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PRESCRIBER EDITION

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Nova Scotia Formulary Updates

End of Biosimilar Transition Period

An important reminder that as of **February 3, 2023,** some original biologic medications won't be covered by Pharmacare if a biosimilar version is approved and available, unless an exemption is granted. To avoid any gaps in coverage, please connect with your patients who have yet to transition to a biosimilar option. All patients who currently have funding for the originator product have also been granted funding for the biosimilar product.

Medications that require switching to biosimilars are included below. Please note, the policy will also apply to other medications on the Nova Scotia Pharmacare formulary as new biosimilar medications are approved. The formulary can be accessed at the following link: https://novascotia.ca/dhw/pharmacare/formulary.asp

DRUG	ORIGINATOR (SWITCH FROM)	BIOSIMILAR (SWITCH TO)
Adalimumab	Humira	Abrilada Amgevita Hadlima Hulio Hyrimoz Idacio Simlandi Yuflyma
Etanercept	Enbrel	Brenzys Erelzi
Infliximab	Remicade	Avsola Inflectra Renflexis

End of Biosimilar Transition Period Continued…

DRUG	ORIGINATOR (SWITCH FROM)	BIOSIMILAR (SWITCH TO)
Insulin glargine	Lantus	Basaglar Semglee
Insulin lispro	Humalog	Admelog
Insulin aspart	NovoRapid	Trurapi Kirsty
Rituximab	Rituxan	Riximyo Ruxience Truxima

NovoRapid vials continue to remain a benefit at this time for those using insulin pumps. As more biosimilar products become available, they will also be added to this policy.

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

For your information, additional supports and services through community pharmacies have been made available related to biosimilar access, including coverage for therapeutic substitutions for insulins. Please reach out to your local pharmacists if you wish to coordinate approaches to care for patients on biosimilar therapies. More information is available at:

https://novascotia.ca/dhw/pharmacare/pharmacists_bulletins/pharmacists-bulletin-january-23-01.pdf

Support for prescribers is available. As communicated over the past year, 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 to biologictherapies@novascotia.ca. The form can be found at: https://novascotia.ca/dhw/pharmacare/documents/biosimilars-patient-list-request-form.pdf.

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 **February 1, 2023**.

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

New Exception Status Benefits Continued…

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

Criteria	**Acute Myeloid Leukemia**
	• As maintenance therapy for adult patients with acute myeloid leukemia (AML) who meet all of the following criteria:
	  ○ Intermediate or poor risk
	  ○ Complete remission (CR) or complete remission with incomplete blood count recovery (CRi) following induction therapy, with or without consolidation treatment.
	  ○ Not eligible for hematopoietic stem cell transplantation (HSCT)
	Clinical Notes:
	• Newly diagnosed includes patients with AML secondary to prior myelodysplastic syndrome (MDS) or chronic myelomonocytic leukemia (CMML).
	• Last dose of chemotherapy should be within 4 months of starting azacitidine maintenance.
	• Treatment should be discontinued upon disease relapse (i.e., appearance of greater than 5% blasts in the bone marrow or peripheral blood), unacceptable toxicity, or if patient becomes eligible for allogeneic bone marrow or stem cell transplant during the treatment period.				

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

Criteria	**Neuromyelitis Optica Spectrum Disorder**
	• For the treatment of patients 12 years of age and older with neuromyelitis optica spectrum disorder (NMOSD) who meet all of the following criteria:
	  ○ Are anti–aquaporin 4 (AQP4) seropositive
	  ○ Must have had at least one relapse of NMOSD in the previous 12 months:
	  ▪ despite an adequate trial of other accessible preventive treatments[1] for NMOSD, OR
	  ▪ because the patient cannot tolerate other preventive treatments[1] for NMOSD
	• Patients must have an EDSS score of 6.5 points or less.
	• Satralizumab should not be initiated during a NMOSD relapse episode.
	Renewal:
	• Requests for renewal will be considered for patients who maintain an EDSS score of less than 8 points.				

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Enspryng (satralizumab)	120mg/mL Prefilled Syringe	02499681	DNP	E (SF)	HLR
Criteria	**Clinical Notes:** • Must be prescribed by a neurologist with expertise in treating NMOSD. **Claim Notes:** • Approval Period: 1 year • Combined use of more than one biologic drug will not be reimbursed. • Approvals will be for a maximum of 120mg at week 0, 2 and 4, then 120 mg every four weeks thereafter. [1]Other accessible preventative treatments include, but are not limited to, monoclonal antibodies including rituximab and other immunosuppressants.				

Criteria Update

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

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Ajovy (fremanezumab)	225 mg/1.5 mL Prefilled Syringe	02497859	DNP	E (SF)	TEV
	225 mg/1.5 mL Autoinjector	02509474	DNP	E (SF)	TEV
Criteria	• For the treatment of patients with episodic[1] or chronic migraine[2], who have experienced an inadequate response, intolerance, or contraindication to at least two oral prophylactic migraine medications of different classes. **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 atleast 4 days per month and less than 15 headache days per month for more than 3 months				

Criteria Update 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	• [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. **Claim Notes:** • Approvals: 6 months • Must be prescribed by a physician who has experience in the management of migraine headaches.				

New Benefits

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

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

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

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

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

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

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

Legend

PRESCRIBER CODES		BENEFIT STATUS		MANUFACTURER CODES	
D	- Physician / Dentist	S	- Seniors' Pharmacare	BGP	- BGP Pharma Inc
N	- Nurse Practitioner	F	- Community Services Pharmacare	BSL	- Bausch Health, Canada Inc.
P	- Pharmacist		- Family Pharmacare	CEL	- Celgene
M	- Midwife	C	- Drug Assistance for Cancer Patients	HLR	- Hoffmann-LaRoche Limited
O	- Optometrist	D	- Diabetes Assistance Program	JNO	- Juno Pharmaceuticals Corp
		E	- Exception status applies	TEV	- Teva Canada Ltd

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New Exception Status Benefits

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

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

Criteria

Rheumatoid Arthritis

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

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

Clinical Notes:

- For patients who do not demonstrate a clinical response to oral methotrexate, or who experience gastrointestinal intolerance, a trial of parenteral methotrexate must be considered.
- Optimal treatment response to DMARDs may take up to 24 weeks, however coverage can be considered if no improvement is seen after 12 weeks of triple DMARD use.
- If patient factors (e.g. intolerance) prevent the use of triple DMARD therapy, these must be described and dual therapy with DMARDs must be tried.
- Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above.

New Exception Status Benefit Continued…

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

Criteria

- Intolerant is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs. The nature of intolerance(s) must be clearly documented.

Claim Notes:

- Must be prescribed by a rheumatologist.
- Concurrent use of more than one biologic DMARD or janus kinase inhibitors will not be reimbursed.
- Approvals will be for a maximum of 15 mg daily.
- Initial Approval: 6 months
- Renewal Approval Period: 1 year. Confirmation of continued response required.

Psoriatic Arthritis

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

Clinical Notes:

- For patients who do not demonstrate a clinical response to oral methotrexate, or who experience gastrointestinal intolerance, a trial of parenteral methotrexate must be considered.
- Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above.

Intolerant is defined as demonstrating serious adverse effects to treatments. The nature of intolerance(s) must be clearly documented.

Claim Notes:

- Must be prescribed by a rheumatologist.
- Concurrent use of biologics not approved.
- Approvals will be for a maximum of 15mg daily.
- Initial coverage period: 6 months.
- Renewal approval: 1 year. Confirmation of continued response required.

Criteria Updates

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

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

Criteria

Ankylosing Spondylitis

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

      OR
    - Have peripheral symptoms and who have failed to respond to, or have contraindications to, the sequential use of at least 2 NSAIDs at the optimum dose for a minimum period of 2 weeks each and have had an inadequate response to an optimal dose or maximal tolerated dose of a DMARD.
- Must be prescribed by a rheumatologist or prescriber with a specialty in rheumatology.
- Requests for renewal must include information showing the beneficial effects of the treatment, specifically:
    - A decrease of at least 2 points on the BASDAI scale, compared with the pre-treatment score; OR
    - Patient and expert opinion of an adequate clinical response as indicated by a significant functional improvement (measured by outcomes such as HAQ or "ability to return to work").

Claim Notes:

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

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

Criteria Updates Continued…

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

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Tagrisso	40mg Tab	02456214	DNP	E (SFC)	AZE
(osimertinib)	80mg Tab	02456222	DNP	E (SFC)	AZE

Criteria

Stage IB-IIIA Non-Small Cell Lung Cancer (NSCLC)

- For adjuvant therapy after tumour resection in patients with Stage IB-IIIA (AJCC 7th edition or equivalent) non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions [exon 19 del] or exon 21 [L858R] substitution mutations.

Clinical Notes:

- Patients should have a good performance status.
- Treatment with osimertinib should continue for a total duration of 3 years, or until disease recurrence or unacceptable toxicity.
- Osimertinib treatment should be initiated within 10 weeks of complete surgical resection if adjuvant chemotherapy was not administered, or within 26 weeks if adjuvant chemotherapy was administered.
- Retreatment with osimertinib in the metastatic setting will be considered if disease recurrence is at least 6 months following completion of adjuvant therapy.

Locally Advanced or Metastatic Non-Small Cell Lung Cancer (NSCLC)

- For the first-line treatment of patients with locally advanced (not amenable to curative-intent therapy) or metastatic non-small cell lung cancer (NSCLC) whose tumors have the following epidermal growth factor receptor (EGFR) mutations: exon 19 deletions [exon 19 del] or exon 21 [L858R] mutations. Eligible patients should be previously untreated in the locally advanced or metastatic setting and have a good performance status.

Clinical Notes:

- Treatment may continue until clinically meaningful disease progression or unacceptable toxicity.
- Retreatment with osimertinib in the metastatic setting will be considered if disease recurrence is at least 6 months following completion of adjuvant therapy.

Locally Advanced or Metastatic T790M Mutation-Positive Non-Small Cell Lung Cancer (NSCLC)

- For the treatment of patients with locally advanced or metastatic epidermal growth factor receptor (EGFR) T790M mutation-positive non-small cell lung cancer (NSCLC) who have progressed on EGFR tyrosine kinase inhibitor (TKI) therapy, or as initial therapy in patients with a de novo EGFR T790M mutation.

Clinical Notes:

- Patients currently receiving alternate first-line EGFR TKI's (e.g. erlotinib, gefitinib, afatinib) whose tumors have the noted EGFR mutations (exon 19 del or L858R) may be switched to osimertinib provided they meet all other funding criteria and have not experienced disease progression.

Criteria Updates Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Tagrisso (osimertinib)	40mg Tab 80mg Tab	02456214 02456222	DNP DNP	E (SFC) E (SFC)	AZE AZE
Criteria	• Patients who have initiated treatment with chemotherapy prior to receiving results of the EGFR mutation status may be switched to osimertinib if otherwise eligible. • Osimertinib may be continued until there is evidence of disease progression or the development of unacceptable toxicity. • Retreatment with osimertinib in the metastatic setting will be considered if disease recurrence is at least 6 months following completion of adjuvant therapy.				

Change in Benefit Status

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

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

New Benefit

Effective **March 1, 2023,** the following product will be added as a benefit in the Nova Scotia Formulary. The benefit status within the Pharmacare Programs is indicated and existing criteria will apply.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Dupixent	175mg/mL Prefilled Pen	02524252	DNP	E (SF)	SAV

Non Insured Product

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

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

Legend

PRESCRIBER CODES	BENEFIT STATUS	MANUFACTURER CODES
D - Physician / Dentist	S - Seniors' Pharmacare	ABV - AbbVie Corporation
N - Nurse Practitioner	F - Community Services Pharmacare	AZE - AstraZeneca Canada Inc.
P - Pharmacist	- Family Pharmacare	NVR - Novartis Pharmaceuticals Canada Inc.
M - Midwife	C - Drug Assistance for Cancer Patients	SAV - Sanofi-Aventis Canada Inc.
O - Optometrist	D - Diabetes Assistance Program	VAR - *various manufacturers*
	E - Exception status applies	

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New Exception Status Benefits

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

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

Criteria

Initiation

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

Renewal

- Proof of beneficial clinical effect, defined as a reduction of at least 50% in the average number of migraine days per month at the time of first renewal compared with baseline.
- For subsequent renewals, proof that the initial 50% reduction in the average number of migraine days per month has been maintained.

Clinical Notes

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

New Exception Status Benefits Continued…

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

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Tukysa	50mg Tab	02499827	DNP	E (SFC)	SGC
(tucatinib)	150mg Tab	02499835	DNP	E (SFC)	SGC
Criteria	**Locally Advanced Unresectable or Metastatic HER2-positive Breast Cancer** • In combination with trastuzumab and capecitabine for the treatment of patients with locally advanced unresectable or metastatic HER2-positive breast cancer who have received prior treatment with trastuzumab, pertuzumab and a HER2-targeted antibody-drug conjugate (e.g., trastuzumab emtansine or trastuzumab deruxtecan), where at least one was given in the advanced or metastatic setting. **Clinical Notes** • Patients should have a good performance status. • Treatment should be discontinued upon disease progression, unacceptable toxicity, or if both trastuzumab and capecitabine are discontinued. **Claim Note** • Claims that exceed the maximum claim amount of $9,999.99 must be divided and submitted as separate transactions using the DIN first and then the following PIN: ○ 00904820				

Criteria Updates

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

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

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

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Lenalidomide	Various	Various	DNP	E (SFC)	VAR

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

New Benefit

Effective **April 1, 2023,** the following product will be added as a benefit in the Nova Scotia Formulary. The benefit status within the Pharmacare Programs is indicated and existing criteria will apply.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Accel-Hyoscine	10mg Tab	02512335	DNP	SF	ACC

Change in Benefit Status

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

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

Legend

PRESCRIBER CODES		BENEFIT STATUS		MANUFACTURER CODES	
D	- Physician / Dentist	S	- Seniors' Pharmacare	ACC	- Accel Pharma Inc.
N	- Nurse Practitioner	F	- Community Services Pharmacare	LIL	- Eli Lilly Canada Inc.
P	- Pharmacist		- Family Pharmacare	NNO	- Novo Nordisk Canada Inc.
M	- Midwife	C	- Drug Assistance for Cancer Patients	SGC	- Seagen Canada Inc.
O	- Optometrist	D	- Diabetes Assistance Program	VAR	- *various manufacturers*
		E	- Exception status applies		

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New Exception Status Benefits

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

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

New Exception Status Benefits Continued…

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

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Reblozyl (luspatercept)	25mg Vial	02505541	DNP	E (SF)	CEL
	75mg Vial	02505568	DNP	E (SF)	CEL

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

New Exception Status Benefits Continued…

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

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

New Benefits

Effective **May 1, 2023,** the following products will be added as benefits in the Nova Scotia Formulary. The benefit status within the Pharmacare Programs is indicated and existing criteria will apply.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Abrilada	20mg/0.4mL Prefilled Syringe	02511061	DNP	E (SF)	PFI
Clasteon	400mg Tab	02245828	DNP	SFC	SNV
Elonox	30mg/0.3mL Prefilled Syringe	02532247	DNP	SFC	FKB
Elonox	40mg/0.4mL Prefilled Syringe	02532255	DNP	SFC	FKB
Elonox	60mg/0.6mL Prefilled Syringe	02532263	DNP	SFC	FKB
Elonox	80mg/0.8mL Prefilled Syringe	02532271	DNP	SFC	FKB
Elonox	100mg/mL Prefilled Syringe	02532298	DNP	SFC	FKB
Elonox HP	120mg/0.8mL Prefilled Syringe	02532301	DNP	SFC	FKB
Elonox HP	150mg/mL Prefilled Syringe	02532328	DNP	SFC	FKB

Legend

PRESCRIBER CODES		BENEFIT STATUS		MANUFACTURER CODES	
D	- Physician / Dentist	S	- Seniors' Pharmacare	CEL	- Celgene
N	- Nurse Practitioner	F	- Community Services Pharmacare	FKB	- Fresenius Kabi Canada
P	- Pharmacist		- Family Pharmacare	MDU	- Medunik Canada Inc.
M	- Midwife	C	- Drug Assistance for Cancer Patients	PFI	- Pfizer Canada Inc.
O	- Optometrist	D	- Diabetes Assistance Program	SNV	- Sunovion Pharmaceuticals Canada Inc.
		E	- Exception status applies	UCB	- UCB Pharma Canada Inc.

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New Exception Status Benefits

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

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

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

New Exception Status Benefits Continued…

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

Change in Benefit Status

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

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

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

Legend

PRESCRIBER CODES	BENEFIT STATUS	MANUFACTURER CODES
D - Physician / Dentist	S - Seniors' Pharmacare	BGN - BeiGene (Canada) ULC
N - Nurse Practitioner	F - Community Services Pharmacare	IPS - Ipsen Biopharmaceuticals Canada Inc.
P - Pharmacist	- Family Pharmacare	LIL - Eli Lilly Canada Inc.
M - Midwife	C - Drug Assistance for Cancer Patients	
O - Optometrist	D - Diabetes Assistance Program	
	E - Exception status applies	

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New Exception Status Benefit

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

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

Criteria Update

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

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

Product Updates

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

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

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

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

New Benefits

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

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Halycil	50mg Tab	02521059	DNP	SF	ARN
Propylthiouracil	50mg Tab	02523019	DNP	SF	PCI

Reminder: Drugs that Are No Longer Exception Status

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

- Acamprosate (Campral) tablets
- Brexpiprazole (Rexulti) tablets
- Buprenorphine (Sublocade) prefilled syringes
- Carvedilol tablets
- Cholinesterase inhibitors (donepezil tablets, galantamine capsules, rivastigmine capsules)

Reminder: Drugs that Are No Longer Exception Status Continued…

- Dapagliflozin tablets
- Duloxetine capsules
- Entecavir tablets
- Gabapentin capsules
- Glucagon (Baqsimi) nasal device
- Lacosamide tablets
- Lamivudine HBV tablets
- Lurasidone tablets
- Mometasone nasal spray
- Naltrexone tablets
- Pioglitazone tablets
- Pregabalin capsules
- Progesterone capsules
- Quetiapine XR tablets
- Raloxifene tablets
- Tenofovir disoproxil fumarate tablets
- Ursodiol tablets

Legend

PRESCRIBER CODES		BENEFIT STATUS		MANUFACTURER CODES	
D	- Physician / Dentist	S	- Seniors' Pharmacare	AAP	- AA Pharma Inc.
N	- Nurse Practitioner	F	- Community Services Pharmacare	ALN	- Alnylam Netherlands BV
P	- Pharmacist		- Family Pharmacare	ARN	- Accelera Pharma Canada Inc
M	- Midwife	C	- Drug Assistance for Cancer Patients	ODN	- Odan Laboratories Ltd.
O	- Optometrist	D	- Diabetes Assistance Program	PCI	- Phebra Canada
		E	- Exception status applies	VAR	- *Various*

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New Exception Status Benefits

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

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Dojolvi (triheptanoin)	100% O/L	02512556	DNP	E (SF)	UGX
Criteria	• For the treatment of adult and pediatric patients with an acute life-threatening long-chain fatty acid oxidation disorders (LC-FAOD) who meet the following criteria: ○ patients with a confirmed diagnosis of LC-FAOD and acute life-threatening events who require alternative therapy to conventional even-chain medium-chain triglyceride (MCT) supplementation, OR ○ patients without a confirmed diagnosis of LC-FAOD presenting with acute life-threatening events consistent with LC-FAOD who require alternative therapy to conventional even-chain MCT supplementation. **Claims Notes:** • Triheptanoin should only be prescribed by clinicians experienced in the management of LC-FAOD. • Approval: 1 year. Confirmation of continued response required. • Claims that exceed the maximum claim amount of $9,999.99 must be divided and submitted as separate transactions using the DIN first and then the following PIN: ○ 00900021				

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Scemblix	20mg Tab	02528320	DNP	E (SFC)	NVR
(asciminib)	40mg Tab	02528339	DNP	E (SFC)	NVR

Criteria	**Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML)**
	• For the treatment of adult patients with Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in the chronic phase who meet the following criteria:
	  ○ Treatment failure on or intolerance to a minimum of two prior tyrosine kinase inhibitor (TKI) therapies.
	  ○ No evidence of a T315I or V299L mutation.
	Clinical Notes:
	• Patients should have a good performance status.
	• Not for use in the acute phase or blast phase.				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Vitrakvi	25mg Cap	02490315	DNP	E (SFC)	BAY
(larotrectinib)	100mg Cap	02490323	DNP	E (SFC)	BAY
	20mg/mL O/L	02490331	DNP	E (SFC)	BAY

Criteria	**Locally advanced unresectable or metastatic solid tumors with a neurotrophic tyrosine receptor kinase (NTRK) gene fusion**
	• For the treatment of adult and pediatric patients with locally advanced unresectable or metastatic solid tumors with NTRK gene fusion without a known acquired resistance mutation. Patient is not a candidate for surgery and/or radiation due to risk of substantial morbidity and have no satisfactory treatment options.
	Clinical Notes:
	• Patients should have a good performance status.
	• Treatment should be discontinued upon disease progression or unacceptable toxicity.
	• Brain metastases are stable, if present.
	• Patients with prior progression on an NTRK inhibitor are not eligible.
	Claim Note:
	• Claims that exceed the maximum claim amount of $9,999.99 must be divided and submitted as separate transactions using the DIN first and then the following PINs:
	  ○ Vitrakvi 100mg Cap - 00900013
	  ○ Vitrakvi 20mg/mL O/L - 00900014				

Change in Benefit Status

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

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

Legend

PRESCRIBER CODES	BENEFIT STATUS	MANUFACTURER CODES
D - Physician / Dentist	S - Seniors' Pharmacare	BAY - Bayer Inc.
N - Nurse Practitioner	F - Community Services Pharmacare	NVR - Novartis Pharmaceuticals Canada Inc.
P - Pharmacist	- Family Pharmacare	UGX - Ultragenyx
M - Midwife	C - Drug Assistance for Cancer Patients	VAR - *Various manufacturers*
O - Optometrist	D - Diabetes Assistance Program	
	E - Exception status applies	

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New Exception Status Benefit

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

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

New Exception Status Benefit Continued…

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

New Benefit

Effective **immediately,** the following product will be added as a benefit in the Nova Scotia Formulary. The benefit status within the Pharmacare Programs is indicated and existing criteria will apply.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Radicava	105mg/5mL Susp	02532611	DNP	E (SF)	MBT

Legend

PRESCRIBER CODES		BENEFIT STATUS		MANUFACTURER CODES	
D	- Physician / Dentist	S	- Seniors' Pharmacare	ALY	- Amylyx Pharmaceuticals, Inc.
N	- Nurse Practitioner	F	- Community Services Pharmacare	MBT	- Mitsubishi Tanabe Pharma Canada Inc
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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New Exception Status Benefits

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

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

Criteria

Mucopolysaccharidosis Type IVA
Initiation Criteria:

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

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

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

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

New Exception Status Benefits Continued…

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

New Exception Status Benefits Continued…

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

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

Criteria Updates

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

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

Criteria

Acute Graft-Versus-Host Disease

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

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

Renewal criteria:

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

Clinical Notes:

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

Claim Notes:

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

Chronic Graft-Versus-Host Disease

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

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

Criteria Updates Continued…

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

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

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

New Benefits

Effective **September 1, 2023,** the following products will be added as benefits in the Nova Scotia Formulary. The benefit status within the Pharmacare Programs is indicated and existing criteria will apply.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Norditropin FlexPro	5mg/1.5mL Prefilled Pen	02529181	DNP	E (SF)	NNO
Norditropin FlexPro	10mg/1.5mL Prefilled Pen	02529203	DNP	E (SF)	NNO
Norditropin FlexPro	15mg/1.5mL Prefilled Pen	02529211	DNP	E (SF)	NNO

Legend

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

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Criteria Update

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

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

Criteria

High-Risk Early Breast Cancer

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

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

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

Clinical Notes:

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

Criteria Updates Continued…

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

New Benefit

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

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Tresiba	100 U/mL Penfill Cartridge	02467860	DNP	SFD	NNO

Legend

PRESCRIBER CODES		BENEFIT STATUS		MANUFACTURER CODES	
D	- Physician / Dentist	S	- Seniors' Pharmacare	AZE	- AstraZeneca Canada Inc.
N	- Nurse Practitioner	F	- Community Services Pharmacare	NNO	- Novo Nordisk Canada Inc.
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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New Exception Status Benefits

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

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

Criteria

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

Renewal Criteria:

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

Claims Notes:

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

New Exception Status Benefits Continued…

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

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Xpovio	20mg Tab	02527677	DNP	E (SFC)	FTI
(selinexor)					

Criteria	• In combination with bortezomib and dexamethasone for the treatment of adult patients with multiple myeloma and who have received at least one prior therapy.
	
	Clinical Notes:
	1. Prior treatment with bortezomib/proteasome inhibitor is permitted if all the following criteria are met:
	  ○ Best response achieved with bortezomib/proteasome inhibitor was at least a partial response
	  ○ Bortezomib/proteasome inhibitor not discontinued for grade 3 or higher toxicity
	  ○ Bortezomib/proteasome inhibitor treatment-free interval has been at least six months.
	2. Treatment should continue until disease progression or unacceptable toxicity.				

New Exception Status Benefits Continued…

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

Criteria Updates

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

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

Criteria Updates Continued…

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

Criteria

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

Advanced Endometrial Carcinoma

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

Clinical Notes:

- Patients should have a good performance status.
- Treatment should continue until disease progression or unacceptable toxicity (can be continued as monotherapy after completing 2 years of combination therapy with pembrolizumab).
- Confirmation that patient does not have MSI-H or dMMR disease must be done prior to initiating treatment.
- No active CNS metastases (eligible if treated/stable).
- If pembrolizumab or lenvatinib is discontinued for toxicity, the other agent can be continued at the discretion of the physician.
- If patient requires and qualifies for re-treatment with pembrolizumab, lenvatinib can also be given at the discretion of the treating physician.

Criteria Updates Continued…

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

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

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

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

Criteria Updates Continued…

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

Change in Benefit Status

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

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

New Benefits

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

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

Legend

PRESCRIBER CODES		BENEFIT STATUS		MANUFACTURER CODES	
D	- Physician / Dentist	S	- Seniors' Pharmacare	AGA	- Amgen Canada Inc.
N	- Nurse Practitioner	F	- Community Services Pharmacare	APO	- ApoPharma Inc.
P	- Pharmacist		- Family Pharmacare	CTL	- Celltrion Healthcare Ltd
M	- Midwife	C	- Drug Assistance for Cancer Patients	EIS	- Eisai Limited
O	- Optometrist	D	- Diabetes Assistance Program	FTI	- Forus Therapeutics Inc.
		E	- Exception status applies	HLR	- Hoffmann-LaRoche Limited
				JAN	- Janssen-Ortho Inc.
				KYE	- KYE Pharmaceuticals Inc.
				MDP	- Medison Pharma Canada Inc.
				PFI	- Pfizer Canada Inc.
				VAR	- *various manufacturers*

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New Exception Status Benefits

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

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

Criteria

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

Renewal Criteria:

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

New Exception Status Benefits Continued…

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

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

New Exception Status Benefits Continued…

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

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Tremfya	100mg/mL Autoinjector	02487314	DNP	E (SF)	JAN
(guselkumab)	100mg/mL Prefilled Syringe	02469758	DNP	E (SF)	JAN

Criteria	**Psoriasis**
	• For patients with severe, debilitating chronic plaque psoriasis who meet all of the following:
	  ○ Body surface area (BSA) involvement of >10% and/or significant involvement of the face, hands, feet or genitals;
	  ○ Failure to, contraindication to or intolerant of methotrexate and cyclosporine;
	  ○ Failure to, intolerant of or unable to access phototherapy;
	  ○ Written request of a dermatologist or prescriber with a specialty in dermatology.
	• Continued coverage is dependent on evidence of improvement, specifically:
	  ○ A >75% reduction in the Psoriasis Area and Severity Index (PASI) score; or
	  ○ A >50% reduction in PASI with a > 5 point improvement in DLQI (Dermatology Life Quality Index); or
	  ○ Significant reduction in BSA involved, with consideration of important regions such as the face, hands, feet or genitals.				

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Tremfya	100mg/mL AutoInjector	02487314	DNP	E (SF)	JAN
(guselkumab)	100mg/mL Prefilled Syringe	02469758	DNP	E (SF)	JAN

Criteria

Clinical Note:

- Treatment should be discontinued if a response has not been demonstrated after 16 weeks.

Claim Notes:

- Concurrent use of biologics not approved.
- Approvals will be for 100mg by subcutaneous injection at weeks 0, 4, followed by maintenance dosing of 100mg every 8 weeks.
- Initial approval period: 16 weeks
- Renewal approval period: 1 year

Psoriatic Arthritis

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

Clinical Notes:

- For patients who do not demonstrate a clinical response to oral methotrexate, or who experience gastrointestinal intolerance, a trial of parenteral methotrexate must be considered.
- Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above.
- Intolerant is defined as demonstrating serious adverse effects to treatments. The nature of intolerance(s) must be clearly documented.

Claim Notes:

- Must be prescribed by a rheumatologist.
- Combined use of more than one biologic DMARD will not be reimbursed.
- Initial approval:12 weeks, loading dose of 100mg at weeks 0, 4, and 8 weeks
- Maximum dose of 100mg every 8 weeks
- Renewal approval: 1 year. Confirmation of continued response required.

Criteria Update

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

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

Criteria

Atopic Dermatitis

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

Renewal criteria:

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

Clinical Note:

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

Claim Notes:

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

Severe Asthma (Pediatric)

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

Criteria Update Continued…

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

Criteria

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

Initial Discontinuation Criteria:

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

Subsequent Discontinuation Criteria:

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

Clinical Notes:

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

Claim Notes:

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

Severe Asthma

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

Criteria Update Continued…

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

Criteria

Initial Discontinuation Criteria:

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

Subsequent Discontinuation Criteria:

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

Clinical Notes:

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

Claim Notes:

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

Change in Benefit Status

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

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

New Benefits

Effective **October 1, 2023,** the following product has been added as a benefit in the Nova Scotia Formulary. The benefit status within the Pharmacare Programs is indicated and existing criteria will apply.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Zejula	100mg Tab	02530031	DNP	E (SFC)	GSK

Effective **November 1, 2023,** the following product has been added as a benefit in the Nova Scotia Formulary. The benefit status within the Pharmacare Programs is indicated and existing criteria will apply.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Yuflyma	40mg/0.4mL Prefilled Syringe	02523760	DNP	E (SF)	CTL

Legend

PRESCRIBER CODES		BENEFIT STATUS		MANUFACTURER CODES	
D	- Physician / Dentist	S	- Seniors' Pharmacare	CTL	- Celltrion Healthcare Ltd
N	- Nurse Practitioner	F	- Community Services Pharmacare	GSK	- GlaxoSmithKline Inc.
P	- Pharmacist		- Family Pharmacare	JAN	- Janssen-Ortho Inc.
M	- Midwife	C	- Drug Assistance for Cancer Patients	LIL	- Eli Lilly Canada Inc.
O	- Optometrist	D	- Diabetes Assistance Program	PFI	- Pfizer Canada Inc.
		E	- Exception status applies	SAV	- Sanofi-Aventis Canada Inc.
				VAR	- *various manufacturers*

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New Exception Status Benefits

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

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

New Exception Status Benefits Continued…

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

New Exception Status Benefits Continued…

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

Criteria Updates

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

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Tasigna (nilotinib)	150mg Tab	02368250	DNP	E (SFC)	NVR
	200mg Tab	02315874	DNP	E (SFC)	NVR

Criteria	**First Line:**
	• For the first-line treatment of adult patients with Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase.
	Second Line:
	• For the treatment of chronic phase and accelerated phase Philadelphia chromosome positive (Ph+) chronic myeloid leukemia (CML) in adult patients who:
	  ○ Are resistant to imatinib;
	  ○ Have progressed to accelerated phase while on imatinib;
	  ○ Are intolerant to previous oral tyrosine kinase inhibitors (TKIs) (i.e. imatinib or dasatinib or both). Sequential use of nilotinib and dasatinib is not permitted except in cases of intolerance (i.e. grade 3 or 4 toxicity).				

Criteria Update Continued…

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

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

Criteria	• For the treatment of moderate to severe atopic dermatitis in patients 12 years of age and older who meet all of the following criteria:
	  ○ Patients must have had an adequate trial (with a documented refractory disease), or were intolerant (with documented intolerance), or are ineligible for each of the following therapies:
	  ▪ maximally tolerated medical topical therapies for AD combined with phototherapy (where available), and;
	  ▪ maximally tolerated medical topical therapies for AD combined with at least 1 of the 4 systemic immunomodulators (methotrexate, cyclosporine, mycophenolate mofetil, or azathioprine)
	  ○ Baseline Physician Global Assessment score of 3 or greater and Eczema Area and Severity Index (EASI) of 7.1 or greater.
	Renewal Criteria:
	• Requests for renewal must provide proof of beneficial clinical effect when defined as a 75% or greater improvement from baseline in the EASI score (EASI-75) 6 months after treatment initiation.
	• Proof of maintenance of EASI-75 response from baseline must be provided for subsequent authorizations.
	Clinical Note:
	• Not to be used in combination with phototherapy, any immunomodulatory agents (including biologics or other janus kinase inhibitor treatment) for moderate to severe AD.
	Claim Notes:
	• The patient must be under the care of a dermatologist, allergist, clinical immunologist, or pediatrician who has expertise in the management of moderate to severe AD.
	• Approvals will be for a maximum of 30mg once daily.
	• Initial approval period: 6 months
	• Renewal approval period: 1 year				

Change in Benefit Status

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

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

New Benefits

Effective **December 1, 2023,** the following products will be added as benefits in the Nova Scotia Formulary. The benefit status within the Pharmacare Programs is indicated and existing criteria will apply.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Depo-Provera	150mg/mL Inj	02523493	DNP	SFC	PFI
Hadlima	40mg/0.4mL Syringe	02533472	DNP	E (SF)	ORG
Hadlima PushTouch	40mg/0.4mL Autoinjector	02533480	DNP	E (SF)	ORG

Temporary Benefit – US-Labelled Prazosin

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

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

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

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

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

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

Temporary Benefit – US-Labelled Vigabatrin Sachets

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

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

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

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

Temporary Benefits Continued…

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

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

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

Legend

PRESCRIBER CODES		BENEFIT STATUS		MANUFACTURER CODES	
D	- Physician / Dentist	S	- Seniors' Pharmacare	ABV	- AbbVie Corporation
N	- Nurse Practitioner	F	- Community Services Pharmacare	AZE	- AstraZeneca Canada Inc.
P	- Pharmacist		- Family Pharmacare	ELV	- Elvium Life Sciences
M	- Midwife	C	- Drug Assistance for Cancer Patients	LIL	- Eli Lilly Canada Inc.
O	- Optometrist	D	- Diabetes Assistance Program	NVR	- Novartis Pharmaceuticals Canada Inc.
		E	- Exception status applies	ORG	- Organon Canada LTD
				PFI	- Pfizer Canada Inc.
				RCH	- Dr. Reddy's Laboratories Inc.
				STR	- SteriMax Inc.
				VAR	- *various manufacturers*

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Nova Scotia Formulary Updates

Short-Term Funding of Victoza and Trulicity During Ozempic Shortage

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

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

Changes in Benefit Status

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

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

Criteria Updates

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

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

Criteria

Treatment: [Criteria Code 40]

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

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

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

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

Criteria Updates Continued…

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

NS Health and IWK Resources:

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

Criteria Updates Continued…

The following new indication will be added to existing criteria effective **January 1, 2024.**

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Cabometyx (cabozantinib)	20mg Tab	02480824	DNP	E (SFC)	IPS
	40mg Tab	02480832	DNP	E (SFC)	IPS
	60mg Tab	02480840	DNP	E (SFC)	IPS
Criteria	**Locally Advanced or Metastatic Differentiated Thyroid Carcinoma (DTC)** For the treatment of adult patients with locally advanced or metastatic differentiated thyroid carcinoma (DTC) who have progressed on at least one prior line of vascular endothelial growth factor receptor (VEGFR)-targeted tyrosine kinase inhibitor (TKI) therapy. **Clinical Notes:** 1. Patients should have a good performance status. 2. Patients should be refractory to radioactive iodine therapy (RAI-R) or not eligible for radioactive iodine therapy. 3. Treatment should continue until disease progression or unacceptable toxicity. 4. Patients will be eligible for funding if intolerant to the prior line of VEGFR-targeted TKI therapy. 5. Cabozantinib may be used in the third line setting for RET fusion positive patients after progression on or intolerance to selpercatinib.				

New Exception Status Benefits

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

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

New Exception Status Benefits Continued…

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

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

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

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

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

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

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

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

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

Temporary Benefit – US-Authorized Vigabatrin Tablets

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

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

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

Criteria:

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

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

New Benefits

Effective **December 1, 2023,** the following product has been added as a benefit in the Nova Scotia Formulary. The benefit status within the Pharmacare Programs is indicated and existing criteria will apply.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Calquence	100mg Tab	02535696	DNP	E (SFC)	AZE

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

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Imvexxy	4mcg Vag Insert	02503689	DNP	SF	KNI
Imvexxy	10mcg Vag Insert	02503697	DNP	SF	KNI
Glycopyrrolate	0.2mg/1mL Inj	02473879	DNP	SFC	STR
Glycopyrrolate	0.4mg/2mL Inj	02473895	DNP	SFC	STR
Glycopyrrolate	4mg/20mL Inj	02473887	DNP	SFC	STR
PMS-Lactulose-Pharma	667mg/mL O/L	02469391	DNP	E (SFC)	PMS

Legend

PRESCRIBER CODES	BENEFIT STATUS	MANUFACTURER CODES
D - Physician / Dentist	S - Seniors' Pharmacare	ABV - AbbVie Corporation
N - Nurse Practitioner	F - Community Services Pharmacare	AGA - Amgen Canada Inc.
P - Pharmacist	- Family Pharmacare	AZE - AstraZeneca Canada Inc.
M - Midwife	C - Drug Assistance for Cancer Patients	IPS - Ipsen Biopharmaceuticals Canada Inc.
O - Optometrist	D - Diabetes Assistance Program	JNO - Juno Pharmaceuticals Corp
	E - Exception status applies	KNI - Knight Therapeutics Inc.
		PMS - Pharmascience Inc.
		RCH - Dr. Reddy's Laboratories Inc.
		SEV - Servier Canada Inc.
		STR - SteriMax Inc.
		VAR - *various manufacturers*