JANUARY 2025 • VOLUME 25-01
PRESCRIBER EDITION

NOVA SCOTIA

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Nova Scotia Formulary Updates

New Exception Status Products

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

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Amvuttra (vutrisiran)	25mg/0.5ml Prefilled Syringe	02542420	DNP	E (SF)	ALN

Criteria

- For the treatment of polyneuropathy in adult patients with hereditary transthyretin-mediated amyloidosis (hATTR) who meet all of the following criteria:
  - Confirmed genetic diagnosis of hATTR.
  - Symptomatic with early-stage neuropathy[1].
  - Does not have New York Heart Association class III or IV heart failure.
  - Has not previously undergone a liver transplant.

Discontinuation Criteria:

- The patient is permanently bedridden and dependent on assistance for basic activities of daily living.

OR

- The patient is receiving end-of-life care.

Clinical Note:

1. Symptomatic early-stage neuropathy is defined as polyneuropathy disability stage I to IIIB or familial amyloidotic polyneuropathy stage I or II.

Claim Notes:

- The patient must be under the care of a physician with experience in the diagnosis and management of hATTR.

New Exception Status Products Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Amvuttra (vutrisiran)	25mg/0.5ml Prefilled Syringe	02542420	DNP	E (SF)	ALN
Criteria	• Combination therapy with other interfering ribonucleic acid drugs or transthyretin stabilizers used to treat hATTR will not be reimbursed. • Initial Approval: 9 months. • Renewal Approval: 12 months. Confirmation of continued response is required. • For claim adjudication contact Nova Scotia Pharmacare Programs.				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Orladeyo (berotralstat hydrochloride)	150mg Cap	02527693	DNP	E (SF)	BCP
Criteria	• For the routine prevention of attacks of type I or II hereditary angioedema (HAE) in patients 12 years of age and older who have experienced at least three HAE attacks within any four-week period and required the use of an acute injectable treatment. **Discontinuation Criteria:** • No reduction in the number of HAE attacks for which acute injectable treatment was received during the first three months of treatment with berotralstat compared to the number of attacks observed before initiating treatment with berotralstat; **OR** • Increase in the number of HAE attacks for which acute injectable treatment was received compared to the number of attacks before initiating treatment with berotralstat. **Clinical Note:** • The pre-treatment attack rate must be provided. For those patients who are already receiving long-term prophylactic treatment for HAE and intend to transition to berotralstat, pre-treatment attack rate prior to long-term prophylactic treatment must be provided. **Claim Notes:** • Must be prescribed by a physician experienced in the diagnosis and treatment of HAE. • Combination use of Orladeyo (berotralstat) with other long-term prophylactic treatment of HAE (e.g., a C1 esterase inhibitor or lanadelumab) will not be funded. • Initial approval period: 3 months. • Renewal approval period: 6 months.				

Criteria Update

The following criteria has been updated and will replace existing criteria effective **February 1, 2025.**

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 based on clinicopathological features. **Clinical Notes:** • Patient 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 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. • Sequencing with olaparib is not funded. Only one of abemaciclib or olaparib will be funded in the adjuvant setting when eligible.				

New Benefits

Effective **February 1, 2025,** the following products will be added as benefits in the Nova Scotia Formulary. The benefit status within the Pharmacare Programs is indicated and existing criteria applies.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Ferriprox MR	1000mg Tab	02536579	DNP	E (SF)	CCC
Mirtazapine	15mg Tab	02532689	DNP	SFC	SAS

Legend

PRESCRIBER CODES	BENEFIT STATUS	MANUFACTURER CODES
D - Physician / Dentist	S - Seniors' Pharmacare	ALN - Alnylam Netherlands BV
N - Nurse Practitioner	F - Community Services Pharmacare	BCP - BioCryst Pharmaceuticals
P - Pharmacist	- Family Pharmacare	CCC - Chiesi Canada Corp
M - Midwife	C - Drug Assistance for Cancer Patients	LIL - Eli Lilly Canada Inc.
O - Optometrist	D - Diabetes Assistance Program	SAS - Sanis Health Inc
	E - Exception status applies	
	G - Sensor-based Glucose Monitoring Program	

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New Exception Status Products

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

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Koselugo	10mg Cap	02530139	DNP	E (F)	ALX
(selumetinib)	25mg Cap	02530147	DNP	E (F)	ALX

Criteria

- For pediatric patients aged 2 to 18 years with neurofibromatosis type 1 (NF1) with symptomatic, inoperable plexiform neurofibromas (PNs).

Initial renewal:

- The physician must document the beneficial clinical effect when requesting continuation of reimbursement.
- Patients on therapy should be monitored for response (e.g., a reduction in pain, improved function, reduction in tumour volume, disease stabilization) using clinical judgment and/or standard imaging.

Second and subsequent renewal criteria (at 18 months after initiation and thereafter):

- The patient does not have disease worsening or progression (e.g., worsening of motor function or pain).

Claim Notes:

- The patient must be under the care of either a neurooncologist or a pediatrician with expertise in neurooncology.
- Initial approval: 18 months
- Renewal Approval: 12 months
- Claims that exceed the maximum claim amount of $9,999.99 must be divided and submitted as separate transactions using the DIN first and then the following PINs:
  - Koselugo 10mg Capsule: 00900042
  - Koselugo 20mg Capsule: 00900043

New Exception Status Products Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Remsima SC (infliximab)	120mg/1.0mL Prefilled Syringe	02511576	DNP	E (SF)	CLT
	120mg/1.0mL Prefilled Pen	02511584	DNP	E (SF)	CLT

Criteria

Rheumatoid Arthritis

- For the treatment of moderately to severely active rheumatoid arthritis, 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 ≥ 20mg 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 of a biologic therapy can be considered if no improvement is seen after 12 weeks of triple DMARD use.
- If patient factors (e.g. intolerance) prevent the use of triple DMARD therapy, these must be described and dual therapy with DMARDs must be tried.
- Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above.
- Intolerant is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs. The nature of intolerance(s) must be clearly documented.

Claim Notes:

- Must be prescribed by a rheumatologist.
- Combined use with other biologic drugs or janus kinase (JAK) inhibitors will not be reimbursed.
- Initial Approval: 6 months.
- Renewal Approval: Long term.
- Approvals will be for both SC and IV formulations.
- SC will be for a maximum of 120 mg once weekly at 0, 1, 2, 3, and 4 weeks for induction, and then every 2 weeks thereafter for maintenance.
- IV will be for 3mg/kg/dose at 0, 2 and 6 weeks for induction, then every 8 weeks thereafter for maintenance.

New Exception Status Products Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Remsima SC (infliximab)	120mg/1.0mL Prefilled Syringe	02511576	DNP	E (SF)	CLT
	120mg/1.0mL Prefilled Pen	02511584	DNP	E (SF)	CLT

Criteria

Crohn's Disease

- For the treatment of patients with moderately to severely active Crohn's disease who are refractory to, intolerant or have contraindications to corticosteroids and other immunosuppressive therapy.

Clinical Notes:

- Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above.
- Intolerant is defined as demonstrating serious adverse effects to treatments. The nature of intolerance(s) must be clearly documented.

Claim Notes:

- Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology.
- Combined use with other biologic drugs or janus kinase (JAK) inhibitors will not be reimbursed.
- The patient who completed an induction regimen with three IV infliximab doses must have achieved a clinical response to induction therapy with infliximab IV at week 10 of treatment to continue to maintenance therapy with infliximab SC.
- Initial Approval: 6 months.
- Renewal Approval: Long term.
- Approvals will be for both SC and IV formulations.
- Maintenance with SC will be for a maximum of 120 mg every two weeks
- IV will be for 5 mg/kg/dose given at 0, 2 and 6 weeks for induction then every 8 weeks thereafter for maintenance.

Ulcerative Colitis

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

New Exception Status Products Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Remsima SC (infliximab)	120mg/1.0mL Prefilled Syringe	02511576	DNP	E (SF)	CLT
	120mg/1.0mL Prefilled Pen	02511584	DNP	E (SF)	CLT

Criteria	• Renewal requests must include information demonstrating the beneficial effects of the treatment, specifically:
	  ○ a decrease in the partial Mayo score ≥ 2 from baseline, AND
	  ○ a decrease in the rectal bleeding subscore ≥ 1.
	Clinical Notes:
	• Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above.
	• Intolerant is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs. The nature of intolerance(s) must be clearly documented.
	• Patients with severe disease do not require a trial of 5-ASA.
	Claim Notes:
	• Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology.
	• Combined use with other biologic drugs or janus kinase (JAK) inhibitors will not be reimbursed.
	• The patient who completed an induction regimen with three IV infliximab doses must have achieved a clinical response to induction therapy with infliximab IV at week 10 of treatment to continue to maintenance therapy with infliximab SC.
	• Initial Approval: 6 months.
	• Renewal Approval: Long term.
	• Approvals will be for both SC and IV formulations.
	• Maintenance with SC will be for a maximum of 120 mg every two weeks.
	• IV will be for 5 mg/kg/dose given at 0, 2 and 6 weeks for induction then every 8 weeks thereafter for maintenance.				

New Exception Status Products Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Welireg (belzutifan)	40mg Tab	02528908	DNP	E (SFC)	FRS
Criteria	• For the treatment of adult patients with von Hippel-Lindau (vHL) disease who require therapy for associated nonmetastatic renal cell carcinoma, central nervous system hemangioblastomas, or nonmetastatic pancreatic neuroendocrine tumours, not requiring immediate surgery. **Clinical Notes:** • Patients should have a good performance status. • Treatment should continue until disease progression or unacceptable toxicity. • 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: o Welireg 40mg Tablet: 00904912				

Criteria Update

The following criteria has been updated and will replace existing criteria effective **March 1, 2025.**

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Kerendia (finerenone)	10mg Tab 20mg Tab	02531917 02531925	DNP DNP	E (SF) E (SF)	BAY BAY
Criteria	• For the treatment of patients with chronic kidney disease (CKD) and type 2 diabetes (T2D) who have an estimated glomerular filtration rate (eGFR) level of at least 25mL/min/1.73 m^2 and albuminuria level of at least 30 mg/g (or 3 mg/mmol). **Exclusion Criteria:** • Patients with chronic heart failure (CHF) New York Heart Association (NYHA) class II to IV; OR • Patients receiving a mineralocorticoid receptor antagonist (MRA). **Discontinuation Criteria:** • eGFR less than 15mL/min/1.73 m^2; OR • Urinary albumin-to-creatinine ratio (UACR) increased from baseline level. **Claim Notes:** • Must be prescribed by, or in consultation with, a nephrologist or prescriber with experience in the diagnosis and management of patients with CKD and T2D. • Approval: 1 year				

Coverage Period Updates for Biologics and Janus kinase (JAK) Inhibitors

Effective February 1, 2025, coverage periods will be standardized for biologics and Janus kinase inhibitors across most indications to the following:

- Initial approval period: 6 months
- Renewal approval period: 1 year OR long-term for biosimilars

Legend

PRESCRIBER CODES	BENEFIT STATUS	MANUFACTURER CODES
D - Physician / Dentist	S - Seniors' Pharmacare	ALX - Alexion Pharma Canada Corp
N - Nurse Practitioner	F - Community Services Pharmacare	BAY - Bayer Inc.
P - Pharmacist	- Family Pharmacare	CLT - Celltrion Healthcare Ltd
M - Midwife	C - Drug Assistance for Cancer Patients	FRS - Merck Canada Ltd.
O - Optometrist	D - Diabetes Assistance Program	
	E - Exception status applies	
	G - Sensor-based Glucose Monitoring Program	

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Nova Scotia Formulary Updates

Infliximab IV (Inflectra) Changes and New Infliximab IV Products

As communicated in a previous Bulletin, a distribution agreement between Pfizer Canada ULC and Celltrion Inc. for the infliximab biosimilar, Inflectra, ended on March 31, 2025.

Pfizer Canada ULC has launched a new biosimilar infliximab IV under the trade name Ixifi and Drug Identification Number (DIN) 02523191.

Celltrion is marketing biosimilar infliximab IV under the existing DIN 02419475 with the trade name Remdantry.

Inflectra will continue to be available for a 6-month transition period between April 1, 2025 and September 30, 2025, after which Inflectra will no longer be available for sale in Canada.

Between April 1 and September 30, the Pfizer labelled Inflectra and Celltrion labelled Remdantry, will be available and share the same Drug Identification Number (DIN 02419475). As a result, effective April 1, 2025, Inflectra claims will require the use of the PIN 66128531.

After April 1, 2025, no further requests for Inflectra will be considered. Coverage will be provided for other funded infliximab biosimilars.

Infliximab IV (Inflectra) Changes and New Infliximab IV Products Continued…

The following infliximab biosimilar products have been listed with the following criteria, effective April 1, 2025:

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Ixifi (infliximab)	100mg/mL Vial	02523191	DNP	E (SF)	PFI
Remdantry (infliximab)	100mg/mL Vial	02419475	DNP	E (SF)	CLT

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:

- Maximum dose 5mg/kg at 0,2, and 6 weeks then every 6-8 weeks thereafter
- Concurrent use of biologics not approved
- Initial period: 6 months
- Renewal approval: Long term

[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.

Crohn's Disease

For the treatment of patients with moderately to severely active Crohn's disease who are refractory to, intolerant or have contraindications to corticosteroids and other immunosuppressive therapy.

Clinical Notes:

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

Infliximab IV (Inflectra) Changes and New Infliximab IV Products Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Ixifi (infliximab)	100mg/mL Vial	02523191	DNP	E (SF)	PFI
Remdantry (infliximab)	100mg/mL Vial	02419475	DNP	E (SF)	CLT

Criteria

- 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 gastroenterologist or physician with a specialty in gastroenterology.
- Combined use with other biologic drugs or janus kinase (JAK) inhibitors will not be reimbursed.
- The patient who completed an induction regimen with three IV infliximab doses must have achieved a clinical response to induction therapy with infliximab IV at week 10 of treatment to continue to maintenance therapy with infliximab SC.
- Initial Approval: 6 months.
- Renewal Approval: Long term.
- Approvals will be for both SC and IV formulations.
- Maintenance with SC will be for a maximum of 120 mg every two weeks
- IV will be for 5 mg/kg/dose given at 0, 2 and 6 weeks for induction then every 8 weeks thereafter for maintenance.

Plaque Psoriasis

For the treatment of patients with chronic moderate to severe plaque psoriasis who meet all of the following:

- Psoriasis Area Severity Index (PASI) greater than 10 and Dermatology Life Quality Index (DLQI) greater than 10, OR major involvement of visible areas, scalp, genitals, or nails;
- Refractory, intolerant to or unable to access phototherapy;
- Refractory, intolerant to or have contraindications to methotrexate (oral or parenteral) at a dose of greater than or equal to 20 mg weekly (greater than or equal to 15 mg if patient is 65 years of age or older) for a minimum of 12 weeks OR cyclosporine (6 weeks treatment).

For continued coverage, patients must meet the following criteria:

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

Infliximab IV (Inflectra) Changes and New Infliximab IV Products Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Ixifi (infliximab)	100mg/mL Vial	02523191	DNP	E (SF)	PFI
Remdantry (infliximab)	100mg/mL Vial	02419475	DNP	E (SF)	CLT

Criteria

Clinical Notes:

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

Claim Notes:

- Must be prescribed by a dermatologist or prescriber with a specialty in dermatology.
- Dosage restricted to infliximab 5mg/kg 0, 2 and 6 weeks then every 8 weeks.
- Combined use of more than one biologic will not be reimbursed.
- Initial Approval: 6 months.
- Renewal Approval: Long term.

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.

Infliximab IV (Inflectra) Changes and New Infliximab IV Products Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Ixifi (infliximab)	100mg/mL Vial	02523191	DNP	E (SF)	PFI
Remdantry (infliximab)	100mg/mL Vial	02419475	DNP	E (SF)	CLT

Criteria

Claim Notes:

- Must be prescribed by a rheumatologist.
- Concurrent use of biologics not approved.
- Maximum dose 5mg/kg 0, 2 and 6 weeks then every 8 weeks.
- Initial Approval: 6 months.
- Renewal Approval: Long term.

Rheumatoid Arthritis

For the treatment of moderately to severely active rheumatoid arthritis, 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 ≥ 20mg 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 of a biologic therapy can be considered if no improvement is seen after 12 weeks of triple DMARD use.
- If patient factors (e.g. intolerance) prevent the use of triple DMARD therapy, these must be described and dual therapy with DMARDs must be tried.
- Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above.
- Intolerant is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs. The nature of intolerance(s) must be clearly documented.

Claim Notes:

- Must be prescribed by a rheumatologist.
- Combined use with other biologic drugs or janus kinase (JAK) inhibitors will not be reimbursed.

Infliximab IV (Inflectra) Changes and New Infliximab IV Products Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Ixifi (infliximab)	100mg/mL Vial	02523191	DNP	E (SF)	PFI
Remdantry (infliximab)	100mg/mL Vial	02419475	DNP	E (SF)	CLT

Criteria

- Initial Approval: 6 months.
- Renewal Approval: Long term.
- Approvals will be for both SC and IV formulations.
- SC will be for a maximum of 120 mg once weekly at 0, 1, 2, 3, and 4 weeks for induction, and then every 2 weeks thereafter for maintenance.
- IV will be for 3mg/kg/dose at 0, 2 and 6 weeks for induction, then every 8 weeks thereafter for maintenance.

Ulcerative Colitis

For the treatment of patients with moderately to severely active ulcerative colitis who have a partial Mayo score > 4, and a rectal bleeding subscore ≥ 2 and are:

- refractory or intolerant to conventional therapy (i.e. 5-ASA for a minimum of 4 weeks, and prednisone ≥ 40mg daily for two weeks or IV equivalent for one week); OR
- corticosteroid dependent (i.e. cannot be tapered from corticosteroids without disease recurrence; or have relapsed within three months of stopping corticosteroids; or require two or more courses of corticosteroids within one year.)

Renewal requests must include information demonstrating the beneficial effects of the treatment, specifically:

- a decrease in the partial Mayo score ≥ 2 from baseline, AND
- a decrease in the rectal bleeding subscore ≥ 1.

Clinical Notes:

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

Claim Notes:

- Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology.
- Combined use with other biologic drugs or janus kinase (JAK) inhibitors will not be reimbursed.
- The patient who completed an induction regimen with three IV infliximab doses must have achieved a clinical response to induction therapy with infliximab IV at week 10 of treatment to continue to maintenance therapy with infliximab SC.

Infliximab IV (Inflectra) Changes and New Infliximab IV Products Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Ixifi (infliximab)	100mg/mL Vial	02523191	DNP	E (SF)	PFI
Remdantry (infliximab)	100mg/mL Vial	02419475	DNP	E (SF)	CLT
Criteria	• Initial Approval: 6 months. • Renewal Approval: Long term. • Approvals will be for both SC and IV formulations. • Maintenance with SC will be for a maximum of 120 mg every two weeks. • IV will be for 5 mg/kg/dose given at 0, 2 and 6 weeks for induction then every 8 weeks thereafter for maintenance.				

New Exception Status Products

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

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Sohonos (palovarotene)	1mg Cap	02524627	DNP	E (SF)	IPS
	1.5mg Cap	02524635	DNP	E (SF)	IPS
	2.5mg Cap	02524643	DNP	E (SF)	IPS
	5mg Cap	02524651	DNP	E (SF)	IPS
	10mg Cap	02524678	DNP	E (SF)	IPS
Criteria	• Coverage is for females aged 8 years and above and males aged 10 years and above with a clinical diagnosis of fibrodysplasia ossificans progressiva (FOP) and the R206H ACVR1 mutation as confirmed by genetic testing. **Clinical Notes:** • Patients must not have complete ankylosis of the whole body. • Palovarotene should be discontinued if it is agreed that the perceived balance of benefits and risks is no longer acceptable or if the patient progresses to complete ankylosis of the whole body. **Claim Note:** • Palovarotene must be prescribed by an expert in the diagnosis and management of FOP.				

New Exception Status Products Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Ticagrelor (Brilinta and generic brands)	60mg Tab	Various	DNP	E (SF)	VAR
Criteria	• In combination with ASA for patients with a history of ST elevation myocardial infarction (STEMI) or non-ST elevation acute coronary syndrome (NSTEACS) in the previous 3 years who are at high risk for subsequent cardiovascular events. **Clinical Note:** • High risk for subsequent cardiovascular events is defined as age 65 years or older, diabetes, second prior spontaneous myocardial infarction, multivessel coronary artery disease, or chronic renal dysfunction (creatinine clearance < 60mL/min). **Claim Notes:** • Approval period: Up to 3 years.				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Truqap (capivasertib)	160mg Tab 200mg Tab	02544733 02544741	DNP DNP	E (SFC) E (SFC)	AZE AZE
Criteria	• In combination with fulvestrant for the treatment of adults with hormone receptor (HR) positive, human epidermal growth factor receptor 2 (HER2) negative locally advanced or metastatic breast cancer with one or more PIK3CA/AKT1/PTEN alterations following progression on at least one endocrine-based regimen in the metastatic setting or recurrence within 12 months of completing adjuvant therapy. **Clinical Notes:** • Patient should have a good performance status. • Treatment should continue until disease progression or unacceptable toxicity. • Capivasertib is only reimbursed in combination with fulvestrant. Capivasertib must be discontinued if fulvestrant is discontinued. • Patients are not eligible if they progressed on prior fulvestrant, received more than two lines of hormone therapy, or received more than one line of chemotherapy in the metastatic setting.				

Change in Benefit Status

Effective **April 1, 2025,** the following products will move to full benefit and no longer require exception status approval.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Foquest	25mg Cap	02470292	DNP	SF	ELV
Foquest	35mg Cap	02470306	DNP	SF	ELV
Foquest	45mg Cap	02470314	DNP	SF	ELV
Foquest	55mg Cap	02470322	DNP	SF	ELV
Foquest	70mg Cap	02470330	DNP	SF	ELV
Foquest	85mg Cap	02470349	DNP	SF	ELV
Foquest	100mg Cap	02470357	DNP	SF	ELV
Riximyo	10mg/mL Vial	02498316	DNP	SF	SDZ
Ruxience	10mg/mL Vial	02495724	DNP	SF	PFI
Truxima	10mg/mL Vial (10mL)	02478382	DNP	SF	TEV
Truxima	10mg/mL Vial (50mL)	02478390	DNP	SF	TEV

New Benefits

Effective **April 1, 2025,** the following products will be added as a benefit in the Nova Scotia Formulary. The benefit status within the Pharmacare Programs is indicated and existing criteria applies.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Mezera	1gm delayed-release Tab	02545012	DNP	SF	AVI
Praluent	300mg/2mL Pen	02547732	DNP	E (SF)	SAV

Legend

PRESCRIBER CODES	BENEFIT STATUS	MANUFACTURER CODES
D - Physician / Dentist / Physician Assistant / Podiatrist	S - Seniors' Pharmacare	AVI - Avir Pharma Inc
N - Nurse Practitioner	F - Community Services Pharmacare	AZE - AstraZeneca Canada Inc.
P - Pharmacist	- Family Pharmacare	CLT - Celltrion
M - Midwife	C - Drug Assistance for Cancer Patients	ELV - Elvium Life Sciences
O - Optometrist	D - Diabetes Assistance Program	IPS - Ipsen Biopharmaceuticals Canada Inc.
	E - Exception status applies	PFI - Pfizer Canada Inc.
	G - Sensor-based Glucose Monitoring Program	SAV - Sanofi-Aventis Canada Inc.
		SDZ - Sandoz Canada Incorporated
		TEV - Teva Canada Ltd.
		VAR - *various manufacturers*

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New Exception Status Product

The following new product has been listed with the following criteria, effective **May 1, 2025**.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Osnuvo (teriparatide)	250mcg/mL Prefilled Ctg Inj	02495589	DNP	E (SF)	AVI

Criteria

- For the treatment of severe osteoporosis in patients who:
  - Have experienced a recent severe vertebral fracture OR
  - Had more than one vertebral fracture and a T-score of -2.5 or less at the total hip or lumbar spine, or femoral neck OR
  - Had failure, intolerance, or contraindication to bisphosphonates (oral and injectable) and denosumab

Clinical Notes:

- Recent fracture is defined as a fracture occurring within the past 2 years
- Severe vertebral fracture is defined as a vertebral body height loss of > 40%

Claim Notes:

- Requests are to be received from a specialist with expertise in anabolic therapy
- Lifetime exposure to be 24 months.

Criteria Updates

The following new indications have been added to existing criteria effective **May 1, 2025**.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Bimzelx	160mg/mL Prefilled Syringe	02525267	DNP	E (SF)	UCB
(bimekizumab)	160mg/mL Autoinjector	02525275	DNP	E (SF)	UCB

Criteria

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;
    - 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
- Approvals will be for 160mg by subcutaneous injection every 4 weeks.
- Initial Approval: 6 months.
- Renewal Approval: 1 year.

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 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.

Criteria Updates Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Bimzelx (bimekizumab)	160mg/mL Prefilled Syringe 160mg/mL Autoinjector	02525267 02525275	DNP DNP	E (SF) E (SF)	UCB UCB

Criteria	• 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")
	Clinical Note:
	• Patients with recurrent uveitis (2 or more episodes within 12 months) as a complication of axial disease, do not require a trial of NSAIDs alone.
	Claim Notes:
	• Must be prescribed by a rheumatologist or prescriber with a specialty in rheumatology.
	• Combined use of more than one biologic DMARD will not be reimbursed
	• Approvals will be for 160mg by subcutaneous injection every 4 weeks.
	• Initial period: 6 months
	  ○ Renewal approval: 1 year.				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Imbruvica (ibrutinib)	140mg Cap	02434407	DNP	E (SFC)	JAN
Criteria	**Chronic Lymphocytic Leukemia** • As a treatment option for adult patients with previously untreated chronic lymphocytic leukemia (CLL), including those with 17p deletion, in combination with venetoclax. **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. • Patients who have progressed on a BTK inhibitor are not eligible. • No active CNS involvement (eligible if treated/stable). • If ibrutinib is discontinued for intolerance, venetoclax monotherapy may be continued. • Patients with small lymphocytic lymphoma (SLL) are eligible for treatment. **Relapsed/Refractory Waldenstrom's Macroglobulinemia** • As a treatment option for adult patients with previously treated relapsed or refractory Waldenström's Macroglobulinemia as monotherapy or in combination with rituximab.				

Criteria Updates Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Imbruvica (ibrutinib)	140mg Cap	02434407	DNP	E (SFC)	JAN
Criteria	**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. • Patients who have progressed on a BTK inhibitor are not eligible				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Tagrisso (osimertinib)	40mg Tab	02456214	DNP	E (SFC)	AZE
	80mg Tab	02456222	DNP	E (SFC)	AZE
Criteria	• In combination with pemetrexed and platinum-based chemotherapy for the first-line treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) whose tumors have EGFR exon 19 deletions or exon 21 (L858R) substitution mutations. **Clinical Notes:** • Patient should have a good performance status. • Treatment with osimertinib should continue until disease progression or unacceptable toxicity. • Pemetrexed and platinum-based chemotherapy is given for 4 cycles and pemetrexed maintenance therapy continued. • Retreatment with osimertinib in the metastatic setting will be considered if recurrence is at least 6 months following completion of adjuvant therapy.				

The following criteria has been added to existing criteria effective **May 1, 2025.**

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Venclexta (venetoclax)	10mg Tab	02458039	DNP	E (SFC)	ABV
	50mg Tab	02458047	DNP	E (SFC)	ABV
	100mg Tab	02458055	DNP	E (SFC)	ABV
	Starter Kit	02458063	DNP	E (SFC)	ABV
Criteria	**Venetoclax with ibrutinib for previously untreated chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL)** • For the treatment of adult patients with previously untreated chronic lymphocytic leukemia (CLL), including those with 17p deletion, in combination with ibrutinib.				

Criteria Updates Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Venclexta (venetoclax)	10mg Tab	02458039	DNP	E (SFC)	ABV
	50mg Tab	02458047	DNP	E (SFC)	ABV
	100mg Tab	02458055	DNP	E (SFC)	ABV
	Starter Kit	02458063	DNP	E (SFC)	ABV
Criteria	**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. • Patients who have progressed on a BTK inhibitor are not eligible. • No active CNS involvement (eligible if treated/stable). • If ibrutinib is discontinued for intolerance, venetoclax monotherapy may be continued. • Patients with small lymphocytic lymphoma (SLL) are eligible for treatment.				

The following criteria has been updated and will replace existing criteria effective **May 1, 2025.**

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Cipro (ciprofloxacin and generics)	250mg Tab	Various	DNPMO	E (SFC)	VAR
	500mg Tab	Various	DNPMO	E (SFC)	VAR
	750mg Tab	Various	DNPMO	E (SFC)	VAR
	100mg/mL O/L	Various	DNPMO	E (SFC)	VAR

Criteria	• For the treatment of complicated urinary tract infections (UTI) or acute uncomplicated pyelonephritis when: **[Criteria Code 01]**
	  ○ Alternative agents are ineffective, not tolerated, or contraindicated, OR
	  ○ The patient has a history of infection with resistant gram-negative bacteria.
	• For the treatment of uncomplicated UTI when all alternative agents are ineffective, not tolerated, or contraindicated. **[Criteria Code 02]**
	• For treatment of bacterial prostatitis. **[Criteria Code 03]**
	• For the treatment of gram-negative infections (e.g. osteomyelitis, joint infections, and infections caused by Pseudomonas aeruginosa), which are resistant to other oral agents. **[Criteria Code 04]**
	• For the treatment of severe (malignant) otitis externa. **[Criteria Code 05]**
	• For the prevention of endophthalmitis in patients who have had cataract surgery with unplanned vitrectomy. **[Criteria Code 06]**
	• For chemoprophylaxis of close contacts of a patient with invasive meningococcal disease, as recommended by Public Health guidelines. **[Criteria Code 08]**				

Criteria Updates Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Cipro (ciprofloxacin and generics)	250mg Tab	Various	DNPMO	E (SFC)	VAR
	500mg Tab	Various	DNPMO	E (SFC)	VAR
	750mg Tab	Various	DNPMO	E (SFC)	VAR
	100mg/mL O/L	Various	DNPMO	E (SFC)	VAR
Criteria	• For the treatment of severe bacterial gastroenteritis when alternative agents (e.g. macrolides, sulfamethoxazole/trimethoprim) are ineffective, not tolerated, or contraindicated. **[Criteria Code 09]** • For the empiric treatment of acute exacerbations of chronic obstructive pulmonary disease (AECOPD) in patients at risk of Pseudomonas infection (e.g. previously isolated Pseudomonas, end stage lung disease, concomitant bronchiectasis, frequent or recent broad spectrum antibiotic use). **[Criteria Code 10]** • For the treatment of lung infections in patients with cystic fibrosis. **[Criteria Code 11]** • For the empiric treatment of outpatient febrile neutropenia. **[Criteria Code 13]** **Clinical Notes**: • If treated with an antibiotic within the past 3 months choose an antibiotic from a different class. • Complicated AECOPD defined as patients with COPD (FEV1/FVC < 0.7) experiencing increased sputum purulence, and either increased dyspnea or sputum volume, and one of the following: o FEV1 < 50% predicted o ≥ 4 exacerbations per year o Ischemic heart disease o Home oxygen use o Chronic oral steroid use				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Levaquin (levofloxacin and generics)	250mg Tab	Various	DNP	E (SFC)	VAR
	500mg Tab	Various	DNP	E (SFC)	VAR
Avelox (moxifloxacin and generics)	400mg Tab	Various	DNP	E (SFC)	VAR
Criteria	• For the completion of therapy instituted in hospital setting for the treatment of nosocomial pneumonia, community acquired pneumonia (CAP) or acute exacerbation of chronic obstructive pulmonary disease (AECOPD). **[Criteria Code 01]** • For the treatment of severe pneumonia in nursing home patients. **[Criteria Code 02]**				

Criteria Updates Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Levaquin **(levofloxacin and generics)**	250mg Tab 500mg Tab	Various Various	DNP DNP	E (SFC) E (SFC)	VAR VAR
Avelox **(moxifloxacin and generics)**	400mg Tab	Various	DNP	E (SFC)	VAR
Criteria	• For the treatment of CAP in patients with radiographic conformation of pneumonia, who have failed treatment with at least one first-line therapy (doxycycline, beta-lactam, or macrolide) or are intolerant or have contraindication(s) to at least two first-line therapies. **[Criteria Code 03]** • For the treatment of complicated AECOPD in patients who have failed treatment with at least one first-line therapy (doxycycline, beta-lactam, trimethoprim-sulfamethoxazole, or macrolide) or are intolerant or have contraindication(s) to at least first-line therapies. **[Criteria Code 04]** • For the treatment of complicated osteomyelitis or joint infections. **[Criteria Code 05]** • For the treatment of pulmonary infections with cystic fibrosis. **[Criteria Code 06]** • For the treatment of tuberculosis in patients who have lab-verified drug resistance or a contraindication or intolerance to first-line drugs. **[Criteria Code 07]** • For the treatment of pyelonephritis (levofloxacin only). **[Criteria Code 08]** **Clinical Notes:** • If the patient has been treated with an antibiotic within the past 3 months, consider an antibiotic from a different class. • Complicated AECOPD is defined as patients with COPD (FEV1/FVC < 0.7) experiencing increased sputum purulence, and either increased dyspnea or sputum volume, and one of the following: o FEV1 < 50% predicted o ≥ 4 exacerbations per year o Ischemic heart disease o Home oxygen use o Chronic oral steroid use				

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]**				

Change in Benefit Status

The following products will be listed as full benefits, effective **May 1, 2025**.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Eletriptan	20mg Tab	Various	DNP	SF	VAR
Eletriptan	40mg Tab	Various	DNP	SF	VAR
Fenofibrate	145mg E Tab	Various	DNP	SF	VAR
Topiramate	50mg Tab	02312085	DNP	SF	PMS
Verapamil	120mg SR Tab	Various	DNP	SF	VAR

New Benefits

Effective **May 1, 2025,** 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
JAMP Topiramate	50mg Tab	02544377	DNP	SF	JPC
Vancomycin HCL	1g/vial Inj	02543982	DNPM	SFC	HIK
Vancomycin HCL	500mg/Vial Inj	02543974	DNPM	SFC	HIK

Legend

PRESCRIBER CODES	BENEFIT STATUS	MANUFACTURER CODES
D - Physician / Dentist / Physician Assistant / Podiatrist	S - Seniors' Pharmacare	AAP - AA Pharma Inc.
	F - Community Services Pharmacare	ABV - AbbVie Corporation
	- Family Pharmacare	AVI - Avir Pharma Inc
N - Nurse Practitioner	C - Drug Assistance for Cancer Patients	AZE - AstraZeneca Canada Inc.
P - Pharmacist	D - Diabetes Assistance Program	HIK - Hikma Canada Limited
M - Midwife	E - Exception status applies	JAN - Janssen-Ortho Inc.
O - Optometrist	G - Sensor-based Glucose Monitoring Program	JPC - Jamp Pharma Corporation
		PMS - Pharmascience Inc.
		UCB - UCB Pharma Canada Inc.
		VAR - *various manufacturers*

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New Exception Status Products

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

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Epidiolex (cannabidiol)	100mg/mL Oral Sol	02543079	DNP	E (SF)	JAZ

Criteria

For the adjunctive treatment of patients aged 2 years or older with confirmed diagnosis of seizures associated the following:

Lennox-Gastaut Syndrome

- Experienced treatment failure on at least 2 antiepileptic drugs
- Currently taking 1 or more antiepileptic drugs at stable doses for at least 4 weeks before initiation
- At least 2 drop seizures per week over a 28-day period before initiation of cannabidiol

Dravet Syndrome

- Not adequately controlled with 2 or more antiepileptic drugs at the time of initiation
- At least 4 convulsive seizures per month

Tuberous Sclerosis Complex

- Currently taking 1 or more antiepileptic drugs at stable doses for at least 4 weeks before initiation
- Experienced treatment failure despite previously or currently receiving treatment with at least 2 antiepileptic drugs
- At least 8 seizures per 28 days before initiation of cannabidiol

Renewal requests for the treatment of seizures associated with Lennox-Gastaut syndrome, Dravet syndrome, or tuberous sclerosis complex diagnosis must provide proof of beneficial clinical effect, without severe toxicity or treatment intolerance.

New Exception Status Products Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Epidiolex (cannabidiol)	100mg/mL Oral Sol	02543079	DNP	E (SF)	JAZ
Criteria	**Claim Notes:** • Cannabidiol should be prescribed by a physician with expertise in the diagnosis and management of patients with Lennox-Gastaut syndrome, Dravet syndrome, or tuberous sclerosis complex. • Cannabidiol should not be reimbursed in patients concurrently using cannabis or other cannabinoid-based medications. • Cannabidiol should not be reimbursed in patients with tuberous sclerosis complex concurrently using mTOR inhibitors. • Initial Approval: 6 months • Renewal Approval: 12 months				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Tyenne (tocilizumab)	80mg/4mL Vial	02552450	DNP	E (SF)	FKB
	200mg/10mL Vial	02552469	DNP	E (SF)	FKB
	400mg/20mL Vial	02552477	DNP	E (SF)	FKB
	162mg/ 0.9mL Prefilled Syringe	02552493	DNP	E (SF)	FKB
	162mg /0.9mL Autoinjector	02552485	DNP	E (SF)	FKB
Criteria	**Effective June 1, 2025, patients currently taking the originator drug product, are required to switch to the biosimilar version by December 1, 2025.** **For tocilizumab-naïve patients whose therapy is initiated after June 1, 2025, the tocilizumab biosimilar will be the product approved.** **Rheumatoid Arthritis (Tyenne 80mg/4mL, 200mg/10mL, 400mg/20mL vial and 162mg/0.9mL SC prefilled syringe and autoinjector)** • For the treatment of moderately to severely active rheumatoid arthritis, in combination with methotrexate or other disease-modifying antirheumatic drugs (DMARDs), in adult patients who are refractory or intolerant to: o methotrexate (oral or parenteral) at a dose of ≥ 20mg weekly (≥15mg if patient is ≥ 65 years of age), or use in combination with another DMARD, for a minimum of 12 weeks AND o methotrexate in combination with at least two other DMARDs, such as hydroxychloroquine and sulfasalazine, for a minimum of 12 weeks				

New Exception Status Products Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Tyenne (tocilizumab)	80mg/4mL Vial	02552450	DNP	E (SF)	FKB
	200mg/10mL Vial	02552469	DNP	E (SF)	FKB
	400mg/20mL Vial	02552477	DNP	E (SF)	FKB
	162mg/ 0.9mL Prefilled Syringe	02552493	DNP	E (SF)	FKB
	162mg /0.9mL Autoinjector	02552485	DNP	E (SF)	FKB
Criteria	**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 of a biologic therapy can be considered if no improvement is seen after 12 weeks of triple DMARD use. • If patient factors (e.g. intolerance) prevent the use of triple DMARD therapy, these must be described and dual therapy with DMARDs must be tried • Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above. • Intolerant is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs. The nature of intolerance(s) must be clearly documented. **Claim Notes:** • Must be prescribed by a rheumatologist. • Combined use of more than one biologic DMARD will not be reimbursed. • Initial Approval: 6 months • Renewal Approval: Long term. • Maximum Dosage Approved: o Tocilizumab: 4mg/kg/dose once every 4 weeks followed by an increase to 8 mg/kg/dose based on clinical response **Polyarticular Juvenile Idiopathic Arthritis (pJIA) (Tyenne 80mg/4mL, 200mg/10mL, 400mg/20mL vial and 162mg/0.9mL SC prefilled syringe and autoinjector)** • For the treatment of children (age 2-17) with moderately to severely active polyarticular juvenile idiopathic arthritis (pJIA) who have had inadequate response to one or more disease-modifying antirheumatic drugs (DMARDs). **Clinical Notes:** • Must be prescribed by, or in consultation with, a rheumatologist who is familiar with the use of biologic DMARDs in children. • Intravenous infusion: Approvals will be for 10mg/kg for patients <30kg or 8mg/kg for patients ≥30kg, to a maximum of 800mg, administered every four weeks.				

New Exception Status Products Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Tyenne (tocilizumab)	80mg/4mL Vial	02552450	DNP	E (SF)	FKB
	200mg/10mL Vial	02552469	DNP	E (SF)	FKB
	400mg/20mL Vial	02552477	DNP	E (SF)	FKB
	162mg/ 0.9mL Prefilled Syringe	02552493	DNP	E (SF)	FKB
	162mg /0.9mL Autoinjector	02552485	DNP	E (SF)	FKB
Criteria	• Subcutaneous injection: Approvals with be for a maximum of 162mg once every three weeks for patients weighing <30kg or 162mg once every two weeks for patients weighing ≥30kg. **Claim Notes:** • Initial approval: 6 months • Renewal Approval: Long term **Systemic Juvenile Idiopathic Arthritis (sJIA) (Tyenne 80mg/4mL, 200mg/10mL, 400mg/20mL vial and 162mg/0.9mL SC prefilled syringe and autoinjector)** • For the treatment of active systemic juvenile idiopathic arthritis (sJIA), in patients 2 years of age or older, who have responded inadequately to non-steroidal anti-inflammatory drugs (NSAIDs) and systemic corticosteroids (with or without methotrexate) due to intolerance or lack of efficacy. **Clinical Notes:** • Must be prescribed by, or in consultation with, a rheumatologist, who is familiar with the use of biologic DMARDs in children. • Intravenous infusion: Approvals will be for 12 mg/kg for patients < 30kg or 8 mg/kg for patients ≥ 30kg, to a maximum of 800mg, administered every two weeks. • Subcutaneous injection: Approvals with be for a maximum of 162mg once every two weeks for patients weighing <30kg or 162mg once every week for patients weighing ≥30kg. **Claim Notes:** • Initial approval period: 6 months • Renewal Approval: Long term **Giant Cell Arteritis (GCA) (Tyenne 162mg/0.9mL SC prefilled syringe and autoinjector)** • For the treatment of Giant Cell Arteritis (GCA) in adult patients who are receiving prednisone at initiation of therapy, or with relapse. **Clinical Notes:** • Patients should be under the care of a physician with the experience of diagnosis and management of GCA. • Duration of therapy with tocilizumab should be limited to 52 weeks per treatment course. If treatment is extended beyond 52 weeks, consideration should be given regarding response to treatment, outcome off therapy and ability to taper glucocorticoids. • Discontinuation of tocilizumab should be considered at 12 weeks if there is no response to therapy.				

New Exception Status Products Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Tyenne (tocilizumab)	80mg/4mL Vial	02552450	DNP	E (SF)	FKB
	200mg/10mL Vial	02552469	DNP	E (SF)	FKB
	400mg/20mL Vial	02552477	DNP	E (SF)	FKB
	162mg/ 0.9mL Prefilled Syringe	02552493	DNP	E (SF)	FKB
	162mg /0.9mL Autoinjector	02552485	DNP	E (SF)	FKB
Criteria	**Claim Notes:** • Initial approval period: 6 months • Renewal Approval: Long term				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Xcopri (cenobamate)	12.5mg Tab	02538652	DNP	E (SF)	EDO
	25mg Tab	02538660	DNP	E (SF)	EDO
	50mg Tab	02538725	DNP	E (SF)	EDO
	100mg Tab	02538733	DNP	E (SF)	EDO
	150mg Tab	02538741	DNP	E (SF)	EDO
	200mg Tab	02538768	DNP	E (SF)	EDO
	12.5-25mg Tab (starter kit)	02538776	DNP	E (SF)	EDO
	50-100mg Tab (starter kit)	02538784	DNP	E (SF)	EDO
	150-200mg Tab (starter kit)	02538792	DNP	E (SF)	EDO
Criteria	• For the adjunctive treatment of refractory partial-onset seizures (POS) in patients who are currently receiving two or more antiepileptic drugs and have had an inadequate response or intolerance to at least three other antiepileptic drugs. **Claim Notes:** • The patient must be under the care of a physician experienced in the treatment of epilepsy.				

New Exception Status Products Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Cabtreo (adapalene/benzoyl peroxide/clindamycin)	0.15%/3.1%/1.2% Gel	02550423	DNP	E*	BSL
Criteria	• Regular benefit for beneficiaries 30 years and under • For treatment of acne vulgaris in beneficiaries over the age of 30				

Criteria Updates

The following criteria has been updated and will replace existing criteria effective **immediately.**

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Aubagio and generics (teriflunomide)	14mg Tab	Various	DNP	E (SF)	VAR

Criteria	• For the treatment of adult patients with relapsing remitting multiple sclerosis (RRMS) who meet all of the following criteria:
	  ○ Ambulatory with or without aid (i.e. has a recent Expanded Disability Status Scale (EDSS) score of less than or equal to 6.5)
	  ○ Experienced one or more disabling relapses or new MRI activity in the past two years
	Clinical Note:
	• Treatment should be discontinued for patients with an EDSS score of greater than or equal to 7.
	Claim Notes:
	• Must be prescribed by a neurologist with experience in the diagnosis and management of multiple sclerosis.
	• Combined use with other disease modifying therapies to treat RRMS will not be reimbursed.
	• Initial Approval: 2 years
	• Renewal Approval: 5 years				

Criteria Updates Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Gilenya and generics (fingolimod)	0.5mg Cap	Various	DNP	E (SF)	VAR

Criteria	• For the treatment of patients with relapsing remitting multiple sclerosis (RRMS) who meet all of the following criteria:
	  ○ Ambulatory with or without aid (i.e. has a recent Expanded Disability Status Scale (EDSS) score of less than or equal to 6.5)
	  ○ Experienced one or more disabling relapses or new MRI activity in the past two years
	Clinical Note:
	• Treatment should be discontinued for patients with an EDSS score of greater than or equal to 7.
	Claim Notes:
	• Must be prescribed by a neurologist with experience in the diagnosis and management of multiple sclerosis.
	• Combined use with other disease modifying therapies to treat RRMS will not be reimbursed.
	• Initial Approval: 2 years
	• Renewal Approval: 5 years				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Glatect, Copaxone and generic (glatiramer acetate)	20mg PFS	Various	DNP	E (SF)	VAR
Criteria	**Effective June 1, 2025, patients currently receiving the originator drug product Copaxone (glatiramer acetate), will be required to transition to an alternate funded glatiramer acetate product by December 1, 2025.** **Glatiramer acetate-naïve patients whose therapy is initiated after June 1, 2020, will continue to be approved for an alternate funded glatiramer acetate product.** • For the treatment of patients with relapsing remitting multiple sclerosis (RRMS) or secondary progressive MS with clear superimposed relapses; who meet all of the following criteria: ○ Ambulatory with or without aid (i.e. has a recent Expanded Disability Status Scale (EDSS) score of less than or equal to 6.5) **Clinical Note:** • Treatment should be discontinued for patients with an EDSS score of greater than or equal to 7.				

Criteria Updates Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Glatect, Copaxone and generic (glatiramer acetate)	20mg PFS	Various	DNP	E (SF)	VAR
Criteria	**Claim Notes:** • Must be prescribed by a neurologist with experience in the diagnosis and management of multiple sclerosis. • Combined use with other disease modifying therapies to treat RRMS will not be reimbursed. • Initial Approval: 2 years • Renewal Approval: long term				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
INTERFERON BETA-1A AND INTERFERON BETA-1B	Various	Various	DNP	E (SF)	VAR
Criteria	• For the treatment of patients with relapsing remitting multiple sclerosis (RRMS) or secondary progressive MS with clear superimposed relapses; who meet all of the following criteria: ○ Ambulatory with or without aid (i.e. has a recent Expanded Disability Status Scale (EDSS) score of less than or equal to 6.5) **Clinical Note:** • Treatment should be discontinued for patients with an EDSS score of greater than or equal to 7. **Claim Notes:** • Must be prescribed by a neurologist with experience in the diagnosis and management of multiple sclerosis. • Combined use with other disease modifying therapies to treat RRMS will not be reimbursed. • Initial Approval: 2 years • Renewal Approval: long term				

Criteria Updates Continued…

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

Criteria	• For the treatment of adult patients with relapsing remitting multiple sclerosis (RRMS) who meet all of the following criteria:
	  ○ Ambulatory with or without aid (i.e. has a recent Expanded Disability Status Scale (EDSS) score of less than or equal to 6.5)
	  ○ Experienced one or more disabling relapses or new MRI activity in the past two years
	Clinical Note:
	• Treatment should be discontinued for patients with an EDSS score of greater than or equal to 7.
	Claim Notes:
	• Must be prescribed by a neurologist with experience in the diagnosis and management of multiple sclerosis.
	• Combined use with other disease modifying therapies to treat RRMS will not be reimbursed.
	• Initial Approval: 2 years
	• Renewal Approval: 5 years				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Mayzent (siponimod)	0.25mg Tab 2mg Tab	02496429 02496437	DNP DNP	E (SF) E (SF)	NVR NVR

Criteria	**Initiation Criteria:**
	• For the treatment of patients with active secondary progressive multiple sclerosis, who meet all the following criteria:
	  ○ a history of relapsing-remitting multiple sclerosis (RRMS)
	  ○ an Expanded Disability Status Scale (EDSS) score of 3.0 to 6.5
	  ○ documented EDSS progression during the two years prior to initiating treatment with siponimod
	Renewal Criteria:
	• Ongoing funding will be provided for those who continue to benefit from treatment and who have an Expanded Disability Status Scale (EDSS) score of 7.0 or less.
	Claims Notes:
	• The patient is under the care of a neurologist with experience in the diagnosis and management of multiple sclerosis.
	• Siponimod should not be used in combination with other disease-modifying treatments (DMTs) used to treat multiple sclerosis.				

Criteria Updates Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Mayzent (siponimod)	0.25mg Tab 2mg Tab	02496429 02496437	DNP DNP	E (SF) E (SF)	NVR NVR
Criteria	• Initial approval period: 2 years • Renewal approval period: 5 years				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Ocrevus (ocrelizumab)	300mg/10mL Vial 300mg/10mL Vial	02467224 00904527	DNP DNP	E (SF) E (SF)	HLR HLR

Criteria

Primary Progressive Multiple Sclerosis

- For the treatment of adult patients with early primary progressive multiple sclerosis (PPMS) who meet all of the following criteria:
    - Recent Expanded Disability Status Scale (EDSS) score equal to or less than 6.5
    - Recent Functional Systems Scale (FSS) score of at least 2 for the pyramidal functions component due to lower extremity findings
    - Disease duration of 10 years for those with an EDSS of less than or equal to 5 or disease duration less than 15 years for those with an EDSS greater than 5
    - Diagnostic imaging features characteristic of inflammatory activity

Clinical Note:

- Treatment should be discontinued for patients with an EDSS score of greater than or equal to 7.

Claim Notes:

- Must be prescribed by a neurologist with experience in the diagnosis and management of multiple sclerosis.
- Initial Approval: 2 years
- Renewal Approval: 5 years

Relapsing Remitting Multiple Sclerosis

- For the treatment of adult patients with relapsing remitting multiple sclerosis (RRMS) who meet all of the following criteria:
    - Experienced one or more disabling relapses or new MRI activity in the last two years
    - Ambulatory with or without aid (i.e. has a recent Expanded Disability Status Scale (EDSS) score of less than or equal to 6.5)

Clinical Note:

- Treatment should be discontinued for patients with an EDSS score of greater than or equal to 7.

Criteria Updates Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Ocrevus	300mg/10mL Vial	02467224	DNP	E (SF)	HLR
(ocrelizumab)	300mg/10mL Vial	00904527	DNP	E (SF)	HLR
Criteria	**Claim Notes:** • Must be prescribed by a neurologist with experience in the diagnosis and management of multiple sclerosis. • Combined use with other disease modifying therapies to treat RRMS will not be reimbursed. • Initial Approval: 2 years • Renewal Approval: 5 years				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Tecfidera and generics	120mg DR Cap	Various	DNP	E (SF)	VAR
(dimethyl fumarate)	240mg DR Cap	Various	DNP	E (SF)	VAR

Criteria	• For the treatment of adult patients with relapsing remitting multiple sclerosis (RRMS) who meet all of the following criteria:
	  ○ Ambulatory with or without aid (i.e. has a recent Expanded Disability Status Scale (EDSS) score of less than or equal to 6.5)
	  ○ Experienced one or more disabling relapses or new MRI activity in the past two years
	Clinical Note:
	• Treatment should be discontinued for patients with an EDSS score of greater than or equal to 7.
	Claim Notes:
	• Must be prescribed by a neurologist with experience in the diagnosis and management of multiple sclerosis.
	• Combined use with other disease modifying therapies to treat RRMS will not be reimbursed.
	• Initial Approval: 2 years
	• Renewal Approval: 5 years				

Criteria Updates Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Tysabri (natalizumab)	300mg/15mL Vial Inj	02286386	DNP	E (SF)	BIG

Criteria	• For the treatment of adult patients with relapsing remitting multiple sclerosis (RRMS) who meet all of the following criteria:
	  ○ Ambulatory with or without aid (i.e. has a recent Expanded Disability Status Scale (EDSS) score of less than or equal to 6.5)
	  ○ Experienced one or more disabling relapses or new MRI activity in the past two years
	  ○ Refractory or intolerant to at least one disease modifying therapy (e.g., interferon, glatiramer, dimethyl fumarate, teriflunomide, ocrelizumab)
	Renewal Criteria:
	• Evidence of continued benefit must be provided (i.e. stability or reduction in the number of relapses in the past year or stability or improvement of EDSS score obtained within the previous 90 days).
	Clinical Note:
	• Treatment should be discontinued for patients with an EDSS score of greater than or equal to 7.
	• A relapse is defined as the appearance of new or worsening neurological symptoms in the absence of fever or infection, lasting at least 24 hours yet preceded by stability for at least one month and accompanied by new objective neurological findings observed through evaluation by a neurologist.
	Claim Notes:
	• Must be prescribed by a neurologist with experience in the diagnosis and management of multiple sclerosis.
	• Combined use with other disease modifying therapies to treat RRMS will not be reimbursed.
	• Initial Approval: 2 years
	• Renewal Approval: 5 years				

Change in Benefit Status

The following products will be listed as full benefits, effective **June 1, 2025**.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Carbamazepine	100mg/5ml O/L	Various	DNP	SFC	VAR
Nitrofurantoin	100mg Cap	Various	DNPM	SFC	VAR

New Benefits

Effective **June 1, 2025,** the following products will be added as benefits in the Nova Scotia Formulary. The benefit status within the Pharmacare Programs is indicated and existing criteria applies.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Amb-Bisacodyl	10mg Supp	02520478	DNP	C	AMB
Bimzelx	320mg/2mL Prefilled Syringe	02553619	DNP	E (SF)	UCB
Bimzelx	320mg/2mL Autoinjector	02553627	DNP	E (SF)	UCB
Orgovyx	120mg Tab	02542137	DNP	SFC	SNV
Teva-Mirtazapine	15mg Tab	02541572	DNP	SFC	TEV

Legend

PRESCRIBER CODES	BENEFIT STATUS	MANUFACTURER CODES
D - Physician / Dentist	S - Seniors' Pharmacare	AMB - Ambicare
N - Nurse Practitioner	F - Community Services Pharmacare	BIG - Biogen Idec Canada Inc.
P - Pharmacist	- Family Pharmacare	BSL - Bausch Health, Canada Inc.
M - Midwife	C - Drug Assistance for Cancer Patients	EDO - Endo Ventures Ltd
O - Optometrist	D - Diabetes Assistance Program	FKB - Fresenius Kabi Canada
	E - Exception status applies	HLR - Hoffmann-LaRoche Limited
	G - Sensor-based Glucose Monitoring Program	JAZ - Jazz Pharmaceuticals Canada
		NVR - Novartis Pharmaceuticals Canada Inc.
		SNV - Sumitomo Pharma Canada Inc.
		TEV - Teva Canada Ltd.
		UCB - UCB Pharma Canada Inc.
		VAR - *various manufacturers*

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New Exception Status Products

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

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Vascepa (icosapent ethyl)	1g Cap	02495244	E (SF)	HLS

Criteria

To reduce the risk of cardiovascular events (cardiovascular death, non-fatal myocardial infarction, non-fatal stroke, coronary revascularization, or hospitalization for unstable angina) in statin-treated patients with elevated triglycerides, who meet all of the following criteria:

- Aged 45 years and older;
- Established cardiovascular disease (secondary prevention);
- Concomitantly treated with a statin;
- Have a fasting triglyceride of 1.7 mmol/L or greater and lower than 5.6 mmol/L at baseline, measured within the preceding three months before starting treatment with icosapent ethyl;
- Have a low-density lipoprotein cholesterol greater than 1.0 mmol/L and lower than 2.6 mmol/L at baseline and be receiving a maximally tolerated statin dose, targeted to achieve a low-density lipoprotein cholesterol lower than 2 mmol/L, for a minimum of four weeks.

Renewal Criteria:

- Patient continues to be treated with a maximally tolerated statin dose.

Claims Notes:

- Approvals will be for a maximum of 4 g daily
- Approvals: 12 months.

New Exception Status Products Continued…

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Velsipity (etrasimod)	2mg Tab	02544903	E (SF)	PFI

Criteria	• For the treatment of adult patients with moderately to severely active ulcerative colitis who have a partial Mayo score > 4, and a rectal bleeding subscore ≥ 2 and are:
	  ○ refractory or intolerant to conventional therapy (i.e. 5-ASA for a minimum of 4 weeks, and prednisone ≥ 40mg daily for two weeks or IV equivalent for one week); or
	  ○ corticosteroid dependent (i.e. cannot be tapered from corticosteroids without disease recurrence; or have relapsed within three months of stopping corticosteroids; or require two or more courses of corticosteroids within one year.)
	• Renewal requests must include information demonstrating the beneficial effects of the treatment, specifically:
	  ○ a decrease in the partial Mayo score ≥ 2 from baseline, and
	  ○ a decrease in the rectal bleeding subscore ≥1.
	Clinical Notes:
	• Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above.
	• Intolerant is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs. The nature of intolerance(s) must be clearly documented.
	• Patients with severe disease do not require a trial of 5-ASA.
	Claim Notes:
	• Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology.
	• Combined use of etrasimod with a biologic DMARD or JAK inhibitor will not be reimbursed.
	• Approvals will be for a maximum dose of 2 mg daily
	• Initial Approval: 6 months
	• Renewal Approval: 1 year			

New Exception Status Products Continued…

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Vyvgart (efgartigimod alfa)	Vyvgart 20mg/mL IV Inj	02541599	E (SF)	AGX

Criteria

For the treatment of adult patients with generalized myasthenia gravis (gMG) who have all the following:

- Positive serologic test for anti-AChR antibodies
- An MG-ADL score at baseline of ≥ 5
- MGFA class II to IV disease
- MG symptoms persist despite an adequate trial and stable dose of the below conventional therapies in the previous 12 months:
    - Acetylcholinesterase inhibitors (pyridostigmine) AND
    - Corticosteroids (prednisone) AND/OR nonsteroidal immunosuppressants (azathioprine, cyclosporine, mycophenolate mofetil, methotrexate or tacrolimus)

Exclusion criteria

Efgartigimod alfa should not be initiated:

- During a gMG exacerbation or crisis OR
- Within 3 months of thymectomy.

Renewal:

- Reimbursement of treatment with efgartigimod alfa should be continued if, after the initial 3 cycles of treatment, there is documented improvement in MG-ADL score of 2 points or greater.
- Reassessment should occur every 12 months thereafter.

Subsequent Renewal:

- The physician must provide proof of no worsening of MG-ADL score.

Claim Notes:

- MG-ADL score must be measured and provided by the physician at baseline.
- Efgartigimod alfa should be prescribed by or in consultation with a neurologist with expertise in managing patients with gMG.
- Efgartigimod alfa should not be used concomitantly with rituximab or complement inhibitors.
- Approvals will be for a dose of 10mg/kg up to a maximum of 1200 mg per infusion administered once weekly for 4 weeks (one treatment cycle)
- Initial Approval: The maximum duration of initial authorization is 3 treatment cycles
- Renewal Approval: 12 months

New Exception Status Products Continued…

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Wainua (eplontersen)	45mg/0.8mL Autoinjector	02548909	E (SF)	AZE
Criteria	For the treatment of polyneuropathy in adult patients with hereditary transthyretin-mediated amyloidosis (hATTR) who meet all of the following criteria: • Confirmed genetic diagnosis of hATTR. • Symptomatic with early-stage neuropathy[1]. • Does not have New York Heart Association class III or IV heart failure. • Has not previously undergone a liver transplant. **Discontinuation Criteria:** • The patient is permanently bedridden and dependent on assistance for basic activities of daily living. OR • The patient is receiving end-of-life care. **Clinical Note:** 1. Symptomatic early-stage neuropathy is defined as polyneuropathy disability stage I to IIIB or familial amyloidotic polyneuropathy stage I or II. **Claim Notes:** • The patient must be under the care of a physician with experience in the diagnosis and management of hATTR. • Combination therapy with other interfering ribonucleic acid drugs or transthyretin stabilizers used to treat hATTR will not be reimbursed. • Initial Approval: 9 months. • Renewal Approval: 12 months. Confirmation of continued response is required.			

Criteria Update

The following new indication has been added to existing criteria effective **July 1, 2025**.

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Cosentyx	150mg/mL Prefilled Pen	02438070	E (SF)	NVR
(Secukinumab)	150mg/mL Prefilled Syringe	02547724	E (SF)	NVR
	300mg Dose Kit	02438070	E (SF)	NVR
	300mg Dose Kit	02547724	E (SF)	NVR

Criteria

For the treatment of patients with active moderate to severe hidradenitis suppurativa (HS) who have not responded to conventional therapy and who meet all of the following criteria:

- A total abscess and nodule count of 3 or greater
- Lesions in at least two distinct anatomic areas, one of which must be Hurley Stage II or III
- An inadequate response to a 90-day trial of oral antibiotics

Initial renewal criteria:

- Requests for renewal should provide objective evidence of a treatment response, defined as at least a 50% reduction in abscess and inflammatory nodule count with no increase in abscess or draining fistula count relative to baseline at week 12.

Subsequent renewal criteria:

- Requests for renewal should provide objective evidence of the preservation of treatment effect (i.e. the current abscess and inflammatory nodule count and draining fistula count should be compared to the count prior to initiating treatment with secukinumab).

Claim Notes:

- Must be prescribed by a dermatologist or physician with experience in the treatment of HS.
- Combined use of more than one biologic DMARD will not be reimbursed.
- Approvals will be for 300mg given at weeks 0, 1, 2, 3, and 4, followed by monthly maintenance dosing. Based on clinical response, a maintenance dose of 300 mg every 2 weeks can be considered.
- Initial Approval: 6 months
- Renewal Approval: 1 year

New Benefit

Effective **July 1, 2025**, 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 applies.

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
JAMP Vitamin B12	1000mcg Tab	80015276	SE	JPC

Change in Benefit Status

The following products will be listed as full benefits effective **July 1, 2025**.

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Fluoxetine	20mg/5mL Syr	Various	SFC	VAR
MYA	3mg/0.02mg Tab	02415380	F	APX
Yaz	3mg/0.02mg Tab	02321157	F	BAY

Legend

BENEFIT STATUS

- S - Seniors' Pharmacare
- F - Community Services Pharmacare
  - Family Pharmacare
- C - Drug Assistance for Cancer Patients
- D - Diabetes Assistance Program
- E - Exception status applies
- G - Sensor-based Glucose Monitoring Program

MANUFACTURER CODES

- AGX - Argenx Canada Inc
- APX - Apotex Inc.
- AZE - AstraZeneca Canada Inc.
- BAY - Bayer Inc.
- JPC - Jamp Pharma Corporation
- HLS - HLS Therapeutics
- NVR - Novartis Pharmaceuticals Canada Inc.
- PFI - Pfizer Canada Inc.
- VAR - *various manufacturers*

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New Exception Status Products

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

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Uplizna (inebilizumab)	10mg/mL Vial	02543931	E (SF)	AGA

Criteria

Initiation:

- For the treatment of adult patients with neuromyelitis optica spectrum disorder (NMOSD) who meet all of the following criteria:
  - Anti-aquaporin-4 immunoglobulin G (AQP4-IgG) seropositive
  - Have had ≥ 1 attack in the prior 12 months or ≥ 2 attacks in the prior 2 years
  - Patients must have an EDSS score of 8 points or less

Renewal:

- The physician should measure and provide EDSS scores every 12 months after the initial authorization to determine if the continuation of inebilizumab reimbursement should occur.

Discontinuation:

- Reimbursement of inebilizumab treatment should be discontinued if the patient's EDSS score is greater than 8 points.

Claim Notes:

- Initial and renewal approval: 12 months
- The prescribing of inebilizumab for the treatment of NMOSD should be restricted to neurologists with expertise in treating NMOSD.

New Exception Status Products Continued…

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Uplizna (inebilizumab)	10mg/mL Vial	02543931	E (SF)	AGA
Criteria	• Inebilizumab should not be initiated during a NMOSD relapse episode. • Inebilizumab should not be reimbursed when used in combination with rituximab, satralizumab, eculizumab, or ravulizumab. • Approvals will be a for a maximum of 300 mg at 0 and 2 weeks and 300 mg every 6 months thereafter.			

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Lysodren (mitotane)	500mg Tab	00463221	C, E (SF)	MDU
Criteria	• For the treatment of advanced adrenocortical cancer. • For the treatment of metastatic adrenocortical cancer in combination with doxorubicin, etoposide, cisplatin.			

Criteria Update

The following new indication has been added to existing criteria effective **August 1, 2025**.

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Alecensaro (alectinib)	150mg Cap	02458136	E (SFC)	HLR
Criteria	**Early-Stage Non-Small Cell Lung Cancer** • For the adjuvant treatment of adult patients with resected ALK-positive non-small cell lung cancer (NSCLC) tumors that are ≥ 4cm and/or are locoregional lymph node positive with no distant spread of disease. **Clinical Notes:** • Treatment should continue until disease recurrence, unacceptable toxicity, or to a maximum of two years. • Patients will be eligible for ALK inhibitors in the advanced setting if disease recurrence occurs at least 6 months after the last dose of adjuvant alectinib. • Patients should have a good performance status.			

New Benefits

Effective **August 1, 2025,** the following products will be added as benefits in the Nova Scotia Formulary. The benefit status within the Pharmacare Programs is indicated and existing criteria applies.

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Brukinsa	160mg Tab	02554267	E (SFC)	BGN
FreeStyle Libre 3 Plus Sensor		97798966	E (SF), G	MID
Wezlana	45mg/0.5mL Prefilled Autoinjector	02553317	E (SF)	AGA
Wezlana	90mg/1.0mL Prefilled Autoinjector	02553309	E (SF)	AGA

Legend

BENEFIT STATUS	MANUFACTURER CODES
S - Seniors' Pharmacare	AGA - Amgen Canada Inc.
F - Community Services Pharmacare	BGN - BeOne Medicines (Canada) ULC
- Family Pharmacare	HLR - Hoffmann-LaRoche Limited
C - Drug Assistance for Cancer Patients	MDU - Medunik Canada Inc.
D - Diabetes Assistance Program	MID - Abbott Diabetes Care / Medisense
E - Exception status applies	
G - Sensor-based Glucose Monitoring Program	

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Nova Scotia Formulary Updates

Criteria and Benefit Status Updates for Chronic Obstructive Pulmonary Disease (COPD) and Asthma Inhalers

An Atlantic Common Drug Review (ACDR) of inhaler therapies for COPD has been completed. This review included:

- A comprehensive assessment of clinical evidence (meta-analyses, RCTs etc.).
- Consideration of the 2023 Canadian Thoracic Society Guideline COPD Pharmacotherapy in Patients with Stable COPD recommendations.
- Consultation with respiratory specialists in Atlantic Canada.

Following this review, the benefit status and criteria for coverage for inhalers used in COPD and asthma will be updated, effective September 1, 2025, as outlined below.

Key Changes to COPD Criteria:

- LAMA inhalers will move **to full benefit status** and no longer require exception status approval.
- LABA inhalers will be considered for patients who have failed or are intolerant to a LAMA inhaler.
- LABA/ICS inhalers will continue to be funded only as a component of triple therapy (LABA/ICS + LAMA) when criteria for triple therapy is met for patients who cannot use fixed dose triple therapy (Trelegy or Breztri).
- LABA/ICS inhalers will continue to be a benefit for patients with a diagnosis of overlapping asthma and COPD.
- Updated criteria for LAMA/LABA and LAMA/LABA/ICS inhalers are outlined below and will enable quicker access to therapy for patients with moderate to severe COPD.
- A new COPD exception status drug form has been created to reflect these changes and streamline requests for therapy.

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Criteria and Benefit Status Updates for Chronic Obstructive Pulmonary Disease (COPD) and Asthma Inhalers Continued…

Key Changes to Asthma Criteria:

- LABA inhalers will no longer be listed as benefits for the treatment of asthma as they are contraindicated for use as single entity agents.
- A new asthma exception status drug form has been created to account for these changes and to streamline requests for therapy.

LAMA Inhalers

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Spiriva Respimat	2.5mcg Inh	02435381	SF	BOE
Spiriva and Generic Brands	18mcg Cap for Inh	Various	SF	VAR
Tudorza Genuair	400mcg Pwr for Inh	02409720	SF	CPC
Seebri	50mcg Cap for Inh	02394936	SF	NVR
Incruse Ellipta	62.5mcg Pwr for Inh	02423596	SF	GSK

LABA Inhalers

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Serevent Diskus (salmeterol)	50mcg	02231129	E (SF)	GSK
Criteria	For the treatment of chronic obstructive pulmonary disease (COPD), as defined by spirometry, in patients who: • experience inadequate control while being treated with a long-acting muscarinic antagonist; OR • are intolerant to a long-acting muscarinic antagonist. ** **[Criteria Code 16]** has been added for use effective June 3, 2024. Criteria code 16 is for inhalers prescribed by a respirologist, clinical immunologist, allergist, internist, medical oncologist or thoracic surgeons. **Clinical Note:** • COPD is defined by spirometry as a post-bronchodilator FEV1/FVC ratio less than 0.7. Spirometry reports from any point in time will be accepted. If spirometry cannot be obtained, reasons must be clearly explained and other evidence of COPD severity provided (i.e. mMRC score and/or CAT score).			

Criteria and Benefit Status Updates for Chronic Obstructive Pulmonary Disease (COPD) and Asthma Inhalers Continued…

LAMA/LABA Inhalers

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Anoro Ellipta **(vilanterol and umeclidinium bromide)**	62.5/25mcg Pwr for Inh	02418401	E (SF)	GSK
Duaklir Genuair **(formoterol and aclidinium bromide)**	12/400mcg Pwr for Inh	02439530	E (SF)	CPC
Inspiolto Respimat **(olodaterol and tiotropium bromide)**	2.5/2.5mcg Inh	02441888	E (SF)	BOE
Ultibro Breezehaler **(indacaterol and glycopyrronium bromide)**	110/50mcg Cap for Inh	02418282	E (SF)	NVR
Criteria	For the treatment of chronic obstructive pulmonary disease (COPD), as defined by spirometry, in patients who: • have moderate to severe COPD (i.e. CAT score ≥ 10 or mMRC score ≥ 2); OR • have experienced an exacerbation in the previous year while on monotherapy i.e. long-acting beta-2 agonist (LABA) OR long-acting muscarinic antagonist (LAMA) ** **[Criteria Code 16]** has been added for use effective June 3, 2024. Criteria code 16 is for inhalers prescribed by a respirologist, clinical immunologist, allergist, internist, medical oncologist or thoracic surgeons. **Clinical Notes:** • COPD is defined by spirometry as a post-bronchodilator FEV1/FVC ratio less than 0.7. Spirometry reports from any point in time will be accepted. If spirometry cannot be obtained, reasons must be clearly explained and other evidence of COPD severity provided (i.e. mMRC score and/or CAT score). • LAMA/LABA combinations are not intended to be used with an inhaled corticosteroid (ICS) unless criteria for triple inhaled therapy (LAMA/LABA/ICS) is met and the patient is unable to use fixed dose triple therapy options (Trelegy 100-62.5-25 mcg or Breztri 160-7.2-5 mcg).			

Criteria and Benefit Status Updates for Chronic Obstructive Pulmonary Disease (COPD) and Asthma Inhalers Continued...

LABA/ICS Inhalers

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Advair Diskus and Generic Brands (salmeterol and fluticasone)	50/100mcg	Various	E (SF)	VAR
Advair Diskus and Generic Brands (salmeterol and fluticasone)	50/250mcg	Various	E (SF)	VAR
Advair Diskus and Generic Brands (salmeterol and fluticasone)	50/500mcg	Various	E (SF)	VAR
Advair HFA (salmeterol and fluticasone)	25/125mcg Inh	02245126	E (SF)	GSK
Advair HFA (salmeterol and fluticasone)	25/250mcg Inh	02245127	E (SF)	GSK
Atectura Breezhaler (indacaterol and mometasone)	150/80mcg Cap	02498685	E (SF)	VAL
Atectura Breezhaler (indacaterol and mometasone)	150/160mcg Cap	02498707	E (SF)	VAL
Atectura Breezhaler (indacaterol and mometasone)	150/320mcg Cap	02498693	E (SF)	VAL
Breo Ellipta (vilanterol and fluticasone furoate)	100/25mcg Pwr for Inh	02408872	E (SF)	GSK
Breo Ellipta (vilanterol and fluticasone furoate)	200/25mcg Pwr for Inh	02444186	E (SF)	GSK
Symbicort Turbuhaler (formoterol and budesonide)	100/6mcg	02245385	E (SF)	AZE

Criteria and Benefit Status Updates for Chronic Obstructive Pulmonary Disease (COPD) and Asthma Inhalers Continued…

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Symbicort Turbuhaler (formoterol and budesonide)	200/6mcg	02245386	E (SF)	AZE
Zenhale (formoterol and mometasone)	5/100mcg Inh	02361752	E (SF)	ORG
Zenhale (formoterol and mometasone)	5/200mcg Inh	02361760	E (SF)	ORG

Criteria

Asthma

For the treatment of asthma in patients who:

- are compliant with optimal doses of inhaled corticosteroids; AND
- remain poorly controlled.

** **[Criteria Code 16]** has been added for use effective June 3, 2024. Criteria code 16 is for inhalers prescribed by a respirologist, clinical immunologist, allergist, internist, medical oncologist or thoracic surgeons.

Clinical Notes:

- Poorly controlled asthma is defined by the presence of persistent symptoms (such as frequent daytime symptoms, nighttime awakenings, activity limitations, increased use of short-acting beta2-agonists, and/or frequent exacerbations) indicating the need for additional symptom management.

Products and Strengths Approved:

Atectura	• 150mcg/80mcg, 150mcg/160mcg and 150mcg/320mcg Capsule for Inhalation
Advair and generic brands	• 50/100mcg, 50/250mcg and 50/500mcg Diskus • HFA 25/125 mcg/dose • HFA 25/250 mcg/dose Inhaler
Breo Ellipta	• 100mcg/25mcg and 200mcg/25mcg dry powder for inhalation
Symbicort	• 100/6mcg Turbuhaler • 200/6mcg Turbuhaler
Zenhale	• 5/100mcg and 5/200mcg

Criteria and Benefit Status Updates for Chronic Obstructive Pulmonary Disease (COPD) and Asthma Inhalers Continued…

Criteria

Overlapping Asthma and Chronic Obstructive Pulmonary Disease

For the treatment of patients with asthma and chronic obstructive pulmonary disease (ACO) overlap, based on patient history and lung function studies indicating an ACO diagnosis.

- Please provide details to support the ACO diagnosis (patient symptoms, risk factors, spirometry etc.).

**** [Criteria Code 16]** has been added for use effective June 3, 2024. Criteria code 16 is for inhalers prescribed by a respirologist, clinical immunologist, allergist, internist, medical oncologist or thoracic surgeons.

Products and Strengths Approved:

Advair and generic brands	• 50/100mcg Diskus • 50/250mcg Diskus • 50/500mcg Diskus
Breo Ellipta	• 100mcg/25mcg dry powder for inhalation
Symbicort	• 100/6mcg Turbuhaler • 200/6mcg Turbuhaler

Chronic Obstructive Pulmonary Disease

For the treatment of chronic obstructive pulmonary disease (COPD), as defined by spirometry, in combination with a long-acting muscarinic antagonist (LAMA), for patients who:

- meet criteria for triple therapy (LAMA/LABA/ICS); AND
- are unable to use fixed dose triple therapy options (Trelegy 100-62.5-25 mcg or Breztri 160-7.2-5 mcg).

**** [Criteria Code 16]** has been added for use effective June 3, 2024. Criteria code 16 is for inhalers prescribed by a respirologist, clinical immunologist, allergist, internist, medical oncologist or thoracic surgeons.

Clinical Note:

- COPD is defined by spirometry as a post-bronchodilator FEV1/FVC ratio less than 0.7. Spirometry reports from any point in time will be accepted. If spirometry cannot be obtained, reasons must be clearly explained and other evidence of COPD severity provided (i.e. mMRC score and/or CAT score).

Products and Strengths Approved:

Advair and generic brands	• 50/100mcg Diskus • 50/250mcg Diskus • 50/500mcg Diskus
Breo Ellipta	• 100mcg/25mcg dry powder for inhalation
Symbicort	• 100/6mcg Turbuhaler • 200/6mcg Turbuhaler

Criteria and Benefit Status Updates for Chronic Obstructive Pulmonary Disease (COPD) and Asthma Inhalers Continued…

LAMA/LABA/ICS Inhalers

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Breztri Aerosphere Inh (formoterol, glycopyrronium bromide and budesonide)	160/7.2/5mcg	02518058	E (SF)	AZE
Trelegy Pwr for Inh (vilanterol, umeclidinium bromide and fluticasone furoate)	100/62.5/25mcg	02474522	E (SF)	GSK
Criteria	For the treatment of chronic obstructive pulmonary disease (COPD), as defined by spirometry, for patients who • have experienced two or more exacerbations of COPD requiring treatment with antibiotics and/or systemic corticosteroids; OR • at least one exacerbation of COPD requiring hospitalization or an emergency department visit; OR • have moderate symptom burden (i.e. CAT score ≥ 10 or mMRC score ≥ 2) despite treatment with dual therapy with a long-acting muscarinic antagonist plus a long-acting beta2-agonist (LAMA/LABA) or a long-acting beta2-agonist plus an inhaled corticosteroid (LABA/ICS). ** **[Criteria Code 16]** has been added for use effective June 3, 2024. Criteria code 16 is for inhalers prescribed by a respirologist, clinical immunologist, allergist, internist, medical oncologist or thoracic surgeons. **Clinical Note:** • COPD is defined by spirometry as a post-bronchodilator FEV1/FVC ratio less than 0.7. Spirometry reports from any point in time will be accepted. If spirometry cannot be obtained, reasons must be clearly explained and other evidence of COPD severity provided (i.e. mMRC score and/or CAT score).			

New Exception Status Benefits

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

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Apretude	30mg Tab	02547465	E (SF)	VIV
(cabotegravir)	600mg/3mL Vial	02547473	E (SF)	VIV
Criteria	• For individuals aged 12 years and older, weighing at least 35 kg, who are considered at risk of acquiring HIV-1 infection as defined by clinical guidelines, for use as pre-exposure prophylaxis (PrEP) to reduce the risk of acquiring HIV-1 infection. **Clinical Notes:** • PrEP should be part of a combination prevention strategy that includes behavioural interventions such as condoms and risk reduction counseling. • PrEP is not recommended for clinical use where there is no or negligible risk of transmissible HIV-1. **Claim Notes:** • Oral tablets are approved for short term use as lead-in therapy or as bridge therapy in the event of a missed injection.			

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Imcivree	10mg/mL Vial	02537745	E (SF)	RYT
(setmelanotide)				
Criteria	For weight management in adult and pediatric patients 6 years of age and older with obesity due to clinically or genetically confirmed Bardet-Biedl syndrome (BBS). **Initial Renewal Criteria:** The physician must provide proof of beneficial clinical effect, including: • at least a 5% reduction in BMI or total body weight in patients who are at least 12 years of age, OR • a reduction in BMI Z score that is considered clinically beneficial by the treating physician as appropriate for patients who are 6 to 11 years of age. **Subsequent Renewal Criteria:** The physician must provide proof that the initial response achieved after the first 26 weeks of therapy with setmelanotide has been maintained, including: • maintenance of BMI or total body weight, OR • maintenance of BMI Z score. **Clinical Notes:** • Obesity is defined as BMI ≥ 30 for patients aged ≥ 16 years, or weight > 97th percentile for age and sex in patients aged < 16 years. • Clinical diagnosis of BBS is to be based on the Beales criteria.			

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Imcivree (setmelanotide)	10mg/mL Vial	02537745	E (SF)	RYT
Criteria	**Claim Notes:** • Initial approval: 26 weeks • Renewal approval: 1 year • The patient must be under the care of an endocrinologist, pediatric endocrinologist, and/or specialist in weight management or obesity. • Approvals will be for a maximum of 2.0 mg daily for patients aged 6 to 17 years old and up to 3.0 mg daily for patients aged 18 years and older.			

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Livmarli (maralixibat)	9.5mg/mL Oral Sol	02539888	E (SF)	MMP

Criteria	For treatment of patients aged 12 months and older with a diagnosis of Alagille syndrome (ALGS) who have demonstrated the following:
	• Evidence of cholestasis (must include at least 1 of the following):
	  ○ total serum bile acid (sBA) > 3 × ULN for age
	  ○ conjugated bilirubin > 1 mg/dL
	  ○ fat-soluble vitamin deficiency otherwise unexplainable
	  ○ GGT > 3 × ULN for age
	  ○ intractable pruritus explainable only by liver disease
	• Moderate to severe itch defined as an average daily score of 2 or more on the ItchRO or CSS for 2 consecutive weeks.
	• Currently treated with, or have received an adequate trial with, a systemic treatment for pruritus before initiating maralixibat.
	Exclusion Criteria:
	Patients with biliary diversion, previous liver transplant, decompensated cirrhosis, or history or presence of other concomitant liver disease.
	Renewal Criteria:
	• Requests for renewal must provide proof of beneficial clinical effect defined as an improvement in pruritus to minimal or no itch (a score of 1 or less) on the ItchRO or CSS.
	• For patients who begin treatment with severe itch (equivalent to an ItchRO or CSS score of 4), an improvement in pruritus by a score of 1 will be considered for coverage renewal.			

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Livmarli (maralixibat)	9.5mg/mL Oral Sol	02539888	E (SF)	MMP
Criteria	**Discontinuation Criteria:** • Reimbursement of maralixibat will be discontinued if the patient receives liver transplantation or biliary diversion surgery. **Clinical Notes:** An adequate trial for systemic treatment of pruritus is defined as a trial of 1 to 3 months with appropriate dosing of a systemic treatment for pruritus based on usual care. This may include UDCA, rifampicin, sertraline, naltrexone, cholestyramine, or antihistamines. **Claim Notes:** • Initial approval duration: 6 months • Renewal approval duration: 1 year • The patient should be under the care of a hepatologist with experience in managing ALGS. • Approvals will be for a maximum of 28.5 mg (3 mL) daily.			

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Myalepta (metreleptin)	3mg Vial	02544555	E (SF)	MDP
	5.8mg Vial	02544563	E (SF)	MDP
	11.3mg Vial	02544571	E (SF)	MDP

Criteria	For the treatment of patients with either of the following:
	• Confirmed congenital generalized lipodystrophy (GL) (Berardinelli-Seip syndrome) or acquired GL (Lawrence syndrome) in adults and children aged 2 years and older with at least 1 metabolic abnormality (diabetes mellitus, insulin resistance, or hypertriglyceridemia).
	• Confirmed familial partial lipodystrophy (PL) or acquired PL (Barraquer-Simons syndrome) in adults and children aged 12 years and older with persistent significant metabolic abnormalities (as defined by baseline hemoglobin A1C ≥ 6.5% and/or fasting TGs ≥ 5.65 mmol/L), for whom standard treatments have failed to achieve adequate metabolic control after at least 12 months since initiating standard treatments.
	• Genetic testing must be conducted and:
	  ○ If genetic testing is positive, then diagnosis is confirmed and treatment with metreleptin can be initiated.
	  ○ If after conducting genetic testing lipodystrophy is not confirmed, treatment can be initiated in patients with confirmed clinical diagnosis based on a comprehensive clinician assessment and if fasting leptin			

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Myalepta	3mg Vial	02544555	E (SF)	MDP
(metreleptin)	5.8mg Vial	02544563	E (SF)	MDP
	11.3mg Vial	02544571	E (SF)	MDP
Criteria	levels are < 12.0 ng/mL in females and < 8.0 ng/mL in males older than 5 years of age or < 6 ng/mL in children aged 6 months to 5 years. **Exclusion Criteria:** Patients should not be pregnant or lactating or have HIV-associated LD. **Initial Renewal Criteria:** The prescriber must provide proof of beneficial metabolic effect defined as 1 or both of the following: • Actual hemoglobin A1C reduction of at least 0.5% from baseline. • Percent fasting TG reduction of at least 15% from baseline. **Subsequent Renewal Criteria:** The prescriber must provide proof of maintenance of reduction in hemoglobin A1C and/or fasting TG from baseline every 12 months for subsequent authorizations. **Clinical Notes:** • A1C and/or fasting TG levels must be provided. **Claim Notes:** • Initial and renewal approval duration: 12 months • Prescribing should be limited to endocrinologists or pediatric endocrinologists with expertise in treating lipodystrophy. • Approvals will be for a maximum dose of 0.13 mg/kg daily for patients ≤40kg and 10mg daily for patients >40 kg.			

New Exception Status Benefits Continued…

Effective **September 1, 2025,** the following anti-vascular endothelial growth factor (VEGF) drugs will be added to the Pharmacare Formulary and can be administered by a community ophthalmologist and dispensed by a community pharmacy.

Please note, existing coverage through current means (i.e., hospital-based or previously designated clinics) will remain an available option.

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Byooviz (ranibizumab)	10mg/mL Inj	02525852	E (SF)	BIG

Criteria	**Active (Wet) Age-Related Macular Degeneration**
	For the treatment of patients with neovascular (wet) age-related macular degeneration (AMD) who meet all of the following criteria:
	• Best Corrected Visual Acuity (BCVA) is greater than 6/96
	• The lesion size is ≤ 12 disc areas in greatest linear dimension
	• There is evidence of recent (<3 months) presumed disease progression [blood vessel growth, as indicated by fluorescein angiography, optical coherence tomography (OCT), or recent visual acuity changes]
	• There is active disease activity and no permanent structural damage to the central fovea (as defined in the Royal College of Ophthalmologists guidelines)
	Renewal Criteria:
	• Patients must meet all of the following criteria:
	  ○ Evidence of continued disease activity.
	  ○ Maintaining adequate response to therapy.
	  ○ Absolute BCVA maintained above 6/120.
	  ○ Reductions in BCVA of < 6 lines compared to either baseline and/or best recorded level since baseline.
	Claim Notes:
	• Must be prescribed and administered by a retina specialist or an ophthalmologist with experience in administering intravitreal injections.
	• Will not be insured in combination with other anti-VEGF drugs for ophthalmic use.
	• Approvals will be for a maximum of 1 vial per eye every 30 days.
	• Approval period: 1 year. Confirmation of continued response is required.
	Diabetic Macular Edema
	For the treatment of patients with diabetic macular edema (DME) who meet the following criteria:
	• Clinically significant center-involving macular edema
	• Best Corrected Visual Acuity (BCVA) is greater than 6/120			

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Byooviz (ranibizumab)	10mg/mL Inj	02525852	E (SF)	BIG

Criteria	**Renewal Criteria:**
	• Patient must meet all of the following criteria:
	  ○ Evidence of continued disease activity.
	  ○ Maintaining adequate response to therapy.
	  ○ Absolute BCVA maintained above 6/120.
	  ○ Reductions in BCVA of < 6 lines compared to either baseline and/or best recorded level since baseline.
	Claim Notes:
	• Must be prescribed and administered by a retina specialist or an ophthalmologist with experience in administering intravitreal injections.
	• Will not be insured in combination with other anti-VEGF drugs for ophthalmic use.
	• Approvals will be for a maximum of 1 vial per eye every 30 days.
	• Approval period: 1 year. Confirmation of continued response is required.
	Retinal Vein Occlusion
	For the treatment of patients with clinically significant center-involving macular edema secondary to non-ischemic branch retinal vein occlusion (BRVO), or central retinal vein occlusion (CRVO) who meet the following criteria:
	• Best Corrected Visual Acuity (BCVA) is greater than 6/120
	Renewal Criteria:
	• Patient must meet all of the following criteria:
	  ○ Evidence of continued disease activity.
	  ○ Maintaining adequate response to therapy.
	  ○ Absolute BCVA maintained above 6/120.
	  ○ Reductions in BCVA of <6 lines compared to either baseline and/or best recorded level since baseline.
	Claim Notes:
	• Must be prescribed and administered by a retina specialist or an ophthalmologist with experience in administering intravitreal injections.
	• Will not be insured in combination with other anti-VEGF drugs for ophthalmic use.
	• Approvals will be for a maximum of 1 vial per eye every 30 days.
	• Approval period: 1 year. Confirmation of continued response is required.			

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Eylea (aflibercept)	2mg/0.05mL Vial	02415992	E (SF)	BAY

Criteria	**Active (Wet) Age-Related Macular Degeneration**
	• For the treatment of patients with neovascular (wet) age-related macular degeneration (AMD) who meet all of the following criteria:
	  ○ Best Corrected Visual Acuity (BCVA) is greater than 6/96
	  ○ The lesion size is ≤ 12 disc areas in greatest linear dimension
	  ○ There is evidence of recent (<3 months) presumed disease progression [blood vessel growth, as indicated by fluorescein angiography, optical coherence tomography (OCT), or recent visual acuity changes]
	  ○ There is active disease activity and no permanent structural damage to the central fovea (as defined in the Royal College of Ophthalmologists guidelines)
	Renewal Criteria:
	• Patient must meet all of the following criteria:
	  ○ Evidence of continued disease activity
	  ○ Maintaining adequate response to therapy
	  ○ Absolute BCVA maintained above 6/120
	  ○ Reductions in BCVA of < 6 lines compared to either baseline and/or best recorded level since baseline
	Claim Notes:
	• Must be prescribed and administered by a retina specialist or an ophthalmologist with experience in administering intravitreal injections.
	• Will not be insured in combination with other anti-VEGF drugs for ophthalmic use.
	• Approvals will be for a maximum of 1 vial per eye every 30 days.
	• Approval period: 1 year. Confirmation of continued response is required.
	Diabetic Macular Edema
	For the treatment of patients with diabetic macular edema (DME) who meet the following criteria:
	• Clinically significant center-involving macular edema
	• Best Corrected Visual Acuity (BCVA) is greater than 6/120
	Renewal Criteria:
	• Patient must meet all of the following criteria:
	  ○ Evidence of continued disease activity
	  ○ Maintaining adequate response to therapy			

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Eylea (aflibercept)	2mg/0.05mL Vial	02415992	E (SF)	BAY
Criteria	○ Absolute BCVA maintained above 6/120 ○ Reductions in BCVA of < 6 lines compared to either baseline and/or best recorded level since baseline. **Claim Notes:** • Must be prescribed and administered by a retina specialist or an ophthalmologist with experience in administering intravitreal injections. • Will not be insured in combination with other anti-VEGF drugs for ophthalmic use. • Approvals will be for a maximum of 1 vial per eye every 30 days. • Approval period: 1 year. Confirmation of continued response is required. **Retinal Vein Occlusion** For the treatment of patients with clinically significant center-involving macular edema secondary to non-ischemic branch retinal vein occlusion (BRVO), or central retinal vein occlusion (CRVO) who meet the following criteria: • Best Corrected Visual Acuity (BCVA) is greater than 6/120 **Renewal Criteria:** • Patient must meet all of the following criteria: ○ Evidence of continued disease activity ○ Maintaining adequate response to therapy ○ Absolute BCVA maintained above 6/120 ○ Reductions in BCVA of <6 lines compared to either baseline and/or best recorded level since baseline **Claim Notes:** • Must be prescribed and administered by a retina specialist or an ophthalmologist with experience in administering intravitreal injections. • Will not be insured in combination with other anti-VEGF drugs for ophthalmic use. • Approvals will be for a maximum of 1 vial per eye every 30 days. • Approval period: 1 year. Confirmation of continued response is required.			

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Eylea HD (aflibercept)	8mg/0.07mL Vial	02545004	E (SF)	BAY

Criteria	**Active Wet Age-Related Macular Degeneration**
	For the treatment of adult patients with neovascular (wet) Age-Related Macular Degeneration (nAMD) who meet all of the following criteria:
	• treatment **naive** to anti-VEGF drugs for nAMD
	• Best Corrected Visual Acuity (BCVA) is greater than 6/96
	• The lesion size is ≤ 12 disc areas in greatest linear dimension
	• There is evidence of recent (<3 months) presumed disease progression [blood vessel growth, as indicated by fluorescein angiography, optical coherence tomography (OCT), or recent visual acuity changes]
	• There is active disease activity and no permanent structural damage to the central fovea (as defined in the Royal College of Ophthalmologists guidelines)
	Renewal Criteria:
	• Patients must meet all of the following criteria:
	  ○ Able to be maintained on a 12-week or greater interval between injections
	  ○ Evidence of continued disease activity.
	  ○ Maintaining adequate response to therapy.
	  ○ Absolute BCVA maintained above 6/120.
	  ○ Reductions in BCVA of < 6 lines compared to either baseline and/or best recorded level since baseline.
	Claim Notes:
	• Must be prescribed and administered by a retina specialist or an ophthalmologist with experience in administering intravitreal injections.
	• Will not be insured in combination with other anti-VEGF drugs for ophthalmic use.
	• Approvals will be for 1 vial per eye every 30 days for the first 3 doses, followed by 1 vial per eye every 12 to 16 weeks.
	• Approval period: 1 year. Confirmation of continued response is required.
	Diabetic Macular Edema
	For the treatment of adult patients with diabetic macular edema who meet all of the following criteria:
	• Clinically significant center-involving macular edema
	• Best Corrected Visual Acuity (BCVA) is greater than 6/120			

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Eylea HD (aflibercept)	8mg/0.07mL Vial	02545004	E (SF)	BAY

Criteria	**Renewal Criteria:**
	• Patients must meet all of the following criteria:
	  ○ Able to be maintained on a 12-week or greater interval between injections.
	  ○ Evidence of continued disease activity.
	  ○ Maintaining adequate response to therapy.
	  ○ Absolute BCVA maintained above 6/120.
	  ○ Reductions in BCVA of < 6 lines compared to either baseline and/or best recorded level since baseline.
	Claim Notes:
	• Must be prescribed and administered by a retina specialist or an ophthalmologist with experience in administering intravitreal injections.
	• Will not be insured in combination with other anti-VEGF drugs for ophthalmic use.
	• Approvals will be for 1 vial per eye every 30 days for the first 3 doses, followed by 1 vial per eye every 12 to 16 weeks.
	• Approval period: 1 year. Confirmation of continued response is required.			

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Ranopto (ranibizumab)	10mg/mL Inj	02542250	E (SF)	TEV
Criteria	**Active (Wet) Age-Related Macular Degeneration** For the treatment of patients with neovascular (wet) age-related macular degeneration (AMD) who meet all of the following criteria: • Best Corrected Visual Acuity (BCVA) is greater than 6/96 • The lesion size is ≤ 12 disc areas in greatest linear dimension • There is evidence of recent (<3 months) presumed disease progression [blood vessel growth, as indicated by fluorescein angiography, optical coherence tomography (OCT), or recent visual acuity changes] • There is active disease activity and no permanent structural damage to the central fovea (as defined in the Royal College of Ophthalmologists guidelines)			

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Ranopto (ranibizumab)	10mg/mL Inj	02542250	E (SF)	TEV

Criteria	**Renewal Criteria:**
	• Patients must meet all of the following criteria:
	  ○ Evidence of continued disease activity.
	  ○ Maintaining adequate response to therapy.
	  ○ Absolute BCVA maintained above 6/120.
	  ○ Reductions in BCVA of < 6 lines compared to either baseline and/or best recorded level since baseline.
	Claim Notes:
	• Must be prescribed and administered by a retina specialist or an ophthalmologist with experience in administering intravitreal injections.
	• Will not be insured in combination with other anti-VEGF drugs for ophthalmic use.
	• Approvals will be for a maximum of 1 vial per eye every 30 days.
	• Approval period: 1 year. Confirmation of continued response is required.
	Diabetic Macular Edema
	For the treatment of patients with diabetic macular edema (DME) who meet the following criteria:
	• Clinically significant center-involving macular edema
	• Best Corrected Visual Acuity (BCVA) is greater than 6/120
	Renewal Criteria:
	• Patient must meet all of the following criteria:
	  ○ Evidence of continued disease activity.
	  ○ Maintaining adequate response to therapy.
	  ○ Absolute BCVA maintained above 6/120.
	  ○ Reductions in BCVA of < 6 lines compared to either baseline and/or best recorded level since baseline.
	Claim Notes:
	• Must be prescribed and administered by a retina specialist or an ophthalmologist with experience in administering intravitreal injections.
	• Will not be insured in combination with other anti-VEGF drugs for ophthalmic use.
	• Approvals will be for a maximum of 1 vial per eye every 30 days.
	• Approval period: 1 year. Confirmation of continued response is required.			

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Ranopto (ranibizumab)	10mg/mL Inj	02542250	E (SF)	TEV
Criteria	**Retinal Vein Occlusion** For the treatment of patients with clinically significant center-involving macular edema secondary to non-ischemic branch retinal vein occlusion (BRVO), or central retinal vein occlusion (CRVO) who meet the following criteria: • Best Corrected Visual Acuity (BCVA) is greater than 6/120 **Renewal Criteria:** • Patient must meet all of the following criteria: ○ Evidence of continued disease activity. ○ Maintaining adequate response to therapy. ○ Absolute BCVA maintained above 6/120. ○ Reductions in BCVA of <6 lines compared to either baseline and/or best recorded level since baseline. **Claim Notes:** • Must be prescribed and administered by a retina specialist or an ophthalmologist with experience in administering intravitreal injections. • Will not be insured in combination with other anti-VEGF drugs for ophthalmic use. • Approvals will be for a maximum of 1 vial per eye every 30 days. • Approval period: 1 year. Confirmation of continued response is required.			

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Vabysmo (faricimab)	6mg/0.05mL Vial	02527618	E (SF)	HLR
	6mg/0.05mL Prefilled Syringe	02554003	E (SF)	HLR
Criteria	**Active (Wet) Age-Related Macular Degeneration** For the treatment of patients with neovascular (wet) age-related macular degeneration (AMD) who meet all of the following criteria: • Best Corrected Visual Acuity (BCVA) is greater than 6/96 • The lesion size is ≤12 disc areas in greatest linear dimension • There is evidence of recent (<3 months) presumed disease progression [blood vessel growth, as indicated by fluorescein angiography, optical coherence tomography (OCT), or recent visual acuity changes]			

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Vabysmo	6mg/0.05mL Vial	02527618	E (SF)	HLR
(faricimab)	6mg/0.05mL Prefilled Syringe	02554003	E (SF)	HLR
Criteria	• There is active disease activity and no permanent structural damage to the central fovea (as defined in the Royal College of Ophthalmologists guidelines) **Renewal Criteria:** • Patients must meet all of the following criteria: o Evidence of continued disease activity o Maintaining adequate response to therapy o Absolute BCVA maintained above 6/120 o Reductions in BCVA of < 6 lines compared to either baseline and/or best recorded level since baseline. **Claim Notes:** • Must be prescribed and administered by a retina specialist or an ophthalmologist with experience in administering intravitreal injections. • Approvals will be for a maximum of 1 vial per eye every 4 weeks for 16 weeks, followed by 1 vial per eye every 8 weeks thereafter. • Approval period: 1 year. Confirmation of continued response is required. **Diabetic Macular Edema** For the treatment of patients with diabetic macular edema (DME) who meet the following criteria: • Clinically significant center-involving macular edema • Best Corrected Visual Acuity (BCVA) is greater than 6/120 **Renewal Criteria:** • Patients must meet all of the following criteria: o Evidence of continued disease activity o Maintaining adequate response to therapy o Absolute BCVA maintained above 6/120 o Reductions in BCVA of < 6 lines compared to either baseline and/or best recorded level since baseline. **Claim Notes:** • Must be prescribed and administered by a retina specialist or an ophthalmologist with experience in administering intravitreal injections. Approvals will be for a maximum of 1 vial per eye every 4 weeks. • Approval period: 1 year. Confirmation of continued response is required.			

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Vabysmo	6mg/0.05mL Vial	02527618	E (SF)	HLR
(faricimab)	6mg/0.05mL Prefilled Syringe	02554003	E (SF)	HLR
Criteria	**Retinal Vein Occlusion** For the treatment of patients with clinically significant center-involving macular edema secondary to non-ischemic branch retinal vein occlusion (BRVO), or central retinal vein occlusion (CRVO) who meet the following criteria: • Best Corrected Visual Acuity (BCVA) is greater than 6/120 **Renewal Criteria:** • Patients must meet all of the following criteria: o Evidence of continued disease activity o Maintaining adequate response to therapy o Absolute BCVA maintained above 6/120 o Reductions in BCVA of <6 lines compared to either baseline and/or best recorded level since baseline **Claim Notes:** • Must be prescribed and administered by a retina specialist or an ophthalmologist with experience in administering intravitreal injections. • Approvals will be for a maximum of 1 vial per eye every 4 weeks. • Approval period: 1 year. Confirmation of continued response is required.			

Criteria Updates

The following new indication has been added to existing criteria effective **September 1, 2025**.

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Xtandi	40mg Cap	02407329	E (SFC)	ASL
(enzalutamide)				
Criteria	**Non-Metastatic Castration-Sensitive Prostate Cancer** For the treatment of patients with non-metastatic castration-sensitive prostate cancer (nmCSPC) with biochemical recurrence at high risk for metastasis after radical prostatectomy or radiation, with or without androgen deprivation therapy (ADT). **Clinical Notes:** • Patients should meet all of the following: o PSA doubling time of ≤9 months o PSA level ≥1 mcg/mL if prior radical prostatectomy (with or without radiation) or ≥2 mcg/mL above nadir in prior radiation			

Criteria Updates Continued…

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Xtandi (enzalutamide)	40mg Cap	02407329	E (SFC)	ASL
Criteria	○ Testosterone ≥5.2 nmol/L (150 mg/dl) ○ No evidence of metastases on conventional imaging. ○ Not a candidate for salvage radiation • Patients should have a good performance status. • Treatment should continue until progression or unacceptable toxicity. Enzalutamide should be held after 36 weeks if PSA is suppressed to ≤0.2mcg/mL and may be restarted based on PSA level. For patients with no prior radical prostatectomy, the PSA level threshold to restart treatment is ≥5 mcg/mL. For patients with prior radical prostatectomy, the PSA level threshold to restart treatment is ≥2 mcg/mL.			

The following criteria has been updated and will replace existing criteria effective **September 1, 2025**

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Emtricitabine and Tenofovir Disoproxil	200mg/300mg Tab	02452006	E (SF)	APX
	200mg/300mg Tab	02490684	E (SF)	ARO
	200mg/300mg Tab	02487012	E (SF)	JPC
	200mg/300mg Tab	02521547	E (SF)	MNT
	200mg/300mg Tab	02443902	E (SF)	MYL
	200mg/300mg Tab	02461110	E (SF)	PMS
	200mg/300mg Tab	02399059	E (SF)	TEV
	200mg/300mg Tab	02274906	E (SF)	GIL
Criteria	• For individuals who are considered at risk of acquiring HIV-1 infection as defined by clinical guidelines, for use as pre-exposure prophylaxis (PrEP) to reduce the risk of acquiring HIV-1 infection. **Clinical Notes:** • PrEP should be part of a combination prevention strategy that includes behavioural interventions such as condoms and risk reduction counseling. • PrEP is not recommended for clinical use where there is no or negligible risk of transmissible HIV-1.			

Change in Benefit Status

Effective **September 1, 2025,** the following products will move to full benefit and no longer require exception status approval.

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Betahistine	16mg Tab	Various	SF	VAR
Betahistine	24mg Tab	Various	SF	VAR

New Benefits

Effective **September 1, 2025,** the following products will be added as benefits in the Nova Scotia Formulary. The benefit status within the Pharmacare Programs is indicated and existing criteria applies.

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Cyanocobalamin	1000mcg/mL Inj	02465507	E (SFC)	HIK
Vemlidy	25mg Tab	02464241	SF	GIL

Temporary Benefit: Australian-Authorized Anagrelide Capsules

Septa Pharmaceuticals Inc. has received approval from Health Canada for the import and release of Australian-authorized Anagrelide 0.5mg capsules to help mitigate a critical shortage in Canada.

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

For more information, you can contact Septa Pharmaceuticals Inc. at (905) 564-5665 or via email at orders@septapharma.com.

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Anagrelide	0.5mg Cap	09858363	E (SF)	SPT

Temporary Benefit: Ireland-Labelled Pegasys Prefilled Syringe

Accelera Pharma Canada Inc. has received approval from Health Canada for the import and release of Ireland-labelled Pegasys 180mcg/0.5mL PFS to help mitigate a critical shortage in Canada.

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

For more information you can contact Accelera Pharma Canada Inc. at 1-855-611-2724 or via email at orders@apcipharma.com.

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Pegasys	180mcg/0.5mL Prefilled Syringe	09858366	SF	ARN

Temporary Benefit: US-Authorized Disopyramide Capsules

Dr. Reddy's Laboratories Canada Inc. has received approval from Health Canada for the import and release of US-authorized Disopyramide 100mg capsules to help mitigate a critical shortage in Canada.

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

For more information you can contact Dr. Reddy's Laboratories Canada Inc. at 1-855-550-5528 or via email at drlca-customerservice@drreddys.com.

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Disopyramide	100mg Cap	09858365	SF	RCH

Legend

BENEFIT STATUS

S - Seniors' Pharmacare
F - Community Services Pharmacare
- Family Pharmacare
C - Drug Assistance for Cancer Patients
D - Diabetes Assistance Program
E - Exception status applies
G - Sensor-based Glucose Monitoring Program

MANUFACTURER CODES

APX	Apotex Inc.
ARN	Accelera Pharma Canada Inc
ARO	Auro Pharma Inc
ASL	Astellas Pharma Canada Inc.
AZE	AstraZeneca Canada Inc.
BAY	Bayer Inc.
BIG	Biogen Idec Canada Inc.
BOE	Boehringer Ingelheim (Canada) Ltd.
CPC	Covis Pharma B.V.
GIL	Gilead Sciences Inc.
GSK	GlaxoSmithKline Inc.
HIK	Hikma Canada Limited
HLR	Hoffmann-LaRoche Limited
JPC	Jamp Pharma Corporation
MDP	Medison Pharma Canada Inc.
MMP	Mirum Pharmaceuticals Inc.
MNT	Mint Pharmaceuticals Inc.
MYL	Mylan Pharmaceuticals ULC.
NVR	Novartis Pharmaceuticals Canada Inc.
ORG	Organon Canada LTD
PMS	Pharmascience Inc.
RCH	Dr. Reddy's Laboratories Inc.
RYT	Rhythm Pharmaceuticals Canada Inc.
SPT	Septa Pharmaceuticals
TEV	Teva Canada Ltd.
VAL	Valeo Pharma Inc.
VAR	*various manufacturers*
VIV	ViiV Health Care Inc.

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NOVA SCOTIA

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Nova Scotia Formulary Updates

New Exception Status Products

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

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Aflivu (aflibercept)	40mg/mL Pre-filled Syringe	02554178	E (SF)	APX
	40mg/mL Vial	02554194	E (SF)	APX
Yesafili (aflibercept)	40mg/mL Pre-filled Syringe	02558238	E (SF)	BIL
	40mg/mL Vial	02535858	E (SF)	BIL
Criteria	**Effective October 1, 2025, patients currently taking the originator drug Eylea, are required to switch to a biosimilar version by January 1, 2026.** **For aflibercept-naïve patients whose therapy is initiated after October 1, 2025, an aflibercept biosimilar will be the product approved.** **Active (Wet) Age-Related Macular Degeneration** For the treatment of patients with neovascular (wet) age-related macular degeneration (AMD) who meet all of the following criteria: • Best Corrected Visual Acuity (BCVA) is greater than 6/96. • The lesion size is ≤ 12 disc areas in greatest linear dimension. • There is evidence of recent (<3 months) presumed disease progression [blood vessel growth, as indicated by fluorescein angiography, optical coherence tomography (OCT), or recent visual acuity changes].			

New Exception Status Products Continued…

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Aflivu	40mg/mL Pre-filled Syringe	02554178	E (SF)	APX
(aflibercept)	40mg/mL Vial	02554194	E (SF)	APX
Yesafili	40mg/mL Pre-filled Syringe	02558238	E (SF)	BIL
(aflibercept)	40mg/mL Vial	02535858	E (SF)	BIL

Criteria

- There is active disease activity and no permanent structural damage to the central fovea (as defined in the Royal College of Ophthalmologists guidelines).

Renewal Criteria:

- Patient must meet all of the following criteria:
  - Evidence of continued disease activity.
  - Maintaining adequate response to therapy.
  - Absolute BCVA maintained above 6/120.
  - Reductions in BCVA of < 6 lines compared to either baseline and/or best recorded level since baseline.

Claim Notes:

- Must be prescribed and administered by a retina specialist or an ophthalmologist with experience in administering intravitreal injections.
- Will not be insured in combination with other anti-VEGF drugs for ophthalmic use.
- Approvals will be for a maximum of 1 vial per eye every 30 days.
- Approval period: 1 year. Confirmation of continued response is required.

Diabetic Macular Edema

For the treatment of patients with diabetic macular edema (DME) for who meet the following criteria:

- Clinically significant center-involving macular edema.
- Best Corrected Visual Acuity (BCVA) is greater than 6/120.

Renewal Criteria:

- Patient must meet all of the following criteria.
  - Evidence of continued disease activity.
  - Maintaining adequate response to therapy.
  - Absolute BCVA maintained above 6/120.
  - Reductions in BCVA of < 6 lines compared to either baseline and/or best recorded level since baseline.

Claim Notes:

- Must be prescribed and administered by a retina specialist or an ophthalmologist with experience in administering intravitreal injections.

New Exception Status Products Continued…

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Aflivu	40mg/mL Pre-filled Syringe	02554178	E (SF)	APX
(aflibercept)	40mg/mL Vial	02554194	E (SF)	APX
Yesafili	40mg/mL Pre-filled Syringe	02558238	E (SF)	BIL
(aflibercept)	40mg/mL Vial	02535858	E (SF)	BIL

Criteria

- Will not be insured in combination with other anti-VEGF drugs for ophthalmic use.
- Approvals will be for a maximum of 1 vial per eye every 30 days.
- Approval period: 1 year. Confirmation of continued response is required.

Retinal Vein Occlusion

For the treatment of patients with clinically significant center-involving macular edema secondary to non-ischemic branch retinal vein occlusion (BRVO), or central retinal vein occlusion (CRVO) who meet the following criteria:

- Best Corrected Visual Acuity (BCVA) is greater than 6/120.

Renewal Criteria:

- Patient must meet all of the following criteria:
  - Evidence of continued disease activity.
  - Maintaining adequate response to therapy.
  - Absolute BCVA maintained above 6/120.
  - Reductions in BCVA of <6 lines compared to either baseline and/or best recorded level since baseline.

Claim Notes:

- Must be prescribed and administered by a retina specialist or an ophthalmologist with experience in administering intravitreal injections.
- Will not be insured in combination with other anti-VEGF drugs for ophthalmic use.
- Approvals will be for a maximum of 1 vial per eye every 30 days.
- Approval period: 1 year. Confirmation of continued response is required.

New Exception Status Products Continued…

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Evkeeza (evinacumab)	345mg/2.3mL Vial	02541769	E (SF)	UGX

Criteria	**Initiation Criteria:**
	For the treatment of homozygous familial hypercholesterolemia (HoFH) in adult and pediatric patients 5 years of age and older with a clinically or genetically confirmed diagnosis if the following criteria are met:
	• Clinical criteria:
	  ○ Untreated TC > 12.93 mmol/L and TGs < 3.39 mmol/L, AND
	  ○ Both parents with documented TC > 6.47 mmol/L, indicative of HeFH, or patient with cutaneous or tendinous xanthoma before the age of 10 years
	• Genetic criteria:
	  ○ Documented functional mutation or mutations in both LDLR alleles, OR
	  ○ Documented homozygous or compound heterozygous mutations in Apo B or PCSK9, or LDLRAP1, or at least 2 such variants at different loci
	• Elevated LDL-C despite an adequate trial of other accessible lipid-lowering therapies; "elevated LDL-C" is defined as LDL-C greater than 1.8 mmol/L at baseline for adult patients and greater than 3.4 mmol/L for children.
	Initial and Subsequent Renewals:
	The prescriber must provide proof of beneficial clinical effect when requesting continuation of reimbursement, defined as reduction in LDL-C from baseline that is considered clinically beneficial by the treating prescriber.
	Claim Notes:
	• Initial approval: 24 weeks
	• Renewal approval: 1 year
	• Approvals will be for a maximum of 15 mg/kg every 4 weeks
	• The prescriber must provide the baseline LDL-C when the initial request for reimbursement occurs after all other treatment options of lipid-lowering therapies have been exhausted.
	• Evinacumab must be prescribed by specialists with qualifications and experience in the diagnosis and management of HoFH (e.g., [pediatric] endocrinologists, cardiologists, lipidologists).			

New Exception Status Products Continued…

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Leqvio (inclisiran)	284mg/1.5 mL Pre-filled Syringe	02518376	E (SF)	NVR

Criteria

For the treatment of heterozygous familial hypercholesterolemia (HeFH) in adult patients who require additional lowering of low-density lipoprotein cholesterol (LDL-C) if the following criteria are met:

- Definite or probable diagnosis of HeFH using the Simon Broome or Dutch Lipid Network criteria or genetic testing; and
- Patient is unable to reach LDL-C target (less than 2.0 mmol/L or at least a 50% reduction in LDL-C from untreated baseline) despite confirmed adherence to at least 3 months of continuous treatment with:
    - high-dose statin (e.g., atorvastatin 80 mg, rosuvastatin 40 mg) in combination with ezetimibe; or
    - ezetimibe alone if high dose statin is not possible due to rhabdomyolysis, contraindication or intolerance.

Initial Renewal Criteria:

- A reduction in LDL-C of at least 40% from baseline or has reached a target LDL-C less than 2.0 mmol/L.

Subsequent Renewal Criteria:

- The patient continues to maintain a reduction in LDL- C of at least 40% from baseline or has reached a target LDL-C less than 2.0 mmol/L.

Clinical Notes:

- LDL-C levels must be provided.
- Intolerance to high dose statin will be considered if patient has developed documented, myopathy or abnormal biomarkers (i.e. creatinine kinase greater than 5 times the upper limit of normal) after trial of at least two statins and
    - for each statin, dose reduction was attempted rather than statin discontinuation, and intolerance was reversible upon statin discontinuation, but reoccurred with statin re-challenge where clinically appropriate; and
    - at least one statin was initiated at the lowest daily starting dose; and
    - other known causes of intolerance or abnormal biomarkers have been ruled out.
- For patients who cannot take a statin due to an intolerance or contraindication, details must be provided (i.e. confirmed rhabdomyolysis, active liver disease, unexplained persistent elevations of serum transaminases exceeding three times the upper limit of normal).
- For patients who cannot take ezetimibe due to an intolerance or contraindication, details must be provided.

Claim Notes:

- Initial approval: 6 months

New Exception Status Products Continued…

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Leqvio (inclisiran)	284mg/1.5 mL Pre-filled Syringe	02518376	E (SF)	NVR
Criteria	• Renewal approval: 1 year • Maximum dose approved: 284 mg initially, at 3 months, then every 6 months thereafter • Inclisiran and PCSK9 inhibitors will not be insured in combination.			

Criteria Update

The following new indications have been added to existing criteria effective **October 1, 2025**.

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Ultomiris (ravulizumab)	300mg/30mL Vial 300mg/3mL Vial 1,100mg/11mL Vial	02491559 02533448 02533456	E (SF) E (SF) E (SF)	ALX ALX ALX
Criteria	**Neuromyelitis Optica Spectrum Disorder (NMOSD)** **Initiation Criteria:** For the treatment of adult patients with neuromyelitis optica spectrum disorder (NMOSD) who are anti-aquaporin-4 immunoglobulin G (AQP4-IgG) seropositive who meet all of the following criteria: • The patient must have had at least 1 attack or relapse of NMOSD in the previous 12 months. • Patients must have an EDSS score of 7 points or less. **Renewal Criteria:** • The physician should measure and provide EDSS scores every 12 months after the initial authorization to determine if the continuation of ravulizumab reimbursement should occur. **Discontinuation Criteria:** • Reimbursement of ravulizumab treatment will be discontinued if the patient's EDSS score is greater than 8 points. **Clinical Notes:** • Ravulizumab should not be initiated during an NMOSD relapse episode.			

Criteria Update Continued…

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Ultomiris (ravulizumab)	300mg/30mL Vial	02491559	E (SF)	ALX
	300mg/3mL Vial	02533448	E (SF)	ALX
	1,100mg/11mL Vial	02533456	E (SF)	ALX

Criteria

Claim Notes:

- Approvals will be for a maximum of:

Body Weight Range (kg)	Loading Dose (mg)	Maintenance Dose (mg)	Dosing Interval
≥ 40 to < 60	2,400	3,000	Every 8 weeks
≥ 60 to < 100	2,700	3,300	Every 8 weeks
≥ 100	3,000	3,600	Every 8 weeks

- Supplemental dosing following treatment with plasma exchange, plasmapheresis, or intravenous immunoglobulin is approved.
- Ravulizumab will not be reimbursed when used in combination with rituximab, satralizumab, eculizumab, or inebilizumab.
- The prescribing of ravulizumab for the treatment of NMOSD should be restricted to neurologists with expertise in treating NMOSD.
- Initial approval period: 12 months
- Renewal approval period: 12 months

Generalized Myasthenia Gravis (gMG)

Initiation Criteria:

For the treatment of adult patients with generalized myasthenia gravis (gMG) who have all of the following:

- Positive serologic test for anti-AChR antibodies
- An MG-ADL score at baseline of ≥ 6
- MGFA class II to IV disease
- MG symptoms persist despite an adequate trial and stable dose of the below conventional therapies in the previous 12 months:
    - Acetylcholinesterase inhibitors (pyridostigmine) AND
    - Corticosteroids (prednisone) AND/OR nonsteroidal immunosuppressants (azathioprine, cyclosporine, mycophenolate mofetil, methotrexate or tacrolimus)
- Vaccination against meningococcal infections.

Criteria Update Continued…

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Ultomiris (ravulizumab)	300mg/30mL Vial	02491559	E (SF)	ALX
	300mg/3mL Vial	02533448	E (SF)	ALX
	1,100mg/11mL Vial	02533456	E (SF)	ALX

Criteria

Exclusion Criteria:

- Ravulizumab should not be initiated:
  - during a gMG exacerbation or crisis OR
  - within 12 months of thymectomy.

Renewal Criteria:

- Reimbursement of ravulizumab treatment should be continued if, after the initial 6 months of treatment, there is a documented MG-ADL score improvement of 2 points or more.
- Reassessment for renewal should occur every 6 months.

Subsequent Renewal Criteria:

- The physician must provide proof that the initial MG-ADL score response achieved after the first 6 months of therapy with ravulizumab has been maintained.

Claim Notes:

- Approvals will be for a maximum of:

Body Weight Range (kg)	Loading Dose (mg)	Maintenance Dose (mg)	Dosing Interval
≥ 40 to < 60	2,400	3,000	Every 8 weeks
≥ 60 to < 100	2,700	3,300	Every 8 weeks
≥ 100	3,000	3,600	Every 8 weeks

- Supplemental dosing following treatment with plasma exchange, plasmapheresis, or intravenous immunoglobulin is approved.
- MG-ADL score must be measured and provided by the physician at baseline.
- Ravulizumab should not be used concomitantly with rituximab, efgartigimod alfa, and/or complement inhibitors such as eculizumab.
- Ravulizumab should be prescribed by or in consultation with a neurologist with expertise in managing patients with gMG.
- Initial approval period: 6 months
- Renewal approval period: 6 months

Legend

BENEFIT STATUS	MANUFACTURER CODES
S - Seniors' Pharmacare	ALX - Alexion Pharma Canada Corp
F - Community Services Pharmacare	APX - Apotex Inc.
- Family Pharmacare	BIL - Biocon Biologics Canada Inc
C - Drug Assistance for Cancer Patients	NVR - Novartis Pharmaceuticals Canada Inc
D - Diabetes Assistance Program	UGX - Ultragenyx
E - Exception status applies	
G - Sensor-based Glucose Monitoring Program	

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NOVA SCOTIA

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Nova Scotia Formulary Updates

New Exception Status Products

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

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Bylvay (odevixibat)	200mcg Cap	02542641	E (SF)	MDP
	400mcg Cap	02542676	E (SF)	MDP
	600mcg Cap	02542684	E (SF)	MDP
	1200mcg Cap	02542692	E (SF)	MDP
Criteria	For the treatment of pruritus in patients aged 6 months or older with progressive familial intrahepatic cholestasis (PFIC) who meet all of the following criteria: • Diagnosis of PFIC1 or PFIC2 • Severe pruritus with an ObsRO scratching score of ≥ 2, while receiving usual care with at least 1 therapy used for symptomatic relief of pruritus. • sBA levels ≥ 100 µmol/L. **Initial Renewal Criteria:** • The prescriber must document response in pruritus, defined as an ObsRO scratching score of ≤ 1 or at least a 1-point decrease from baseline. • If no response is observed after 3 months following the initial authorization, renewal of odevixibat will be for a 3-month trial of up to 120 mcg/kg per day dose (maximum of 7,200 mcg per day) and the patient will be required to then demonstrate response in pruritus, defined as an ObsRO scratching score of ≤ 1 or at least a 1-point decrease from baseline. **Subsequent Renewal Criteria:** • Subsequent renewals require documentation of continued maintenance of pruritus response.			

New Exception Status Products Continued…

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Bylvay	200mcg Cap	02542641	E (SF)	MDP
(odevixibat)	400mcg Cap	02542676	E (SF)	MDP
	600mcg Cap	02542684	E (SF)	MDP
	1200mcg Cap	02542692	E (SF)	MDP
Criteria	**Clinical Notes:** • Genetic testing must be conducted to confirm patients' PFIC subtype. • Usual care treatment of pruritus may include UDCA, rifampicin, cholestyramine, or antihistamines. • Odevixibat should be discontinued upon liver transplant. • Odevixibat must be prescribed by an expert in managing PFIC. **Claim Notes:** • Initial approval: 3 months • Renewal approval: 6 months **Maximum dosage approved** • The maximum duration of initial authorization is 3 months of treatment with a dose of 40 mcg/kg per day. • Odevixibat will be renewed at the 40 mcg/kg per day dose only if patients experience a documented response in pruritis after 3 months of treatment.			

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Fruzaqla	1mg Cap	02551454	E (SFC)	TAK
(fruquintinib)	5mg Cap	02551462	E (SFC)	TAK
Criteria	As monotherapy for the treatment of adult patients with metastatic colorectal adenocarcinoma who: • Have been previously treated with, or are not candidates for, available therapies including fluoropyrimidine, oxaliplatin, and irinotecan-based chemotherapy, anti-VEGF agents, anti-EGFR agents (if RAS wild-type), and trifluridine-tipiracil. • For MSI-H or dMMR tumors: have been treated with an immune checkpoint inhibitor, if eligible. • For BRAF-mutant positive tumors: have been treated with a BRAF inhibitor, if eligible. **Clinical Notes:** • Patients should have a good performance status. • Treatment should continue until disease progression or unacceptable toxicity. • No active CNS metastases (eligible if treated/stable). • Patients with small bowel or appendiceal adenocarcinoma are eligible.			

New Exception Status Products Continued…

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Fruzaqla (fruquintinib)	1mg Cap 5mg Cap	02551454 02551462	E (SFC) E (SFC)	TAK TAK
Criteria	• Patients who have received adjuvant/neoadjuvant chemotherapy and had recurrence during or within six months of completion can count the adjuvant/neoadjuvant therapy as one of the required minimum three prior regimens.			

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Rystiggo (rozanolixizumab)	140mg/mL Single Dose Vial	02556081	E (SF)	UCB

Criteria

Initiation Criteria:

For the treatment of adult patients with generalized myasthenia gravis (gMG) who have all the following:

- Positive serologic test for:
  - AChR antibodies; OR
  - MuSK antibodies
- An MG-ADL score at baseline of ≥ 3, with at least 3 points from nonocular symptoms
- MGFA class II to IV disease
- MG symptoms persist despite an adequate trial and stable dose of the below conventional therapies in the previous 12 months:
  - Acetylcholinesterase inhibitors (pyridostigmine) AND
  - Corticosteroids (prednisone) AND/OR nonsteroidal immunosuppressants (azathioprine, cyclosporine, mycophenolate mofetil, methotrexate or tacrolimus)

Exclusion Criteria:

Rozanolixizumab should not be initiated:

- During a gMG exacerbation or crisis OR
- Within 6 months of thymectomy.

Renewal Criteria:

- Reimbursement of treatment with rozanolixizumab should be continued if, after the initial 6 weeks of treatment, there is documented improvement in MG-ADL score of 2 points or greater.
- Reassessment should occur every 12 months thereafter.

Subsequent Renewal Criteria:

- The physician must provide proof of no worsening of MG-ADL score.

New Exception Status Products Continued…

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Rystiggo (rozanolixizumab)	140mg/mL Single Dose Vial	02556081	E (SF)	UCB

Criteria

Claim Notes:

- MG-ADL score must be measured and provided by the physician at baseline.
- Rozanolixizumab should be prescribed by or in consultation with a neurologist with expertise in managing patients with gMG.
- Rozanolixizumab should not be used concomitantly with rituximab, efgartigimod alfa, and/or complement inhibitors such as eculizumab.
- Approvals will be for a maximum of:

Body Weight	≥35 to <50 kg	≥50 to <70 kg	≥70 to <100 kg	≥100 kg
Dosage	280 mg	420 mg	560 mg	840 mg

- Therapy is administered once weekly for 6 weeks with subsequent treatment cycles based on clinical evaluation with a minimum of 4 weeks between treatment cycles.
- Initial Approval: 6 weeks
- Renewal Approval: 12 months

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Tibsovo (ivosidenib)	250mg Tab	02549980	E (SFC)	SEV

Criteria

In combination with azacitadine for the treatment of adult patients with newly diagnosed AML with an IDH1 R132 mutation who are not eligible to receive intensive induction chemotherapy.

Clinical Notes:

- Patients are not eligible to receive intensive induction chemotherapy due to the presence of at least one of the following:
  - Age ≥75 years
  - ECOG performance status ≥2
  - Severe cardiac disorder
  - Severe pulmonary disorder
  - Creatinine clearance <45 mL/minute
  - Bilirubin level >1.5x ULN

New Exception Status Products Continued…

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Tibsovo (ivosidenib)	250mg Tab	02549980	E (SFC)	SEV
Criteria	○ Any other comorbidity judged to be incompatible with intensive induction chemotherapy. • Treatment should continue until disease progression or unacceptable toxicity. • No prior treatment for AML, except treatments to stabilize the disease (ex: hydroxyurea, leukapheresis). • No prior IDH1 inhibitor use. • Patients who have been previously treated with a hypomethylating agent or chemotherapy for the treatment of myelodysplastic syndromes (MDS) are not eligible. • Must be given in combination with azacitadine (ivosidenib monotherapy is not funded). • Patients with high risk MDS are not eligible.			

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Zilbrysq (zilucoplan)	16.6mg/0.416mL Pre-filled Syringe 23mg/0.574mL Pre-filled Syringe 32.4mg/0.81mL Pre-filled Syringe	02549220 02549239 02549247	E (SF) E (SF) E (SF)	UCB UCB UCB
Criteria	**Initiation Criteria:** For the treatment of adult patients with generalized myasthenia gravis (gMG) who have all the following: • Positive serologic test for anti-AChR antibodies • An MG-ADL score at baseline of ≥ 6 • MGFA class II to IV disease • MG symptoms persist despite an adequate trial and stable dose of the below conventional therapies in the previous 12 months: ○ Acetylcholinesterase inhibitors (pyridostigmine) AND ○ Corticosteroids (prednisone) AND/OR nonsteroidal immunosuppressants (azathioprine, cyclosporine, mycophenolate mofetil, methotrexate or tacrolimus) • Vaccination against meningococcal infections. **Exclusion Criteria:** Zilucoplan should not be initiated: • During a gMG exacerbation or crisis OR • Within 12 months of thymectomy.			

New Exception Status Products Continued…

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Zilbrysq (zilucoplan)	16.6mg/0.416mL Pre-filled Syringe	02549220	E (SF)	UCB
	23mg/0.574mL Pre-filled Syringe	02549239	E (SF)	UCB
	32.4mg/0.81mL Pre-filled Syringe	02549247	E (SF)	UCB
Criteria	**Renewal Criteria:** • Reimbursement of treatment with zilucoplan should be continued if, after the initial 6 months of treatment, there is documented improvement in MG-ADL score of 2 points or greater. • Reassessment should occur every 6 months thereafter. **Subsequent Renewal:** • The physician must provide proof that the initial response achieved after the first 6 months of therapy with zilucoplan for the MG-ADL score has been maintained. **Claim Notes:** • MG-ADL score must be measured and provided by the physician at baseline. • Treatment with zilucoplan should be discontinued in case of serious adverse events related to zilucoplan or secondary infection, such as meningococcal infection. • Zilucoplan should be prescribed by or in consultation with a neurologist with expertise in managing patients with gMG. • Zilucoplan should not be used concomitantly with rituximab, complement inhibitors or efgartigimod alfa. • Approvals will be for a maximum dose of 16.6mg daily for patients <56 kg, 23 mg daily for patients ≥56 kg to <77 kg and 32.4mg daily for patients ≥77 kg. • Initial Approval: 6 months • Renewal Approval: 6 months			

The Nova Scotia Biosimilar Initiative aims to expand the use of lower cost biosimilars on the Pharmacare Programs. On November 1, 2025, a new omalizumab biosimilar drug, Omlyclo, will be listed on the Nova Scotia Formulary.

Effective November 1, 2025, patients currently taking the originator drug product are required to switch to the biosimilar version by April 30, 2026.

For omalizumab-naïve patients whose therapy is initiated after November 1, 2025, the omalizumab biosimilar will be the product approved.

Prescribers can apply for an exemption if a patient can't switch to a biosimilar for clinical reasons. More information on this process can be found on our website: https://novascotia.ca/dhw/pharmacare/information-for-prescribers-about-biosimilars.asp

New Exception Status Products Continued…

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Omlyclo	75mg/0.5mL Pre-filled Syringe	02553805	E (SF)	CLT
(omalizumab)	150mg/1.0mL Pre-filled Syringe	02553813	E (SF)	CLT

Criteria

Allergic Asthma

Initiation Criteria:

For the treatment of moderate to severe asthma in patients 6 years or older who meet all of the following criteria:

- Asthma remains inadequately controlled despite the use of a high-dose inhaled corticosteroid (ICS) and a long-acting inhaled beta2-agonist (LABA).
- Has within the past 12 months required:
    - hospitalization for asthma; OR
    - two or more urgent visits for asthma to a physician or an emergency department; OR
    - two or more courses of high-dose oral corticosteroids.
- The patient has a documented positive skin test or in vitro reactivity to a perennial aeroallergen.

Discontinuation Criteria:

- Baseline asthma control questionnaire score has not improved since the initiation of treatment, OR
- Number of clinically significant asthma exacerbations has increased since the initiation of treatment.

Clinical Notes:

- High-dose inhaled corticosteroids is defined as greater than or equal to 500 mcg of fluticasone propionate or equivalent daily dose.
- For patients 6 to 11 years old, 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 baseline and a re-assessment of asthma symptom control using an asthma control questionnaire score must be provided.
- A baseline and a re-assessment of the number of clinically significant asthma exacerbations must be provided.

Claim Notes:

- Should be prescribed by a respirologist, clinical immunologist or allergist. Individual consideration may be given for extenuating circumstances where access to these specialists is not possible.
- Combined use of omalizumab with other biologics used to treat asthma will not be reimbursed.
- Approvals will be for a maximum dose of 375 mg every 2 weeks
- Initial approval duration: 6 months

New Exception Status Products Continued…

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Omlyclo (omalizumab)	75mg/0.5mL Pre-filled Syringe 150mg/1.0mL Pre-filled Syringe	02553805 02553813	E (SF) E (SF)	CLT CLT
Criteria	• Renewal approval duration: Long-term **Chronic Idiopathic Urticaria (CIU)** **Initiation Criteria:** For the treatment of adults and adolescents (12 years of age or older) with moderate to severe chronic idiopathic urticaria (CIU) who remain symptomatic (presence of hives and/or associated itching) despite optimum management with available oral therapies. **Renewal Criteria:** • Continued coverage will be authorized if the patient has achieved: o complete symptom control for less than 12 consecutive weeks; or o partial response to treatment, defined as at least a ≥ 9.5 point reduction in baseline urticaria activity score over 7 days (UAS7); or o complete symptom control on omalizumab and tried stopping therapy but experienced symptom relapse of their urticaria while off treatment **Clinical Notes:** • Treatment cessation could be considered for patients who experience complete symptom control for at least 12 consecutive weeks at the end of a 24 week treatment period. **Claim Notes:** • Prescribed by a specialist (allergist, immunologist, dermatologist, etc.) or other authorized prescriber with knowledge of CIU treatment. • Combined use of omalizumab with other biologics used to treat CIU will not be reimbursed. • Approvals will be for a maximum dose of 300mg every 4 weeks. • Initial Approval: 6 months • Renewal Approval: Long-term			

Criteria Updates

The following criteria has been updated and will replace existing criteria effective **November 1, 2025**.

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

The following new indication has been added to existing criteria effective **November 1, 2025** and applies to the following new and existing products.

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Steqeyma (ustekinumab)	45mg/0.5mL Single-use Vial	02558270	E (SF)	CLT

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

Criteria Update Continued…

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Steqeyma (ustekinumab)	45mg/0.5mL Single-use Vial	02558270	E (SF)	CLT
Criteria	○ a decrease in the rectal bleeding subscore ≥ 1. **Clinical Notes:** • Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above. • Intolerant is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs. The nature of intolerance(s) must be clearly documented. • Patients with severe disease do not require a trial of 5-ASA. **Claim Notes:** • Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology. • Combined use of more than one biologic DMARD will not be reimbursed. • Initial reimbursement will be for a single intravenous dose of up to 520mg at Week 0 and a subcutaneous dose of 90mg at Week 8 and 16. Subsequent reimbursement for maintenance dosing is 90mg subcutaneously every 8 weeks. • Initial Approval: 6 months. • Renewal Approval: Long term.			

Change in Benefit Status

Effective **November 1, 2025**, the following products will be delisted as benefits under the Pharmacare Programs.

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Anthralin Oint	0.4%	00901113	**Non Insured**	N/A
Anthralin Soft Paste	0.05%	00902063	**Non Insured**	N/A
Anthralin Soft Paste	0.1%	00900907	**Non Insured**	N/A
Anthralin Soft Paste	0.2%	00900915	**Non Insured**	N/A
Anthralin Weak Oint	0.2%	00901105	**Non Insured**	N/A
Levetiracetam Oral Susp*		99099941	**Non Insured**	N/A
LCD Preparations**	(20%)	00358495	**Non Insured**	N/A

* Please note this product is now commercially available.

** LCD (coal tar) preparations PIN 00358494 is still available for use.

Legend

BENEFIT STATUS	MANUFACTURER CODES
S - Seniors' Pharmacare	ABV - AbbVie Corporation
F - Community Services Pharmacare	CLT - Celltrion Healthcare Ltd
- Family Pharmacare	MDP - Medison Pharma Canada Inc.
C - Drug Assistance for Cancer Patients	SEV - Servier Canada Inc.
D - Diabetes Assistance Program	TAK - Takeda Canada Inc.
E - Exception status applies	UCB - UCB Pharma Canada Inc.
G - Sensor-based Glucose Monitoring Program	

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PharmacareNEWS

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Nova Scotia Formulary Updates

New Exception Status Products

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

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Ferinject (ferric carboxymaltose)	50mg/mL Single-use Vial	02546078	E (SFC)	CSL

Criteria

Iron Deficiency Anemia

- For the treatment of iron deficiency anemia in patients intolerant to oral iron replacement products; OR
- For patients who have not responded to adequate therapy with oral iron.

Notes:

- Given the safety concerns associated with IV iron, it is expected that the patients will be carefully screened and will have tried various oral iron options before being eligible for IV iron.
- Details regarding oral iron tried, length of therapy, and outcome must be provided.

Iron Deficiency in Heart Failure

For the treatment of adult patients with heart failure and NYHA class II or III and who have:

- LVEF ≤ 40%
- Ferritin ≤ 300 mcg/L with a TSAT < 15%

Initial and Subsequent Renewal

If a patient requires iron repletion again after receiving the full dose of ferric carboxymaltose, the physician must provide proof that the patient meets initial approval criteria (NYHA class II or III, LVEF ≤ 40%, and ferritin ≤ 300 mcg/L with a TSAT < 15%).

New Exception Status Products Continued…

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Ferinject (ferric carboxymaltose)	50mg/mL Single-use Vial	02546078	E (SFC)	CSL
Criteria	**Claim Notes:** • Must be prescribed by a cardiologist or clinician experienced in the management of chronic HF • Initial and renewal approval duration: 24 weeks			

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Noyada (captopril)	5mg/5mL Oral Solution 25mg/5mL Oral Solution	02543907 02543915	E (SF) E (SF)	ETH ETH
Criteria	• For patients who require administration through a feeding tube. **[Criteria Code 37]** • For patients 19 years of age and younger, who cannot use a tablet or capsule. **[Criteria Code 38]**			

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Pexegra (pegfilgrastim)	10mg/mL Pre-filled Syringe	02553945	E (SFC)	JPC
Criteria	For the prevention of febrile neutropenia in patients with non-myeloid malignancies receiving myelosuppressive chemotherapy with curative intent who: • are at high risk of febrile neutropenia due to chemotherapy regimen, co-morbidities or pre-existing severe neutropenia; **[Criteria Code 01]** OR • have had an episode of febrile neutropenia, neutropenic sepsis or profound neutropenia in a previous cycle of chemotherapy; **[Criteria Code 02]** OR • have had a dose reduction, or treatment delay greater than one week due to neutropenia **[Criteria Code 03]** **Clinical Note:** • Patients with non-curative cancer receiving chemotherapy with palliative intent are not eligible for coverage of pegfilgrastim for prevention of febrile neutropenia.			

Criteria Updates

The following new indication has been added to existing criteria effective **December 1, 2025**.

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Dimethyl Fumarate	120mg DR Cap 240 mg DR Cap	Various Various	E (SF) E (SF)	VAR VAR
Criteria	**Radiologically Isolated Syndrome** • For the treatment of adult patients with radiologically isolated syndrome (RIS) who are diagnosed with RIS by a neurologist based on the most current RIS criteria. **Claims Notes:** • Must be prescribed by a neurologist with experience in the diagnosis and management of RIS. • Combined use with other disease modifying therapies to treat RIS will not be reimbursed. • Initial approval: 2 years • Renewal approval: 5 years			

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Teriflunomide	14mg Tab	Various	E (SF)	VAR
Criteria	**Radiologically Isolated Syndrome** • For the treatment of adult patients with radiologically isolated syndrome (RIS) who are diagnosed with RIS by a neurologist based on the most current RIS criteria. **Claims Notes:** • Must be prescribed by a neurologist with experience in the diagnosis and management of RIS. • Combined use with other disease modifying therapies to treat RIS will not be reimbursed. • Initial approval: 2 years • Renewal approval: 5 years			

Criteria Updates Continued…

The following criteria has been updated to include criteria codes effective **December 1, 2025**.

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
pms-Ipratropium	125mcg/mL Polynebs	02231135	E (SFC)	PMS
AA-Ipravent	250mcg/mL Inh Sol	02126222	E (SFC)	AAP
pms-Ipratropium	250mcg/mL Polynebs	02231244	E (SFC)	PMS
Teva-Ipratropium	250mcg/mL Sterinebs	02216221	E (SFC)	TEV
pms-Ipratropium	250mcg/mL Polynebs	02231245	E (SFC)	PMS
pms-Salbutamol	0.5mg/mL Polynebs	02208245	E (SFC)	PMS
pms-Salbutamol	1mg/mL Polynebs	02208229	E (SFC)	PMS
Teva-Salbutamol	1mg/mL Sterinebs	01926934	E (SFC)	TEV
pms-Salbutamol	2mg/mL Polynebs	02208237	E (SFC)	PMS
Teva-Salbutamol	2mg/mL Sterinebs	02173360	E (SFC)	TEV
Ventolin	5mg/mL Resp Sol	02213486	E (SFC)	GSK
Ipratropium & Salbutamol	0.5mg/2.5mg/2.5mL Inh Sol	02483394	E (SFC)	MDN
Teva-Combo Sterinebs		02272695	E (SFC)	TEV
Criteria	• For adult patients with a vital capacity of 900mL or less **[Criteria Code 01]** • For adult patients with a respiratory rate greater than 25 breaths/minute. **[Criteria Code 02]** • For patients who have demonstrated they cannot follow instructions, cannot hold the spacer device or cannot hold the device long enough to actuate it. **[Criteria Code 03]**			

Change in Benefit Status

Effective **December 1, 2025**, the following product will be delisted as a benefit under the Pharmacare Programs.

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Docusate Sodium	100mg Cap	00716731	**Non Insured**	TAR

New Benefits

Effective **December 1, 2025,** 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	BENEFIT STATUS	MFR
Axberi	30mg/0.3mL Pre-filled Syringe	02539977	SFC	BAX
Axberi	40mg/0.4mL Pre-filled Syringe	02539985	SFC	BAX
Axberi	60mg/0.6mL Pre-filled Syringe	02540002	SFC	BAX
Axberi	80mg/0.8mL Pre-filled Syringe	02540010	SFC	BAX
Axberi	100mg/1mL Pre-filled Syringe	02540045	SFC	BAX
Axberi HP	120mg/0.8mL Pre-filled Syringe	02540029	SFC	BAX
Axberi HP	150mg/1mL Pre-filled Syringe	02540037	SFC	BAX
Clobazam	Oral Suspension	00903405	F*	N/A
Loperamide	2mg Cap	02544989	SFC	JPC
Omeprazole	Oral Suspension	00903104	FC*	N/A
Quetiapine	Oral Suspension	00904441	F*	N/A
Solu-Medrol (no preservative)	40mg/Vial	02367947	SFC	PFI
Solu-Medrol (no preservative)	125mg/Vial	02367955	SFC	PFI

*New compound benefits for individuals 19 years and under

Legend

BENEFIT STATUS

S - Seniors' Pharmacare
F - Community Services Pharmacare
- Family Pharmacare
C - Drug Assistance for Cancer Patients
D - Diabetes Assistance Program
E - Exception status applies
G - Sensor-based Glucose Monitoring Program

MANUFACTURER CODES

AAP - AA Pharma Inc.
BAX - Baxter Corporation
CSL - CSL Behring Canada Inc.
ETH - Ethypharm Inc
GSK - GlaxoSmithKline Inc.
JPC - Jamp Pharma Corporation
MDN - MDA Inc
PFI - Pfizer Canada Inc.
PMS - Pharmascience Inc.
TAR - Taro Pharmaceuticals Inc.
TEV - Teva Canada Ltd.
VAR - *various manufacturers*

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PharmacareNEWS

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Nova Scotia Formulary Updates

New Subscription Option for Monthly Pharmacare News Bulletins

You can now subscribe to receive an email notification when the latest Pharmacare News Bulletin becomes available. **Subscribe here.**

Please note: Nova Scotia Pharmacare News Bulletins will no longer be mailed after the March 2026 bulletin. All future bulletins will be available online only.

New Exception Status Products

The following new products have been listed with the following criteria, effective **January 1, 2026**.

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Abilify Asimtufii (aripiprazole)	720mg/2.4mL Pre-filled Syringe	02554569	E (SF)	OTS
	960mg/3.2mL Pre-filled Syringe	02554577	E (SF)	OTS
Criteria	For the treatment of patients who are: • not adherent to an oral antipsychotic, OR • currently receiving a long-acting injectable antipsychotic and require an alternative long-acting injectable antipsychotic. **Claim Note:** • Requests will not be considered for the treatment of psychotic symptoms related to dementia.			

New Exception Status Products Continued…

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Otulfi (ustekinumab)	45mg/0.5mL Pre-filled Syringe	02554283	E (SF)	FKB
	90mg/mL Pre-filled Syringe	02554291	E (SF)	FKB
	130mg/26mL Vial	02554305	E (SF)	FKB
Criteria	**Plaque Psoriasis** For the treatment of patients with chronic moderate to severe plaque psoriasis who meet all of the following: • Psoriasis Area Severity Index (PASI) greater than 10 and Dermatology Life Quality Index (DLQI) greater than 10, OR major involvement of visible areas, scalp, genitals, or nails; • Refractory, intolerant to or unable to access phototherapy; • Refractory, intolerant to or have contraindications to methotrexate (oral or parenteral) at a dose of greater than or equal to 20 mg weekly (greater than or equal to 15 mg if patient is 65 years of age or older) for a minimum of 12 weeks OR cyclosporine (6 weeks treatment). For continued coverage, patients must meet the following criteria: • Greater than or equal to 75% reduction in PASI score, OR • Greater than or equal to 50% reduction in PASI and greater than or equal to 5 points in the DLQI OR • Significant reduction in BSA involved, with consideration of specific regions such as face, hands, feet or genital region and situations such as itch and recalcitrant plaques. **Clinical Notes:** • For patients who do not demonstrate a clinical response to oral methotrexate, or who experience gastrointestinal intolerance, a trial of parenteral methotrexate may be considered if clinically appropriate. • Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above. • Intolerant is defined as demonstrating serious adverse effects to treatments. The nature of intolerance(s) must be clearly documented. **Claim Notes:** • Must be prescribed by a dermatologist or prescriber with a specialty in dermatology. • Combined use of more than one biologic will not be reimbursed.			

New Exception Status Products Continued…

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Otulfi (ustekinumab)	45mg/0.5mL Pre-filled Syringe	02554283	E (SF)	FKB
	90mg/mL Pre-filled Syringe	02554291	E (SF)	FKB
	130mg/26mL Vial	02554305	E (SF)	FKB
Criteria	• Approvals will be for a maximum of 45mg subcutaneously at Week 0, 4 and 16 weeks, followed by a maintenance dose of 45mg subcutaneously every 12 weeks. Response must be assessed prior to fourth dose. • Initial Approval: 6 months • Renewal Approval: Long term **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 45mg subcutaneously at Weeks 0 and 4, and maintenance dosing of 45mg subcutaneously every 12 weeks. For patients >100kg, doses of 90mg may be considered.			

New Exception Status Products Continued…

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Otulfi (ustekinumab)	45mg/0.5mL Pre-filled Syringe	02554283	E (SF)	FKB
	90mg/mL Pre-filled Syringe	02554291	E (SF)	FKB
	130mg/26mL Vial	02554305	E (SF)	FKB
Criteria	• Initial Approval: 6 months • Renewal Approval: Long term **Crohn's Disease** For the treatment of patients with moderately to severely active Crohn's disease who are refractory to, intolerant or have contraindications to corticosteroids and other immunosuppressive therapy. **Clinical Notes:** • Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above. • Intolerant is defined as demonstrating serious adverse effects to treatments. The nature of intolerance(s) must be clearly documented. **Claim Notes:** • Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology. • Combined use of more than one biologic disease-modifying antirheumatic drugs (DMARD) or janus kinase inhibitors (JAK) will not be reimbursed. • Initial reimbursement will be for a single intravenous dose of up to 520mg at Week 0 and a subcutaneous dose of 90mg at Week 8 and 16. Subsequent reimbursement for maintenance dosing is 90mg subcutaneously every 8 weeks. • Initial Approval: 6 months • Renewal Approval: Long term **Ulcerative Colitis** For the treatment of patients with moderately to severely active ulcerative colitis who have a partial Mayo score > 4, and a rectal bleeding subscore ≥ 2 and are: o refractory or intolerant to conventional therapy (i.e. 5-ASA for a minimum of 4 weeks, and prednisone ≥ 40mg daily for two weeks or IV equivalent for one week); OR			

New Exception Status Products Continued…

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Otulfi (ustekinumab)	45mg/0.5mL Pre-filled Syringe	02554283	E (SF)	FKB
	90mg/mL Pre-filled Syringe	02554291	E (SF)	FKB
	130mg/26mL Vial	02554305	E (SF)	FKB
Criteria	○ corticosteroid dependent (i.e. cannot be tapered from corticosteroids without disease recurrence; or have relapsed within three months of stopping corticosteroids; or require two or more courses of corticosteroids within one year.) • Renewal requests must include information demonstrating the beneficial effects of the treatment, specifically: ○ a decrease in the partial Mayo score ≥ 2 from baseline, AND ○ a decrease in the rectal bleeding subscore ≥ 1. **Clinical Notes:** • Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above. • Intolerant is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs. The nature of intolerance(s) must be clearly documented. • Patients with severe disease do not require a trial of 5-ASA. **Claim Notes:** • Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology. • Combined use of more than one biologic DMARD will not be reimbursed. • Initial reimbursement will be for a single intravenous dose of up to 520mg at Week 0 and a subcutaneous dose of 90mg at Week 8 and 16. Subsequent reimbursement for maintenance dosing is 90mg subcutaneously every 8 weeks. • Initial Approval: 6 months. • Renewal Approval: Long term.			

Change in Benefit Status

Effective **January 1, 2026**, the following products will be added as benefits in the Nova Scotia Formulary. The benefit status within the Pharmacare Programs is indicated and existing criteria applies.

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Dasatinib	80mg Tablets	Various	E (SFC)	Various
Dasatinib	140mg Tablets	Various	E (SFC)	Various

New Benefits

The following products have been added as benefits; however, billing for methadone oral compounds remains unchanged. All methadone oral compound solutions must continue to be billed per mg using Methadone Oral Compound Sol PIN 00999734, regardless of the stock solution used. Only methadone stock solutions listed as benefits on the formulary may be used to prepare methadone oral compounds (e.g. methadone powder is not an approved ingredient and must not be used). Claims billed using the DINs for any methadone HCl 10mg/mL solution will be rejected.

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Odan-Methadone (Cherry Flavored)	10mg/mL Sol	02495872*	SFC	ODN
pms-Methadone (Cherry Flavored)	10mg/mL Sol	02552736*	SFC	PMS
Methadose	10mg/mL Sol	02394596*	SFC	MAL
Jamp Methadone	10mg/mL Sol	02495783*	SFC	JPC
Odan-Methadone (Unflavored)	10mg/mL Sol	02495880*	SFC	ODN
pms-Methadone (Unflavored)	10mg/mL Sol	02552728*	SFC	PMS
Methadose	10mg/mL Sol	02394618*	SFC	MAL

*Continue to bill using PIN 00999734

Legend

BENEFIT STATUS	MANUFACTURER CODES
S - Seniors' Pharmacare	FKB - Fresenius Kabi Canada
F - Community Services Pharmacare	JPC - Jamp Pharma Corporation
- Family Pharmacare	MAL - Mallinckrodt Canada Ulc
C - Drug Assistance for Cancer Patients	ODN - Odan Laboratories Ltd.
D - Diabetes Assistance Program	OTS - Otsuka Canada Pharmaceuticals
E - Exception status applies	PMS - Pharmascience Inc.
G - Sensor-based Glucose Monitoring Program	VAR - *various manufacturers*