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NOVA SCOTIA

PharmacareNEWS

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Nova Scotia Formulary Updates

Criteria Code for COPD and Asthma Inhalers

Effective June 3, criteria code 16 can be used for COPD and asthma inhalers when prescribed by a respirologist, clinical immunologist, allergist, internist, medical oncologist, or thoracic surgeon. Once the code has been used, then the beneficiary will have long term approval for all similar funded inhalers as long as there is at least one dispense per year.

New Exception Status Benefits

The Nova Scotia Biosimilar Initiative aims to expand the use of lower cost biosimilars on the Pharmacare Programs. On June 1, 2024, two new ustekinumab biosimilar drugs, Jamteki and Wezlana, will be listed on the Nova Scotia Formulary.

Effective June 1, 2024, patients currently taking the originator drug product Stelara, are required to switch to a biosimilar version by December 1, 2024.

For ustekinumab-naïve patients whose therapy is initiated after June 1, 2024, an ustekinumab 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 Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Jamteki	45mg/0.5mL Prefilled Syringe	02543036	DNP	E (SF)	JPC
(ustekinumab)	90mg/1.0mL Prefilled Syringe	02543044	DNP	E (SF)	JPC

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.
- 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: 16 weeks.
- Renewal Approval: 1 year

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Jamteki (ustekinumab)	45mg/0.5mL Prefilled Syringe	02543036	DNP	E (SF)	JPC
	90mg/1.0mL Prefilled Syringe	02543044	DNP	E (SF)	JPC
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; 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. • Initial period 6 months. • 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. • Renewal approval: 1 year. Confirmation of continued response required.				

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Wezlana (ustekinumab)	45mg/0.5mL Prefilled Syringe	02544180	DNP	E (SF)	AGA
	90mg/1.0mL Prefilled Syringe	02544199	DNP	E (SF)	AGA
	45mg/0.5mL Vial	02544202	DNP	E (SF)	AGA
	130mg/26mL Vial	02544210	DNP	E (SF)	AGA

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.
- 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: 16 weeks.
- Renewal Approval: 1 year

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Wezlana (ustekinumab)	45mg/0.5mL Prefilled Syringe	02544180	DNP	E (SF)	AGA
	90mg/1.0mL Prefilled Syringe	02544199	DNP	E (SF)	AGA
	45mg/0.5mL Vial	02544202	DNP	E (SF)	AGA
	130mg/26mL Vial	02544210	DNP	E (SF)	AGA

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; 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.
- Initial period 6 months.
- 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.
- Renewal approval: 1 year. Confirmation of continued response required.

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 Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Wezlana (ustekinumab)	45mg/0.5mL Prefilled Syringe	02544180	DNP	E (SF)	AGA
	90mg/1.0mL Prefilled Syringe	02544199	DNP	E (SF)	AGA
	45mg/0.5mL Vial	02544202	DNP	E (SF)	AGA
	130mg/26mL Vial	02544210	DNP	E (SF)	AGA

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 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: 16 weeks
- Renewal Approval: 1 year

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.
- 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.

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Wezlana (ustekinumab)	45mg/0.5mL Prefilled Syringe	02544180	DNP	E (SF)	AGA
	90mg/1.0mL Prefilled Syringe	02544199	DNP	E (SF)	AGA
	45mg/0.5mL Vial	02544202	DNP	E (SF)	AGA
	130mg/26mL Vial	02544210	DNP	E (SF)	AGA
Criteria	• Initial Approval: 16 weeks • Renewal Approval: 1 year				

Criteria Update: Plaque Psoriasis

The plaque psoriasis criteria for the following products has been updated effective June 1, 2024:

- Adalimumab biosimilars
- Bimzelx (bimekizumab)
- Cosentyx (secukinumab)
- Etanercept biosimilars
- Ilumya (tildrakizumab)
- Infliximab biosimilars
- Siliq (brodalumab)
- Skyrizi (risankizumab)
- Taltz (ixekizumab)
- Tremfya (guselkumab)

Please see the full criteria for plaque psoriasis under the ustekinumab listing on pages 2-3.

Criteria Update: Crohn's Disease

The Crohn's disease criteria for the following products has been updated effective June 1, 2024:

- Adalimumab biosimilars
- Entyvio (vedolizumab)
- Infliximab biosimilars
- Skyrizi (risankizumab)

Please see the full criteria for Crohn's disease under the ustekinumab listing on page 7.

Change in Benefit Status

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

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Pantoprazole Magnesium	40mg Tab	Various	DNP	SFC	VAR

New Benefits

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

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Octasa	800mg Tab	02465752	DNP	SF	PDP
Octasa	1600mg Tab	02529610	DNP	SF	PDP

Legend

PRESCRIBER CODES	BENEFIT STATUS	MANUFACTURER CODES
D - Physician / Dentist	S - Seniors' Pharmacare	AGA - Amgen Canada Inc.
N - Nurse Practitioner	F - Community Services Pharmacare	JPC - Jamp Pharma Corporation
P - Pharmacist	- Family Pharmacare	PDP - PendoPharm, Division of Pharmascience Inc.
M - Midwife	C - Drug Assistance for Cancer Patients	VAR - *various manufacturers*
O - Optometrist	D - Diabetes Assistance Program	
	E - Exception status applies	
	G - Sensor-based Glucose Monitoring Program	