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NOVA SCOTIA

PharmacareNEWS

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New Exception Status Benefits

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

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Trelegy Ellipta (fluticasone furoate/ umeclidinium /vilanterol)	100mcg/ 62.5mcg/ 25mcg	02474522	DNP	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 beta-2 agonist/long-acting muscarinic antagonist (LABA/LAMA). **Clinical Notes:** • COPD is defined by spirometry as a post-bronchodilator FEV_1/FVC ratio of less than 0.70. Spirometry reports from any point in time will be accepted. If spirometry cannot be obtained, reasons must be clearly explained and other evidence of COPD severity provided (i.e. MRC Dyspnea Scale Score grade). • Inadequate control while being treated with a LABA/LAMA for at least two months is defined as persistent symptoms or experiencing two or more exacerbations of COPD in the previous year requiring treatment with antibiotics and/or systemic corticosteroids or at least one exacerbation of COPD requiring hospitalization. • Patients should not be started on a LABA, LAMA and an inhaled corticosteroid (triple inhaled therapy) as initial therapy.				

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Caprelsa (vandetanib)	100mg Tab 300mg Tab	02378582 02378590	DNP DNP	E (SFC) E (SFC)	SAV SAV
Criteria	• For the treatment of symptomatic and/or progressive medullary thyroid cancer (MTC) in patients with unresectable locally advanced or metastatic disease. Treatment should be for patients with a good performance status and should continue until disease progression or unacceptable toxicity				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Cathflo (alteplase)	2mg Vial	02245859	DNP	E (SF)	HLR
Criteria	• For the treatment of home hemodialysis central venous catheter occlusion. **Clinical Note:** • Not intended for regularly scheduled use.				

Criteria Updates

The following criteria have been updated effective **immediately:**

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Actemra (tocilizumab)	162mg/ 0.9mL Autoinjector	02483327	DNP	E (SF)	HLR
Criteria	• For the treatment of 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 ≥ 20 mg weekly (≥15mg if patient is ≥65 years of age), or use in combination with another DMARD, for a minimum of 12 weeks AND ○ Methotrexate in combination with at least two other DMARDs, such as hydroxychloroquine and sulfasalazine, for a minimum of 12 weeks **Clinical Notes:** • For patients who do not demonstrate a clinical response to oral methotrexate, or who experience gastrointestinal intolerance, a trial of parenteral methotrexate must be considered. • Optimal treatment response to DMARDs may take up to 24 weeks, however coverage of a biologic therapy can be considered if no improvement is seen after 12 weeks of triple DMARD use.				

Criteria Updates Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Actemra (tocilizumab)	162mg/ 0.9mL Autoinjector	02483327	DNP	E (SF)	HLR
Criteria	• 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: 1 year. Confirmation of continued response is required. • **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				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Erelzi (etanercept)	25mg/0.5mL Prefilled Syringe	02462877	DNP	E (SF)	SDZ
	50mg/mL Prefilled Syringe	02462869	DNP	E (SF)	SDZ
	50mg/mL Prefilled Autoinjector	02462850	DNP	E (SF)	SDZ
Criteria	• 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: o The sequential use of at least two NSAIDs at maximal tolerated dose for a minimum of two weeks each; AND o 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 o Leflunomide for a minimum of 10 weeks or sulfasalazine for a minimum of 3 months.				

Criteria Updates Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Erelzi	25mg/0.5mL Prefilled Syringe	02462877	DNP	E (SF)	SDZ
(etanercept)	50mg/mL Prefilled Syringe	02462869	DNP	E (SF)	SDZ
	50mg/mL Prefilled Autoinjector	02462850	DNP	E (SF)	SDZ
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. • 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. • Renewal approval: 1 year. Confirmation of continued response required. **For etanercept-naïve patients whose etanercept therapy is initiated after January 1, 2020 a biosimilar will be the product that is approved.**				

Criteria Update: Exception Status Criteria for Chronic Obstruction Pulmonary Disease Medications

An Atlantic Common Drug Review (ACDR) of inhaler therapy for COPD included a comprehensive review of clinical evidence (meta-analyses, RCTs etc.), consideration of the 2017 Canadian Thoracic Society and international COPD recommendations, and consultation with respiratory specialists in Atlantic Canada. Based on this review the criteria for coverage for inhalers used in COPD has changed (coverage for asthma is unchanged).

What remains the same?

- Spirometry is required to confirm a COPD diagnosis, as recommended by respiratory specialists and COPD clinical practice guidelines. A COPD diagnosis, as defined by spirometry, is a post bronchodilator $FEV_1/FVC < 0.7$. Bourbeau 2017, GOLD 2017
- Progression to LAMA/LABA dual long acting bronchodilator therapy requires prior use of long acting bronchodilator monotherapy, although the minimum time frame is reduced to one month – see key changes below re: dual bronchodilator therapy.

Key changes to criteria

- **Long acting bronchodilator therapy (LABA or LAMA)**
    - There is no longer a requirement for specific doses of short-acting bronchodilators prior to approval of a long acting bronchodilator.

Criteria Update: Exception Status Criteria for Chronic Obstruction Pulmonary Disease Medications Continued…

- Criteria for approval of either a LABA or LAMA inhaler include COPD patients experiencing **persistent symptoms** or **moderate to severe exacerbations.**
  - **Persistent symptoms** are defined by a Medical Research Council (MRC) score of at least 3 or a COPD Assessment Test (CAT) score ≥ 10 and a post- bronchodilator FEV_1 < 80% predicted.
    - The CAT score is an addition which coincides with recommendations in clinical practice guidelines.
    - The FEV_1 cutoff has been increased to 80% to coincide with the definition of moderate COPD.
  - **Exacerbations** are defined as experiencing 2 or more moderate exacerbations of COPD in the previous year requiring treatment with antibiotics and/or systemic corticosteroids OR at least 1 acute severe exacerbation of COPD (AECOPD) requiring hospital admission.
  - A clinical note: LAMA monotherapy is recommended over LABA for prevention of exacerbations. Bourbeau 2017, GOLD 2017

- **Dual bronchodilator therapy** (i.e., LABA/LAMA in one inhaler) may be approved after at least one month of monotherapy with either a LAMA or LABA.
  - The timeframe is reduced to 1 month to allow faster access to patients with persistent symptoms despite a trial of monotherapy with either a LAMA or LABA.
- **LABA/ICS** inhalers are funded only as a component of triple therapy (LABA/ICS + LAMA) following the use of LABA/LAMA for at least 2 months; **OR,** for patients with characteristics of both COPD and asthma (i.e., asthma/COPD overlap - ACO).
  - LABA/ LAMA are generally preferred over a LABA/ICS unless there are features of ACO.
  - It is acknowledged that there is a lack of consensus on the definition for ACO, or the appropriate pharmacotherapy. The criteria for approval of a LABA/ICS inhaler in ACO will be based on patient history and lung function studies. Bourbeau 2017
  - Note: Since the ACDR recommendations, updated Canadian Thoracic Society COPD guidelines were published in October 2019 which identify a role for LABA/ICS, primarily in patients with an eosinophil count ≥ 300 /µL and at high risk for exacerbations. Bourbeau 2019 However, eosinophil counts are not a consideration in the latest criteria update.
- **Triple inhaler therapy (LABA/ICS + LAMA or combined in one inhaler)**
  - Approval for triple therapy (LABA/ICS plus LAMA) requires the patient to have persistent symptoms or moderate to severe exacerbations while being treated for at least 2 months with a LAMA/LABA inhaler; or, in patients with asthma/COPD overlap after treatment with a LABA/ICS inhaler.
  - Note: Triple therapy is not recommended as initial therapy for COPD

Note: Inhaler technique and adherence to treatment should be assessed prior to making changes to inhaler therapy.

Criteria Update: Exception Status Criteria for Chronic Obstruction Pulmonary Disease Medications Continued…

Inhaler abbreviations: LABA= Long acting beta$_2$- agonist; LAMA= Long acting muscarinic antagonist; ICS = Inhaled corticosteroid

References

Bourbeau J, Bhutani M, Hernandez P, Marciniuk DD, Aaron S et al CTS position statement : Pharmacotherapy in patients with COPD -An update. Can J Resp, Critical Care and Sleep Medicine 2017; 1 (4) 222-241

Bourbeau J, Bhutani M, Hernandez P, Aaron SD, Balter M, et al (2019): Canadian Thoracic Society Clinical Practice Guideline on pharmacotherapy in patients with COPD – 2019 update of evidence, Can J Resp, Critical Care, and Sleep Medicine. 2019; 3:4, 210-232, DOI: 10.1080/24745332.2019.1668652

Global Strategy for the Diagnosis, Management and Prevention of COPD, Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2017. Available from: http://goldcopd.org. [Internet].

In accordance with the ACDR recommendations, the following criteria are revised:

Long Acting Beta$_2$-Agonists

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Foradil (formoterol)	12mcg Cap for Inh	02230898	DNP	E (SF)	NVR
Onbrez (indacaterol)	75mcg Micronized Pwd for Inh	02376938	DNP	E (SF)	NVR
Serevent (salmeterol)	50mcg/dose Diskus	02231129	DNP	E (SF)	GSK

Criteria

- For the treatment of chronic obstructive pulmonary disease (COPD), as defined by spirometry, in patients who experience:
  - persistent symptoms, as defined by Medical Research Council (MRC) Dyspnea Scale of at least Grade 3 or a COPD Assessment test (CAT) score of at least 10 and have a post-bronchodilator FEV_1 less than 80% predicted; OR
  - two or more moderate exacerbations of COPD in the previous year requiring treatment with antibiotics and/or systemic corticosteroids; OR
  - at least one acute severe exacerbation of COPD requiring hospitalization.

Clinical Note:

- COPD is defined by spirometry as a post-bronchodilator FEV_1/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. MRC Dyspnea Scale grade).

Claim Note:

- Requests for combination therapy of single agent long-acting bronchodilators, i.e. long-acting beta-2 agonist (LABA) and long-acting muscarinic antagonist (LAMA), will not be considered. Products which combine a LABA/LAMA in a single device are available as special authorization benefits with their own criteria.

Criteria Update: Exception Status Criteria for Chronic Obstruction Pulmonary Disease Medications Continued…

Long-Acting Muscarinic Antagonists

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Tudorza Genuair (aclidinium bromide)	400mcg Pwr for Inh	02409720	DNP	E (SF)	ALM
Seebri Breezhaler (glycopyrronium bromide)	50mcg Cap for Inh	02394936	DNP	E (SF)	NVR
Spiriva (tiotropium bromide)	18mcg Cap for Inh	02246793	DNP	E (SF)	BOE
Spiriva Respimat (tiotropium bromide monohydrate)	2.5mcg/actuation Inh Sol	02435381	DNP	E (SF)	BOE
Incruse Ellipta (umeclidinium)	62.5mcg Dry Pwr for Oral Inh	02423596	DNP	E (SF)	GSK

Criteria

- For the treatment of chronic obstructive pulmonary disease (COPD), as defined by spirometry, in patients who experience:
  - persistent symptoms, as defined by Medical Research Council (MRC) Dyspnea Scale of at least Grade 3 or a COPD Assessment test (CAT) score of at least 10 and have a post-bronchodilator FEV_1 less than 80% predicted; OR
  - two or more moderate exacerbations of COPD in the previous year requiring treatment with antibiotics and/or systemic corticosteroids; OR
  - at least one acute severe exacerbation of COPD requiring hospitalization.
- For the treatment of COPD, as defined by spirometry, in combination with a long-acting beta-$_2$ agonist/inhaled corticosteroid (LABA/ICS), for patients who experience inadequate control while being treated with a LABA/ICS or a long-acting beta-$_2$ agonist/long-acting muscarinic receptor antagonists (LABA/LAMA).

Clinical Notes:

- COPD is defined by spirometry as a post-bronchodilator FEV_1/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. MRC Dyspnea Scale grade).
- Inadequate control while being treated with a LABA/LAMA or LABA/ICS for at least two months is defined as persistent symptoms for at least two months, or experiencing two or more exacerbations of COPD in the previous year requiring treatment with antibiotics and/or systemic corticosteroids or at least one exacerbation of COPD requiring hospitalization.

Claim Note:

- Requests for combination therapy of single agent long-acting bronchodilators, i.e. LABA and LAMA, will not be considered. Products which combine a LABA/LAMA in a single device are available as special authorization benefits with their own criteria.

Criteria Update: Exception Status Criteria for Chronic Obstruction Pulmonary Disease Medications Continued…

Long-Acting Beta$_2$-Agonists/Inhaled Corticosteroids

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Advair	50/100mcg Diskus	02240835	DNP	E (SF)	GSK
(salmeterol/ fluticasone)	50/250mcg Diskus	02240836	DNP	E (SF)	GSK
	50/500mcg Diskus	02240837	DNP	E (SF)	GSK
	HFA 25/125mcg/dose Inh	02245126	DNP	E (SF)	GSK
	HFA 25/250mcg/dose Inh	02245127	DNP	E (SF)	GSK
Breo Ellipta	100mcg/25mcg Pwr for Inh	02408872	DNP	E (SF)	GSK
(fluticasone furoate and vilanterol)					
Symbicort	100/6mcg Turbuhaler	02245385	DNP	E (SF)	AZE
(formoterol/ budesonide)	200/6mcg Turbuhaler	02245386	DNP	E (SF)	AZE

Criteria

- For the treatment of chronic obstructive pulmonary disease (COPD), as defined by spirometry, in combination with a long-acting muscarinic antagonist (LAMA), in patients who experience inadequate control while being treated with a long-acting beta-$_2$ agonist/long-acting muscarinic antagonist (LABA/LAMA).
- For the treatment of patients with asthma / 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.).

Clinical Notes:

- COPD is defined by spirometry as a post-bronchodilator FEV_1/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. MRC Dyspnea Scale grade).
- Inadequate control while being treated with a LABA/LAMA for at least two months is defined as persistent symptoms, or experiencing two or more exacerbations of COPD in the previous year requiring treatment with antibiotics and/or systemic corticosteroids or at least one exacerbation of COPD requiring hospitalization.

Criteria Update: Exception Status Criteria for Chronic Obstruction Pulmonary Disease Medications Continued…

Long-Acting Beta$_2$-Agonists/Long-Acting Muscarinic Antagonist

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Ultibro Breezhaler **(indacaterol and glycopyrronium bromide)**	110/50mcg Cap for Inh	02418282	DNP	E (SF)	NVR
Anoro Ellipta **(vilanterol and umeclidinium bromide)**	62.5/25mcg Pwd for Inh	02418401	DNP	E (SF)	GSK
Duaklir Genuair **(formoterol and aclidinium bromide)**	12/400mcg Inh	02439530	DNP	E (SF)	AZE
Inspiolto Respimat **(olodaterol and tiotropium bromide)**	2.5mcg/2.5mcg Inh	02441888	DNP	E (SF)	BOE
Criteria	• For the treatment of chronic obstructive pulmonary disease (COPD), as defined by spirometry, in patients who experience inadequate control while being treated with either a long-acting beta-$_2$ agonist (LABA) or long-acting muscarinic antagonist (LAMA). **Clinical Notes:** • COPD is defined by spirometry as a post-bronchodilator FEV_1/FVC ratio less than 0.70. Spirometry reports from any point in time will be accepted. If spirometry cannot be obtained, reasons must be clearly explained, and other evidence of COPD severity provided (i.e. Medical Research Council (MRC) Dyspnea Scale grade). • Inadequate control is defined as persistent symptoms (e.g. MRC Dyspnea Scale of at least grade 3 or COPD Assessment test (CAT) score of at least 10) after at least one month of a LAMA or LABA. • LABA/LAMA combinations are not intended to be used with an inhaled corticosteroid (ICS) unless criteria for triple inhaled therapy (LABA/LAMA/ICS) is met.				

New Products

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

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Desferoxamine Inj	2g Vial	02247022	DNP	SF	PFI
Doloral	1mg/mL Syr	00614491	DN	SFC	ATL
Doloral	5mg/mL Syr	00614505	DN	SFC	ATL
pms-Zopiclone	3.75mg Tab	02458543	DNP	SFC	PMS
Sodium Chloride Inj USP	9mg/mL	02304341	DNPM	SF	TLG

Criteria Code for Hepatitis C Medications

Criteria code 34 has been added for use effective December 1, 2019 for the medications listed below. Criteria code 34 will allow payment of a patient's initial 28 day supply only. Criteria code 34 should be provided by the prescribing physician only, who has recognized that it is imperative that the patient start therapy immediately, for example, in patients who might not initiate therapy if there was a delay.

A written request must be provided to the Pharmacare office to allow coverage for the remaining duration of therapy.

- Epclusa (sofosbuvir/velpatasvir)
- Harvoni (sofosbuvir/ledipasvir)
- Maviret (glecaprevir/pibrentasvir)
- Sovaldi (sofosbuvir)
- Vosevi (sofosbuvir/velpatasvir/voxilaprevir)
- Zepatier (elbasvir/grazoprevir)

New Forms

New request forms for COPD and hepatitis C medications can be found at the following link:
https://novascotia.ca/dhw/pharmacare/exception-status-drugs.asp