <p>Clinical Notes:</p> <ol style="list-style-type: none"> Patients should have a good performance status and no risk factors for seizures. Treatment should continue until unacceptable toxicity or disease progression. <p>Claim Notes:</p> <ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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. <p>Clinical Notes:</p> <ol style="list-style-type: none"> Patients should have a good performance status and no risk factors for seizures. Treatment should continue until unacceptable toxicity or disease progression. <p>Claim Notes:</p> <ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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 <p>Clinical Notes:</p> <ol style="list-style-type: none"> Patients should have a good performance status. Treatment should be discontinued upon disease progression or unacceptable toxicity. <p>Claim Notes:</p> <ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> • For patients with severe, debilitating chronic plaque psoriasis who meet all of the following: <ul style="list-style-type: none"> ○ 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: <ul style="list-style-type: none"> ○ 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. <p>Clinical Note:</p> <ul style="list-style-type: none"> • 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.

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.

This change will affect Nova Scotia Pharmacare program beneficiaries and does not impact those who, for example, are using their private insurance.

Any exceptions to this policy will require an Exception Status Drug (ESD) Request Form.

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.

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.

We have clinical staff who are working on this initiative who can help with education, discussion on specific patients, and making connections with patient support programs. Should we be able to support you in any way in the management of your patients, please reach out to us at biologictherapies@novascotia.ca

We encourage you to transition patients as early as possible to ensure you have additional support, your patients do not have breaks in coverage, and so that public funds can be used in the most cost-effective way possible.

While most of these medications would be prescribed by specialists, family physicians should note that insulins are also included in this policy and patients will require a transition from an originator to a biosimilar version of these insulins.

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: [Information for Prescribers about the Nova Scotia Biosimilar Initiative | novascotia.ca](http://novascotia.ca/biologictherapies) or contact us by email at biologictherapies@novascotia.ca

Legend

PRESCRIBER CODES	BENEFIT STATUS	MANUFACTURER CODES
D - Physician / Dentist	S - Seniors' Pharmacare	ASL - Astellas Pharma Canada Inc.
N - Nurse Practitioner	F - Community Services Pharmacare	JAN - Janssen-Ortho Inc.
P - Pharmacist	- Family Pharmacare	PFI - Pfizer Canada Inc.
M - Midwife	C - Drug Assistance for Cancer Patients	SAV - Sanofi-Aventis Canada Inc.
O - Optometrist	D - Diabetes Assistance Program	SDZ - Sandoz Canada Incorporated
	E - Exception status applies	TEV - Teva Canada Ltd.
		VAR - <i>various manufacturers</i>

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Nova Scotia Formulary Updates

New Exception Status Benefits

- Ajovy (fremanezumab)
- Monoferric (ferric derisomaltose)
- Opsumit (macitentan)
- Riabni (rituximab)

Criteria Updates

- Androgel and generic brands (testosterone)
- Testim (testosterone)
- Zofran and generic brands (ondansetron)
- Cosentyx (secukinumab)

Change in Benefit Status

- Sublocade (buprenorphine)

New Products

- JAMP-Hydrocortisone
- Mirtazapine

Non-Insured Products

- Envarsus PA ER

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 episodic¹ or chronic migraine², 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: <ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> For the treatment of iron deficiency anemia in patients who: <ul style="list-style-type: none"> are intolerant to oral iron replacement products, OR have not responded to an adequate trial of oral iron Notes: <ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> The diagnosis of PAH should be confirmed by right heart catheterization. Claim Notes: <ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	Various	DNP	E (SFC)	VAR
	5g/pkt Top Gel	Various	DNP	E (SFC)	VAR
Testim (testosterone)	1% Top Gel Tube	02280248	DNP	E (SFC)	PAL
Criteria	<ul style="list-style-type: none"> For use in gender affirming hormone therapy. <p>Claim Note:</p> <ul style="list-style-type: none"> Maximum dose approved is 5g gel per day. 				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Zofran and generic brands (ondansetron)	4mg/5mL O/L	Various	DNP	E (SFC)	VAR
	4mg Tab	Various	DNP	E (SFC)	VAR
	4mg OD Tab/Film	Various	DNP	E (SFC)	VAR
	8mg Tab	Various	DNP	E (SFC)	VAR
	8mg OD Tab/Film	Various	DNP	E (SFC)	VAR
Criteria	<ul style="list-style-type: none"> 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	<p>Ankylosing Spondylitis</p> <ul style="list-style-type: none"> • For the treatment of patients with moderate to severe ankylosing spondylitis (e.g., Bath AS Disease Activity Index (BASDAI) score \geq 4 on 10 point scale) who: <ul style="list-style-type: none"> ○ 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: <ul style="list-style-type: none"> ○ A decrease of at least 2 points on the BASDAI scale, compared with the pre-treatment score, or ○ Patient and expert opinion of an adequate clinical response as indicated by a significant functional improvement (measured by outcomes such as HAQ or "ability to return to work"). <p>Clinical Note:</p> <ul style="list-style-type: none"> • 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. <p>Claim Notes:</p> <ul style="list-style-type: none"> • Must be prescribed by a rheumatologist or prescriber with a specialty in rheumatology. • Combined use 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

Legend

PRESCRIBER CODES	BENEFIT STATUS	MANUFACTURER CODES
D - Physician / Dentist	S - Seniors' Pharmacare	AGA - Amgen Canada Inc.
N - Nurse Practitioner	F - Community Services Pharmacare	ICL - Indivior Canada Limited
P - Pharmacist	- Family Pharmacare	JAN - Janssen-Ortho Inc.
M - Midwife	C - Drug Assistance for Cancer Patients	JPC - Jamp Pharma Corporation
O - Optometrist	D - Diabetes Assistance Program	NVR - Novartis Pharmaceuticals Canada Inc.
	E - Exception status applies	PAL - Paladin Labs Inc.
		PFI - Pfizer Canada Inc.
		SIV - Sivem Pharmaceuticals
		TEV - Teva Canada Ltd.
		VAR - <i>various manufacturer</i>

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Nova Scotia Formulary Updates

New Exception Status Benefits

- Zejula (niraparib)
- Adlyxine (lixisenatide)
- Entyvio (vedolizumab)

Criteria Updates

- Entyvio (vedolizumab)
- Lenvima (lenvatinib)
- Nexavar (sorafenib)

New Benefits

- Ceftazidime

New Diabetic Products

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
Zejula (niraparib)	100mg Cap	02489783	DNP	E (SFC)	GSK
Criteria	<p>Newly Diagnosed Advanced Epithelial Ovarian, Fallopian Tube or Primary Peritoneal Cancer</p> <ul style="list-style-type: none"> • 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. <p>Clinical Notes:</p> <ul style="list-style-type: none"> • 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	<p>Relapsed, Platinum Sensitive Advanced Epithelial Ovarian, Fallopian tube or Primary Peritoneal Cancer</p> <ul style="list-style-type: none"> 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. <p>Clinical Notes:</p> <ul style="list-style-type: none"> 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	02464276	DNP	E (SF)	SAV
	0.1mg/mL Prefilled Pen	02464284	DNP	E (SF)	SAV
Criteria	<ul style="list-style-type: none"> For the treatment of type 2 diabetes mellitus when added to: <ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> See <i>Criteria Updates</i> 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	<p>Crohn's Disease</p> <ul style="list-style-type: none"> For patients with moderate to severely active Crohn's disease and are: <ul style="list-style-type: none"> refractory or have contraindications to an adequate course of 5-aminosalicylic acid and corticosteroids and other immunosuppressive therapy. <p>Clinical Notes:</p> <ul style="list-style-type: none"> Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above. <p>Claim Notes:</p> <ul style="list-style-type: none"> Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology. Combined use of more than one biologic DMARD will not be reimbursed. 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 (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	<p>Ulcerative Colitis</p> <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> refractory or intolerant to conventional therapy (i.e. 5-ASA for a minimum of 4 weeks, and prednisone ≥ 40mg daily for two weeks or IV equivalent for one week); or corticosteroid dependent (i.e. cannot be tapered from corticosteroids without disease recurrence; or have relapsed within three months of stopping corticosteroids; or require two or more courses of corticosteroids within one year.) Renewal requests must include information demonstrating the beneficial effects of the treatment, specifically: <ul style="list-style-type: none"> a decrease in the partial Mayo score ≥ 2 from baseline, and a decrease in the rectal bleeding subscore ≥1. <p>Clinical Notes:</p> <ul style="list-style-type: none"> Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above. Intolerant is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs. The nature of intolerance(s) must be clearly documented. Patients with severe disease do not require a trial of 5-ASA. <p>Claim Notes:</p> <ul style="list-style-type: none"> Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology. Combined use 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	02484056	DNP	E (SFC)	EIS
	8mg Cap	02468220	DNP	E (SFC)	EIS
	12mg Cap	02484129	DNP	E (SFC)	EIS
Criteria	<ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> 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 <p>Clinical Notes:</p> <ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> 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) <p>Clinical Note:</p> <ul style="list-style-type: none"> 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

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
Tyless Blood Glucose Test Strips (50)	97799338	DNP	SFD	TKS
Tyless Blood Glucose Test Strips (100)	97799341	DNP	SFD	TKS

Legend

PRESCRIBER CODES	BENEFIT STATUS	MANUFACTURER CODES
D - Physician / Dentist	S - Seniors' Pharmacare	BAY - Bayer Inc.
N - Nurse Practitioner	F - Community Services Pharmacare	EIS - Eisai Limited
P - Pharmacist	- Family Pharmacare	GSK - GlaxoSmithKline Inc.
M - Midwife	C - Drug Assistance for Cancer Patients	SAV - Sanofi-Aventis Canada Inc.
O - Optometrist	D - Diabetes Assistance Program	STR - SteriMax Inc.
	E - Exception status applies	TAK - Takeda Canada Inc.
		TKS - Tykess Pharmaceuticals

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Nova Scotia Formulary Updates

New Exception Status Benefits

- Abrilada (adalimumab)
- Simlandi (adalimumab)
- Duobrii (halobetasol propionate and tazarotene)

Criteria Update

- Ofev (nintedanib)

Budesonide for Patients with Non-severe COVID-19 Respiratory Symptoms

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
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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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 (nintedanib)	100mg Capsule	02443066	DNP	E (SF)	BOE
	150mg Capsule	02443074	DNP	E (SF)	BOE
Criteria	<p>Chronic Fibrosing Interstitial Lung Disease</p> <p>Initiation criteria</p> <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> the patient has a forced vital capacity greater than or equal to 45% of predicted. <p>Renewal criteria</p> <ul style="list-style-type: none"> 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. <p>Clinical Notes:</p> <ul style="list-style-type: none"> The patient's clinical status should be evaluated every 12 months. <p>Claim Notes:</p> <ul style="list-style-type: none"> 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 				

Budesonide for Patients with Non-severe COVID-19 Respiratory Symptoms

As per the [NS Health COVID-19 medication recommendations](#), the use of inhaled budesonide (800 mg BID) can be assessed on a case-by-case basis for individuals with mild respiratory symptoms of COVID-19 (do not require: new or additional supplemental oxygen, intravenous fluids, or physiological support) within 14 days of symptom onset. The full [prescribing protocol](#) can be accessed online through the links provided herein.

Pulmicort Turbuhaler is available as a full benefit for beneficiaries of the Nova Scotia Pharmacare Programs. In addition, pharmacists are able to assess and prescribe this therapy for COVID-19 patients, as per the Nova Scotia College of Pharmacists' *Standards of Practice: Prescribing Drugs* (Appendix G – Prescribing for a Diagnosis Supported by a Protocol, SARS-CoV-2).

Resources:

NS Health COVID-19 medication recommendations:

http://policy.nshealth.ca/Site_Published/covid19/document_render.aspx?documentRender.IdType=6&documentRender.GenericField=&documentRender.Id=85287

Prescribing protocol:

https://pans.ns.ca/sites/default/files/inhaled_budesonide_prescribing_protocol_package_document-may_2_fillable.pdf

Legend

PRESCRIBER CODES	BENEFIT STATUS	MANUFACTURER CODES
D - Physician / Dentist	S - Seniors' Pharmacare	BOE - Boehringer Ingelheim (Canada) Ltd.
N - Nurse Practitioner	F - Community Services Pharmacare	BSL - Bausch Health, Canada Inc.
P - Pharmacist	- Family Pharmacare	JPC - Jamp Pharma Corporation
M - Midwife	C - Drug Assistance for Cancer Patients	PFI - Pfizer Canada Inc.
O - Optometrist	D - Diabetes Assistance Program	
	E - Exception status applies	

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Nova Scotia Formulary Updates

New Exception Status Benefits

- Crysvida (burosumab)
- Entuzity (human insulin R)
- Calquence (acalabrutinib)
- Mayzent (siponimod)
- Tegsedi (inotersen)
- Baqsimi (glucagon)

Criteria Updates

- Forxiga (dapagliflozin)
- Rituximab Biosimilars
- Venclexta (venetoclax)

New Diabetic Product

Non-Insured Products

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

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
Crysvida (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	<ul style="list-style-type: none"> ○ 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: <ul style="list-style-type: none"> ○ 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: <ul style="list-style-type: none"> ○ Hyperparathyroidism; or ○ Nephrocalcinosis; or ○ Evidence of fracture or pseudo-fracture based on radiographic assessment. <p>Claim Notes:</p> <ul style="list-style-type: none"> ● 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. 				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Entuzity (human insulin R)	500 U/mL KwikPen	02466864	DNP	E (SFD)	LIL
Criteria	<ul style="list-style-type: none"> ● 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. <p>Claims Notes:</p> <ul style="list-style-type: none"> ● Treatment must be initiated by an endocrinologist or prescriber with a specialty in endocrinology. 				

New Exception Status Benefits Continued...

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Calquence (acalabrutinib)	100mg Cap	02491788	DNP	E (SFC)	AZE
Criteria	<p>Previously Untreated Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL)</p> <ul style="list-style-type: none"> 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. <p>Clinical Notes:</p> <ul style="list-style-type: none"> 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. <p>Claim Notes:</p> <ul style="list-style-type: none"> 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. <p>Relapsed/ Refractory Chronic Lymphocytic Leukemia (CLL)/ Small Lymphocytic Lymphoma (SLL)</p> <ul style="list-style-type: none"> 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. <p>Clinical Notes:</p> <ul style="list-style-type: none"> Patients should have a good performance status. Treatment should be continued until disease progression or unacceptable toxicity. <p>Claim Notes:</p> <ul style="list-style-type: none"> 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	<p>Secondary Progressive Multiple Sclerosis</p> <p>Initiation Criteria:</p> <ul style="list-style-type: none"> • For the treatment of patients with active secondary progressive multiple sclerosis, who meet all the following criteria: <ul style="list-style-type: none"> ○ a history of relapsing-remitting multiple sclerosis (RRMS) ○ an Expanded Disability Status Scale (EDSS) score of 3.0 to 6.5 ○ 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). <p>Renewal Criteria:</p> <ul style="list-style-type: none"> • Patients who do NOT exhibit evidence of disease progression since the previous assessment. Disease progression is defined as: <ul style="list-style-type: none"> ○ 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 <li style="text-align: center;">OR ○ 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: <ul style="list-style-type: none"> ○ progression to an EDSS score of equal to or greater than 7.0 at any time during siponimod treatment ○ confirmed worsening of at least 20% on the timed 25-foot walk (T25W) since initiating siponimod treatment <p>Clinical Notes:</p> <ul style="list-style-type: none"> • Patients should be assessed for a response to siponimod every six months. <p>Claims Notes:</p> <ul style="list-style-type: none"> • 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	<p>Polyneuropathy in Hereditary Transthyretin-Mediated Amyloidosis</p> <ul style="list-style-type: none"> For the treatment of polyneuropathy in adult patients with hereditary transthyretin-mediated amyloidosis (hATTR) who meet all of the following criteria: <ul style="list-style-type: none"> 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 <p>Discontinuation Criteria:</p> <ul style="list-style-type: none"> The patient is permanently bedridden and dependent on assistance for basic activities of daily living OR The patient is receiving end-of-life care. <p>Clinical Note:</p> <ul style="list-style-type: none"> Symptomatic early-stage neuropathy is defined as polyneuropathy disability stage I to IIIB or familial amyloidotic polyneuropathy stage I or II. <p>Claims Note:</p> <ul style="list-style-type: none"> 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. 				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Baqsimi (glucagon)	3mg Nasal Powder	02492415	DNP	E (SFD)	LIL
Criteria	<ul style="list-style-type: none"> 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. <p>Claim Notes:</p> <ul style="list-style-type: none"> Approval duration: long term. Quantity limit: up to two devices per year. The prescriber or pharmacist can request additional devices if clinically required. 				

Criteria Updates

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

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Forxiga (dapagliflozin)	5mg Tab	02435462	DNP	E (SF)	AZE
	10mg Tab	02435470	DNP	E (SF)	AZE
Criteria	<p>Heart Failure with Reduced Ejection Fraction</p> <ul style="list-style-type: none"> 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 \leq 40%) as an adjunct to standard of care therapies. <p>Clinical note:</p> <ul style="list-style-type: none"> Standard of care therapies include beta-blockers, angiotensin converting enzyme inhibitors (ACEIs) or angiotensin receptor blockers (ARBs), plus a mineralocorticoid receptor antagonist. 				

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	<p>For rituximab-naïve patients whose rituximab therapy is initiated after November 1, 2020, a rituximab biosimilar will be the product approved.</p> <ul style="list-style-type: none"> For the treatment of rheumatoid arthritis¹, vasculitis², or other autoimmune diseases³. <p>Clinical Notes:</p> <ol style="list-style-type: none"> Severe intolerance or other contraindication to an anti-TNF agent or failed an adequate trial of an anti-TNF agent. Severe intolerance or other contraindication to cyclophosphamide or failed an adequate trial of cyclophosphamide. Previously failed treatments must be provided if applicable. <p>Claims Notes:</p> <ul style="list-style-type: none"> Must be prescribed by a specialist. Approval period: long term 				

*Form for rituximab biosimilars available at <https://novascotia.ca/dhw/pharmacare/documents/forms/Rituximab-Request-for-Coverage.pdf>

Criteria Updates Continued...

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	<p>Venetoclax with obinutuzumab for previously untreated chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL)</p> <ul style="list-style-type: none"> 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. <p>Clinical Notes:</p> <ul style="list-style-type: none"> 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. <p>Venetoclax with Azacitidine for newly diagnosed acute myeloid leukemia (AML)</p> <ul style="list-style-type: none"> 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. <p>Clinical Notes:</p> <ul style="list-style-type: none"> 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. <p>Claim Notes:</p> <ul style="list-style-type: none"> 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. <p>Venetoclax monotherapy for chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) in patients who have received at least one prior therapy</p> <ul style="list-style-type: none"> 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 				

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	<p>who have failed a B-cell receptor inhibitor (BCRi). Treatment should be continued until disease progression or unacceptable toxicity.</p> <p>Clinical Notes:</p> <ul style="list-style-type: none"> 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. <p>Venetoclax with rituximab for chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) in patients who have received at least one prior therapy</p> <ul style="list-style-type: none"> 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. <p>Clinical Notes:</p> <ul style="list-style-type: none"> 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

Legend

PRESCRIBER CODES	BENEFIT STATUS	MANUFACTURER CODES
D - Physician / Dentist	S - Seniors' Pharmacare	ABV - AbbVie Corporation
N - Nurse Practitioner	F - Community Services Pharmacare	AKT - Akcea Therapeutics, Inc.
P - Pharmacist	- Family Pharmacare	AZE - AstraZeneca Canada Inc.
M - Midwife	C - Drug Assistance for Cancer Patients	BTD - Becton Dickinson Canada
O - Optometrist	D - Diabetes Assistance Program	LIL - Eli Lilly Canada Inc.
	E - Exception status applies	NVR - Novartis Pharmaceuticals Canada Inc.
		UGX - Ultragenyx Pharmaceutical Inc.
		VAR - various manufacturers
		VIV - ViiV Health Care Inc.

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Nova Scotia Formulary Updates

New Exception Status Benefits

- Alunbrig (brigatinib)
- Yuflyma (adalimumab)
- Ilumya (tildrakizumab)
- Verkazia (cyclosporine)

New Benefits

- Skyrizi (risankizumab)

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
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 <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • 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. 				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Yuflyma (adalimumab)	40mg/0.4mL Prefilled Pen	02523779	DNP	E (SF)	CTL
Criteria	<ul style="list-style-type: none"> • 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
Ilumya (tildrakizumab)	100 mg/mL Prefilled Syringe	02516098	DNP	E (SF)	SUN
Criteria	<ul style="list-style-type: none"> For patients with severe, debilitating chronic plaque psoriasis who meet all of the following: <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> 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. <p>Clinical Note:</p> <ul style="list-style-type: none"> Treatment should be discontinued if a response has not been demonstrated after 16 weeks. <p>Claim Notes:</p> <ul style="list-style-type: none"> 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
Verkazia (cyclosporine)	0.1% Ophthalmic Emulsion	02484137	DNP	E (F)	SNN
Criteria	<ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> Grade 3 (severe) or 4 (very severe) on the Bonini scale, or Grade 4 (marked) or 5 (severe) on the modified Oxford scale. <p>Discontinuation Criteria:</p> <ul style="list-style-type: none"> Treatment should be discontinued if no improvement in signs and symptoms of VKC is observed, or 				

New Exception Status Benefits Continued...

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Verkazia (cyclosporine)	0.1% Ophthalmic Emulsion	02484137	DNP	E (F)	SNN
Criteria	<ul style="list-style-type: none"> Treatment should be discontinued if signs and symptoms of VKC have resolved. <p>Clinical Notes:</p> <ul style="list-style-type: none"> 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 reinstate treatment if signs and symptoms of severe VKC recur and they meet the initiation criteria. <p>Claim Notes:</p> <ul style="list-style-type: none"> 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

Legend

PRESCRIBER CODES	BENEFIT STATUS	MANUFACTURER CODES
D - Physician / Dentist	S - Seniors' Pharmacare	ABV - AbbVie Corporation
N - Nurse Practitioner	F - Community Services Pharmacare	CTL - Celltrion Healthcare Canada Ltd.
P - Pharmacist	- Family Pharmacare	SNN - Santen Canada Inc.
M - Midwife	C - Drug Assistance for Cancer Patients	SUN - Sun Pharma Inc.
O - Optometrist	D - Diabetes Assistance Program	TAK - Takeda Canada Inc.
	E - Exception status applies	

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- Lynparza (olaparib)
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- Donepezil
- Galantamine
- Lacosamide
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Cystic Fibrosis Therapies Update

New Diabetic Products

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	<p>Clinical Notes:</p> <ol style="list-style-type: none"> 1. Wild-type ATTR-cardiomyopathy (CM) consists of all of the following: <ol style="list-style-type: none"> 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: <ol style="list-style-type: none"> 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) <p>Claim Notes:</p> <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> ○ 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	<p>Relapsing Remitting Multiple Sclerosis (RRMS)</p> <ul style="list-style-type: none"> For the treatment of adult patients with relapsing remitting multiple sclerosis (RRMS) who meet all of the following criteria: <ul style="list-style-type: none"> An Expanded Disability Status Scale (EDSS) score of less than 6.0 Evidence of active disease defined as at least one of the following: <ul style="list-style-type: none"> 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. <p>Renewal Criteria:</p> <ul style="list-style-type: none"> 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. <p>Claims Notes:</p> <ul style="list-style-type: none"> 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	<p>Wilson's Disease</p> <ul style="list-style-type: none"> For the treatment of Wilson's disease in patients who have experienced intolerance or have a contraindication to d-penicillamine. <p>Clinical Notes:</p> <ul style="list-style-type: none"> 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	<p>Claims Notes:</p> <ul style="list-style-type: none"> 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. <p>Approval: 12 months</p>				

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	<ul style="list-style-type: none"> For persons with a singleton gestation who are: <ul style="list-style-type: none"> greater than 20 weeks gestation <p>AND</p> 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	<ul style="list-style-type: none"> In combination with ASA for patients with: <ul style="list-style-type: none"> 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. <p>Clinical Note:</p> <ul style="list-style-type: none"> 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. <p>Claim Note:</p> <ul style="list-style-type: none"> 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 (olaparib)	100mg Tab	02475200	DNP	E (SFC)	AZE
	150mg Tab	02475219	DNP	E (SFC)	AZE
Criteria	<p>Metastatic Castrate-Resistant Prostate Cancer</p> <ul style="list-style-type: none"> 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. <p>Clinical Note:</p> <ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> For patients who require budesonide for sinonasal irrigation when it is prescribed by, or in consultation with, a specialist (e.g., ENT, allergists, immunologists). <p>Claim Notes:</p> <ul style="list-style-type: none"> 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	<p>Polyarticular Juvenile Idiopathic Arthritis (pJIA)</p> <ul style="list-style-type: none"> 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). <p>Notes:</p> <ul style="list-style-type: none"> 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. <p>Systemic Juvenile Idiopathic Arthritis (sJIA)</p> <ul style="list-style-type: none"> 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. <p>Notes:</p> <ul style="list-style-type: none"> 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 <p>Renewal Approval: 1 year. Confirmation of continued response is required.</p>				

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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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 \(pfizer.ca\)](https://www.pfizer.ca/healthcare-professionals/dh-cpl-cortef-06jun2022-en.docx)

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

Legend

PRESCRIBER CODES	BENEFIT STATUS	MANUFACTURER CODES
D - Physician / Dentist	S - Seniors' Pharmacare	AZE - AstraZeneca Canada Inc.
N - Nurse Practitioner	F - Community Services Pharmacare	HLR - Hoffmann-LaRoche Limited
P - Pharmacist	- Family Pharmacare	JPC - Jamp Pharma Corporation
M - Midwife	C - Drug Assistance for Cancer Patients	MAR - Marcan Pharmaceuticals Inc
O - Optometrist	D - Diabetes Assistance Program	MSR - Medisure Canada
	E - Exception status applies	MYL - Mylan Pharmaceuticals ULC.
		NVR - Novartis Pharmaceuticals Canada Inc.
		PFI - Pfizer Canada Inc.
		VAR - Various manufacturers
		VTX - Vertex Pharmaceuticals

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Nova Scotia Formulary Updates

Non-Insured Product

- Zolgensma (onasemnogene abeparvovec)

New Exception Status Benefit

- Evrysdi (risdiplam)

Criteria Updates

- Benzydamine
- Akynzeo (netupitant /palonosetron)
- Emend (aprepitant)

Change in Benefit Status

- Rexulti (brexpiprazole)

New Benefit

- Xolair

Nova Scotia Formulary Updates

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
Evryydi (risdiplam)	0.75mg/mL Pws for Sol	02514931	DNP	E (F)	HLR
Criteria	<ul style="list-style-type: none"> ○ 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: <ul style="list-style-type: none"> ○ 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*. <p>The decision to discontinue reimbursement should be based on 2 assessments separated by no longer than a 12-week interval.</p> <p>Claim Notes:</p> <ul style="list-style-type: none"> • Coverage for risdiplam will not be provided in combination with other SMA drug therapies or post administration of onasemnogene abeparvovec. • Approval: 12 months <p>* 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.</p>				

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	<ul style="list-style-type: none"> For oncology patients only. [Criteria Code 01] 				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Akynzeo (netupitant/palonosetron)	300mg/0.5mg Capsule	02468735	DNP	E (SFC)	ELV
Criteria	<ul style="list-style-type: none"> In combination with dexamethasone for the prevention of acute and delayed nausea and vomiting in patients receiving: <ul style="list-style-type: none"> 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] <p>Clinical Notes:</p> <ul style="list-style-type: none"> 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 $\geq 1500\text{mg/m}^2$. 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	<ul style="list-style-type: none"> In combination with a 5-HT3 antiemetic and dexamethasone for the prevention of acute and delayed nausea and vomiting in patients receiving: <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> 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 $\geq 1500\text{mg/m}^2$. 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

Legend

PRESCRIBER CODES	BENEFIT STATUS	MANUFACTURER CODES
D - Physician / Dentist	S - Seniors' Pharmacare	ELV - Elvium Life Sciences
N - Nurse Practitioner	F - Community Services Pharmacare	FRS - Merck Canada Ltd.
P - Pharmacist	- Family Pharmacare	HLR - Hoffmann-LaRoche Limited
M - Midwife	C - Drug Assistance for Cancer Patients	NVR - Novartis Pharmaceuticals Canada Inc.
O - Optometrist	D - Diabetes Assistance Program	OTS - Otsuka Canada Pharmaceuticals
	E - Exception status applies	VAR - various manufacturers

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Nova Scotia Formulary Updates

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 biologitherapies@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 biologitherapies@novascotia.ca.

For more information you may refer to the following link:

<https://novascotia.ca/dhw/pharmacare/information-for-prescribers-about-biosimilars.asp>

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	<ul style="list-style-type: none"> 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. <p>Clinical Notes</p> <ul style="list-style-type: none"> Patients should have a good performance status. Treatment should be discontinued upon disease progression or unacceptable toxicity. 				

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	<ul style="list-style-type: none"> For the acute, intermittent treatment of “OFF” episodes in patients with Parkinson’s Disease (PD) who meet the following criteria: <ul style="list-style-type: none"> 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). <p>Clinical Notes</p> <ul style="list-style-type: none"> 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. <p>Claims Notes</p> <ul style="list-style-type: none"> 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 				

New Exception Status Benefits Continued...

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Waymade-Trientine (trientine hydrochloride)	250mg Cap	02515067	DNP	E (SF)	WMD
Criteria	<p>Wilson's disease</p> <ul style="list-style-type: none"> For the treatment of Wilson's disease in patients who have experienced intolerance or have a contraindication to d-penicillamine. <p>Clinical Notes</p> <ul style="list-style-type: none"> Intolerance is defined as demonstrating serious adverse effects to treatments. The nature of intolerance(s) must be clearly documented. <p>Claims Notes</p> <ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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). <p>Clinical Notes</p> <ul style="list-style-type: none"> 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. 				

New Exception Status Benefits Continued...

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Hulio (adalimumab)	20mg/0.4mL Prefilled Syringe	02502380	DNP	E (SF)	BGP
Criteria	<ul style="list-style-type: none"> Please refer to the Pharmacare Formulary (https://novascotia.ca/dhw/pharmacare/formulary.asp) for the adalimumab criteria. 				

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	<ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> 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) <p>Discontinuation Criteria</p> <ul style="list-style-type: none"> The patient has: <ul style="list-style-type: none"> NYHA class IV heart failure, or received an implanted CMAD, or received a heart or liver transplant. <p>Clinical Notes</p> <ol style="list-style-type: none"> Wild-type ATTR-cardiomyopathy (CM) consists of all of the following: <ol style="list-style-type: none"> absence of a variant transthyretin (TTR) genotype TTR precursor protein identification by immunohistochemistry, scintigraphy, or mass spectrometer evidence of cardiac involvement by echocardiography with end-diastolic interventricular septal wall thickness greater than 12 mm presence of amyloid deposits in biopsy tissue (fat aspirate, salivary gland, median nerve connection tissue sheath, or cardiac tissue) or positive findings on 				

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	<p>technetium-99m pyrophosphate (Tc-99m-PYP) scintigraphy with single-photon emission computed tomography (SPECT) scanning</p> <p>2. Hereditary ATTR-CM consists of all of the following:</p> <ol style="list-style-type: none"> presence of a variant TTR genotype associated with CM and presenting with a CM phenotype evidence of cardiac involvement by echocardiography with end-diastolic interventricular septal wall thickness greater than 12 mm 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 <p>Claim Notes</p> <ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> Genetic documentation of 5q SMA homozygous gene deletion, homozygous mutation, or compound heterozygote, AND Patients who: <ul style="list-style-type: none"> 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 				

Criteria Updates Continued...

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Spinraza (nusinersen)	12mg/5mL Vial	02465663	DNP	E (SF)	BIG
Criteria	<ul style="list-style-type: none"> ▪ are under the age of 18 with symptom onset after six months of age, AND <ul style="list-style-type: none"> ○ 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. • For continued coverage, the patient must meet the following criteria: <ul style="list-style-type: none"> ○ 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. <p>Claims Notes</p> <ul style="list-style-type: none"> • Coverage for nusinersen will not be provided in combination with other SMA drug therapies or post administration of onasemnogene abeparvovec. <p>*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.</p>				

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

Legend

PRESCRIBER CODES	BENEFIT STATUS	MANUFACTURER CODES
D - Physician / Dentist	S - Seniors' Pharmacare	AZE - AstraZeneca Canada Inc.
N - Nurse Practitioner	F - Community Services Pharmacare	BGP - BGP Pharma Inc
P - Pharmacist	- Family Pharmacare	BIG - Biogen Idec Canada Inc.
M - Midwife	C - Drug Assistance for Cancer Patients	CEL - Celgene
O - Optometrist	D - Diabetes Assistance Program	PDP - PendoPharm, Division of Pharmascience Inc.
	E - Exception status applies	PFI - Pfizer Canada Inc.
		SNV - Sunovion Pharmaceuticals Canada Inc.
		WMD - Waymade Canada Inc

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Nova Scotia Formulary Updates

New Exception Status Benefit

- Kuvan (sapropterin dihydrochloride)

Nova Scotia Formulary Updates

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 (sapropterin dihydrochloride)	100mg Tablet	02350580	DNP	E (SF)	BMR
	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 (sapropterin dihydrochloride)	100mg Tablet	02350580	DNP	E (SF)	BMR
	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 (sapropterin dihydrochloride)	100mg Tablet	02350580	DNP	E (SF)	BMR
	100mg Sachet	02482207	DNP	E (SF)	BMR
	500mg Sachet	02482215	DNP	E (SF)	BMR
Criteria	Renewal Criteria: <ul style="list-style-type: none"> Renewals will be considered for patients who demonstrate ongoing response to treatment. Renewal Approval Duration: 1 year 				

Legend

PRESCRIBER CODES	BENEFIT STATUS	MANUFACTURER CODES
D - Physician / Dentist	S - Seniors' Pharmacare	BMR - BioMarin Pharmaceuticals Canada
N - Nurse Practitioner	F - Community Services Pharmacare	
P - Pharmacist	- Family Pharmacare	
M - Midwife	C - Drug Assistance for Cancer Patients	
O - Optometrist	D - Diabetes Assistance Program	
	E - Exception status applies	

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Nova Scotia Formulary Updates

New Exception Status Benefits

- Braftovi (encorafenib)
- Inqovi (decitabine and cedazuridine)
- Mektovi (binimetinib)

Criteria Update

- Tretinoin (vitamin A acid topical preparations)

Nova Scotia Formulary Updates

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	<u>Metastatic Melanoma</u> In combination with binimetinib for the treatment of patients with BRAF V600 mutation-positive unresectable or metastatic melanoma. Clinical Notes: <ul style="list-style-type: none">• 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: <ul style="list-style-type: none">• 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	<p><u>Metastatic Colorectal Cancer</u></p> <p>In combination with panitumumab or cetuximab for the treatment of patients with metastatic colorectal cancer who meet all of the following criteria:</p> <ul style="list-style-type: none"> • Presence of BRAF V600E mutation • Disease progression following at least one prior therapy in the metastatic setting • No previous treatment with an EGFR inhibitor <p>Clinical Notes:</p> <ul style="list-style-type: none"> • Patients should have a good performance status. • Treatment should be discontinued upon disease progression or unacceptable toxicity. <p>Claim Notes:</p> <ul style="list-style-type: none"> • 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	<p><u>Myelodysplastic Syndrome</u></p> <p>For the treatment of patients with myelodysplastic syndromes (MDS), including previously treated and untreated, who meet all of the following criteria:</p> <ul style="list-style-type: none"> • 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 <p>Clinical Notes:</p> <ul style="list-style-type: none"> • 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	<p><u>Metastatic Melanoma</u></p> <p>In combination with encorafenib for the treatment of patients with BRAF V600 mutation-positive unresectable or metastatic melanoma.</p> <p>Clinical Notes:</p> <ul style="list-style-type: none"> • 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. <p>Claim Notes:</p> <ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Regular benefit for beneficiaries 30 years and under • For treatment of acne vulgaris in beneficiaries over the age of 30 				

Legend

PRESCRIBER CODES	BENEFIT STATUS	MANUFACTURER CODES
D - Physician / Dentist	S - Seniors' Pharmacare	BSL - Bausch Health Canada Inc.
N - Nurse Practitioner	F - Community Services Pharmacare	GSK - GlaxoSmithKline Inc.
P - Pharmacist	- Family Pharmacare	PFI - Pfizer Canada Inc.
M - Midwife	C - Drug Assistance for Cancer Patients	TAI - Taiho Pharma Canada
O - Optometrist	D - Diabetes Assistance Program	
	E - Exception status applies	