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PHARMACISTS' EDITION

NOVA SCOTIA

# PharmacareNEWS

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## Nova Scotia Formulary Updates

### Changes in Benefit Status and Criteria Update: Topiramate

The Atlantic Common Drug Review (ACDR) recommended the following changes to the benefit status of topiramate, effective **February 1, 2016**.

**Full Benefits**

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| topiramate | 25mg Tab | Various | DNP | SF | VAR |
| topiramate | 100mg Tab | Various | DNP | SF | VAR |
| topiramate | 200mg Tab | Various | DNP | SF | VAR |

In addition, effective **February 1, 2016**, there will be the following changes:

**Criteria Change**

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| topiramate | 15mg Sprinkle Cap | 02239907 | DNP | E(SF) | JAN |
| | 25mg Sprinkle Cap | 02239908 | DNP | E(SF) | JAN |
| Criteria | • For patients who require topiramate, cannot take the tablet form, and require sprinkle capsules for proper administration. | | | | |

**Delisting**

The benefit status of pms-Topiramate 50mg Tab (02312085) will change to non-insured status. This strength is more costly compared to the other available strengths.

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## Change in Benefit Status: Escitalopram

The Atlantic Common Drug Review (ACDR) recommended that the following categories be listed as full benefits, effective February 1, 2016.

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MRP FEBRUARY 22, 2016 | MFR |
|---|---|---|---|---|---|---|
| escitalopram | 10mg Tab | Various | DNP | SFC | 0.4318 | VAR |
| escitalopram | 20mg Tab | Various | DNP | SFC | 0.4597 | VAR |

## Criteria Updates

The criteria for tocilizumab IV for rheumatoid arthritis (RA) has been updated to align with other currently listed biologics indicated in the management of RA. The requirement for prior failure of a tumour-necrosis factor (TNF)-alpha inhibitor has been removed.

Effective February 1, 2016, the revised criteria for tocilizumab IV for RA is as follows:

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| Actemra® (tocilizumab) | 80mg/4mL Inj | 02350092 | DNP | E (SF) | HLR |
| | 200mg/10mL Inj | 02350106 | DNP | E (SF) | HLR |
| | 400mg/20mL Inj | 02350114 | DNP | E (SF) | HLR |

**Criteria**

**Rheumatoid Arthritis (RA)**

- for patients with a diagnosis of active rheumatoid arthritis (RA) who:
  - have not responded or who have had intolerable toxicity to an adequate trial[1] of combination therapy of at least two traditional DMARDs[2] or
  - if combination therapy is not an option, an adequate trial[1] of at least three traditional DMARDs[2] in sequence as monotherapy and
  - patients must have had an adequate trial[1] of leflunomide. Exceptions can be considered in cases where leflunomide is contraindicated or not tolerated
- therapy must include methotrexate alone or in combination unless contraindicated or not tolerated
- written request of a rheumatologist or prescriber with a specialty in rheumatology
- after initial coverage period, can be reassessed for yearly coverage dependent on patient achieving an improvement in symptoms of at least 20%

Criteria Update: Actemra® Continued...

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| Actemra® (tocilizumab) | 80mg/4mL Inj | 02350092 | DNP | E (SF) | HLR |
| | 200mg/10mL Inj | 02350106 | DNP | E (SF) | HLR |
| | 400mg/20mL Inj | 02350114 | DNP | E (SF) | HLR |
| Criteria | Initial Coverage Duration and Maximum Dosage approved:<br>Tocilizumab IV<br>• initial coverage for 16 weeks at dose of 4mg/kg every 4 weeks, yearly coverage dependent on patient achieving an improvement in symptoms of at least 20%<br>• maximum dose: 800 mg every 4 weeks<br>[1] An adequate trial is 5 months for IM gold, 6 months for penicillamine, 4 months for hydroxychloroquine and 3 months for all other traditional DMARDs as well as leflunomide, infliximab and etanercept.<br>[2] Traditional agents include methotrexate, IM gold, sulfasalazine, hydroxychloroquine, azathioprine, chloroquine, penicillamine and cyclosporine.<br>*Please note that the concurrent use of anti-TNF agents will not be approved. | | | | |

Effective February 1, 2016, the criteria for Januvia and Janumet will be updated as per the national Common Drug Review recommendations. This update will bring the criteria in line with the other currently listed dipeptidyl peptidase-4 inhibitors (DPP4s).

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| Januvia® (sitagliptin) | 25mg Tab | 02388839 | DNP | E (SF) | FRS |
| | 50mg Tab | 02388847 | DNP | E (SF) | FRS |
| | 100mg Tab | 02303922 | DNP | E (SF) | FRS |
| Criteria | For the treatment of Type II diabetes for patients with:<br>• inadequate glycemic control on metformin and a sulfonylurea; and<br>• for whom insulin is not an option | | | | |

Criteria Updates: Januvia® and Janumet® Continued...

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| Janumet® (metformin/ sitagliptin) | 50/500mg Tab | 02333856 | DNP | E (SF) | FRS |
| | 50/850mg Tab | 02333864 | DNP | E (SF) | FRS |
| | 50/1000mg Tab | 02333872 | DNP | E (SF) | FRS |
| | 50/1000mg XR Tab | 02416794 | DNP | E (SF) | FRS |
| Criteria | For the treatment of Type II diabetes for patients:<br>• who are already stabilized on therapy with metformin, a sulfonylurea and sitagliptin to replace the individual components of sitagliptin and metformin; and<br>• for whom insulin is not an option. | | | | |

Cimzia (certolizumab pegol) is currently listed with criteria for rheumatoid arthritis (RA). It has now been reviewed by the Canadian Drug Expert Committee (CDEC) for Psoriatic Arthritis and Ankylosing Spondylitis and will be listed with the following additional criteria:

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| Cimzia® (certolizumab pegol) | 200mg/mL SC Inj | 02331675 | DNP | E (SF) | UCB |
| Criteria | Psoriatic Arthritis:<br>For the treatment of adult patients with active psoriatic arthritis who meet all of the following:<br>• have at least three active and tender joints;<br>• have not responded to an adequate trial with two DMARDs or have an intolerance or contraindication to DMARDs.<br>Notes:<br>Must be prescribed by a rheumatologist or prescriber with a specialty in rheumatology.<br>After initial coverage period, can be reassessed for yearly coverage dependent on patient achieving an improvement in symptoms of at least 20%<br>Initial Coverage Duration and Maximum Dosage approved:<br>• initial coverage period 3 months. Loading dose of 400mg at Weeks 0, 2 and 4.<br>• maximum maintenance dose of 200mg every 2 weeks or alternatively, 400mg every 4 weeks, and not in combination with other anti-TNF agents. | | | | |

Criteria Updates: Cimzia® Continued...

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| Cimzia® (certolizumab pegol) | 200mg/mL SC Inj | 02331675 | DNP | E (SF) | UCB |

**Criteria**

**Ankylosing Spondylitis:**

For the treatment of adult patients with moderate to severe ankylosing spondylitis (e.g., 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 3 months observation, 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 3 months observation and have had an inadequate response to an optimal dose or maximal tolerated dose of a DMARD.

Notes:
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").

**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.

Initial Coverage Duration and Maximum Dosage approved:

- initial coverage period 6 months. Loading dose of 400mg at Weeks 0, 2 and 4.
- maximum maintenance dose of 200mg every 2 weeks or alternatively, 400mg every 4 weeks, and not in combination with other anti-TNF agents.

## New Product

The following product is a new listing to the Nova Scotia Formulary, effective February 1, 2016. The benefit status within the Nova Scotia Pharmacare Programs is indicated.

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| Simbrinza® | 10mg-2mg/ml Oph Susp | 02435411 | DNP | SF | ALC |

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## Other Funding Decisions

### Nexavar® (sorafenib)

Nexavar (sorafenib) was reviewed by the pCODR Expert Review Committee (pERC) and it was recommended that coverage not be expanded to include the use of sorafenib for the treatment of locally advanced or metastatic, progressive differentiated thyroid carcinoma (DTC) refractory to radioactive iodine. The committee made this recommendation because they were not able to conclude that there is a net clinical benefit with sorafenib compared to placebo in this population. The effect on overall survival has not been established and treatment was associated with a decline in quality of life and significant rates of high grade toxicity. The criteria for Nexavar (sorafenib) will remain unchanged.

### Stivarga® (regorafenib)

Stivarga (regorafenib) was reviewed by the pCODR Expert Review Committee (pERC) and it was recommended that coverage not be expanded to include the use of regorafenib for the treatment of metastatic colorectal cancer in patients who have previously been treated with multiple other therapies. The committee made the recommendation because, compared to placebo plus best supportive care, regorafenib provided only a very modest progression-free and overall survival benefit and treatment is associated with moderate, but not insignificant toxicities. The criteria for Stivarga (regorafenib) will remain unchanged.

## New Diabetic and Ostomy Products

Effective February 1, 2016, a number of new SureComfort Diabetic supplies as well as CareSens BG test strips and Hollister ostomy products will be added as full benefits under the Nova Scotia Pharmacare Programs. The specific products and associated billing PINs (as per the OPINIONS website) can be found in the most recent update of the Nova Scotia Formulary, which will be available on the Nova Scotia Pharmacare website.

# Nova Scotia Pharmacare Programs Updates

## Changes to the Nova Scotia Seniors' Pharmacare Program

As of April 1, 2016, Seniors' Pharmacare members will pay 20% of the cost of their prescription at the counter; this copayment is down from 30%. After a member's copayments total $382, they will no longer make a copayment until the start of the next fiscal year (April 1 to March 31).

Seniors' Pharmacare members' premiums will be determined by their income.

### Premiums for single seniors

- Income below $22,986: will not pay any premium
- Earning $22,986 to $35,000: less than $40/month
- Earning $35,000 to $75,000: $40 to $100/month, based on income
- Earning more than $75,000: $100/month

Changes to the Nova Scotia Seniors' Pharmacare Program Continued…

Premiums for couples

- Combined income below $26,817: will not pay any premium
- Combined income of $26,817 to $40,000: less than $40/month each
- Combined income of $40,000 to $100,000: $40 to $100/month each, based on income
- Combined income above $100,000: $100/month each

For more information you may wish to visit: http://novascotia.ca/dhw/pharmacare/seniors-pharmacare.asp

## Pharmacare Payment Schedule

The Pharmacare payment schedule is available online at the following link:
http://novascotia.ca/dhw/pharmacare/pharmacists-guide.asp

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## Nova Scotia Formulary Updates

### New Exception Status Benefits

The following products have been reviewed by the Common Drug Review (CDR) and will be listed as an exception status benefit, with the following criteria, effective March 1, 2016.

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| Duaklir™ Genuair® (aclidinium/ formoterol) | 400µg/12µg metered dose for inhalation | 02439530 | DNP | E (SF) | AZE |

**Criteria**

- for the treatment of moderate to severe chronic obstructive pulmonary disease (COPD), as defined by spirometry, in patients with an inadequate response to a long-acting beta-2 agonist (LABA) or long-acting anticholinergic (LAAC).

Clinical Notes:

1. Moderate to severe COPD is defined by spirometry (post-bronchodilator) FEV1 < 60% predicted and FEV1/FVC ratio of < 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 regarding COPD severity must be provided for consideration (i.e. Medical Research Council (MRC) Dyspnea Scale score of at least Grade 3). MRC Grade 3 is described as: walks slower than people of same age on the level because of shortness of breath (SOB) from COPD or has to stop for breath when walking at own pace on the level.

2. Inadequate response is defined as persistent symptoms after at least 2 months of long-acting beta-2 agonist (LABA) or long-acting anticholinergic therapy (LAAC).

New Exception Status Benefits Continued…

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| Incruse™ Ellipta®<br>(umeclidinium (as bromide)) | 62.5mcg dry powder for oral inhalation | 02423596 | DNP | E (SF) | GSK |

**Criteria**

- for the treatment of moderate to severe chronic obstructive pulmonary disease (COPD) as defined by spirometry; OR
- for the treatment of COPD in patients with an inadequate response to short acting bronchodilators.
- Combination therapy with a long-acting beta-2 agonist /inhaled corticosteroid (LABA/ICS) and a long acting anticholinergic (LAAC) inhaler will be considered in patients with: moderate to severe COPD, as defined by spirometry, a history of COPD exacerbation(s) and an inadequate response to LABA/ICS or LAAC.

Clinical Notes:

1. Moderate to severe COPD is defined by spirometry as a post bronchodilator FEV1 < 60% predicted and FEV1/FVC ratio of < 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 Score of at least Grade 3. MRC Grade 3 is described as: walks slower than people of same age on the level because of shortness of breath from COPD or has to stop for breath when walking at own pace on the level.
2. Inadequate response to short acting bronchodilators is defined as persistent symptoms, i.e., MRC of at least Grade 3, after at least 2 months of short acting bronchodilator at the following doses*:
    - 8 puffs per day of short acting beta-2 agonist or
    - 12 puffs per day of ipratropium or
    - 6 puffs per day of ipratropium plus salbutamol combination inhaler

    * Inadequate response to LABA/ICS or LAAC is defined as persistent symptoms after at least 2 months of therapy.
3. COPD exacerbation is defined as an increase in symptoms requiring treatment with antibiotics and/or systemic (oral or intravenous) corticosteroids.

Note:

- Coverage for LABA and LAAC as two separate inhalers will not be considered.
- Inhalers which combine a LABA/LAAC are also available as ESD benefits. These products have their own criteria which are listed in the NS Formulary.

New Exception Status Benefits Continued…

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| Aptiom™ (eslicarbazepine) | 200mg Tab | 02426862 | DNP | E (SF) | SNV |
| | 400mg Tab | 02426870 | DNP | E (SF) | SNV |
| | 600mg Tab | 02426889 | DNP | E (SF) | SNV |
| | 800mg Tab | 02426897 | DNP | E (SF) | SNV |
| Criteria | • As adjunctive treatment for patients with refractory partial-onset seizures who meet all of the following criteria:<br>o are under the care of a physician experienced in the treatment of epilepsy, and<br>o are currently receiving two or more antiepileptic drugs, and<br>o in whom all other antiepileptic drugs are ineffective or not appropriate<br>Notes:<br>• Any combination of lacosamide, perampanel or eslicarbazepine will not be reimbursed. | | | | |

## New Product

The following product is a new listing to the Nova Scotia Formulary, effective March 1, 2016. The benefit status within the Nova Scotia Pharmacare Programs is indicated.

| PRODUCT | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|
| Lodalis® 3.75g powder for oral suspension | 02432463 | DNP | SF | VLN |

## New Diabetic Products

The following products are new listings to the Nova Scotia Formulary, effective March 1, 2016. The benefit status within the Nova Scotia Pharmacare Programs is indicated.

| PRODUCT | DIN/PIN | PRODUCT NUMBER | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| Insupen Pen Needle, 4mm, 33g | 97799383 | 22640 | DNP | SFD | DOM |
| Insupen Pen Needle, 4mm, 32g | 97799399 | 22620 | DNP | SFD | DOM |

# Pharmacare Reimbursement

## Changes to Maximum Reimbursable Prices:

Provinces and territories continue to work together to lower generic drug prices through the pan-Canadian Pharmaceutical Alliance.

Effective April 1, 2016, the Maximum Reimbursable Prices (MRPs) of four drugs will be set at 18% of brand price: Donepezil, Ezetimibe, Quetiapine and Zopiclone.

| PRODUCT | NEW MRP |
|---|---|
| donepezil 5mg tab | $0.8255 |
| donepezil 10mg tab | $0.8255 |
| ezetimibe 10mg tab | $0.3260 |
| quetiapine 25mg tab | $0.0889 |
| quetiapine 100mg tab | $0.2372 |
| quetiapine 200mg tab | $0.4764 |
| quetiapine 300mg tab | $0.6953 |
| zopiclone 5mg tab | $0.1782 |
| zopiclone 7.5mg tab | $0.2250 |

# Nova Scotia Pharmacare Programs Updates

## Seniors' Pharmacare Program

As you are likely aware, not all of the formerly planned changes will be moving forward as previously communicated in the January Pharmacare News Bulletin. However, there will be changes that allow more seniors to qualify for a lower premium as follows:

Single seniors earning less than $22,986 will not pay a premium while those earning $22,986 to $35,000 will pay up to $424/year.

Couples with a combined income between $26,817 and $40,000 will each pay a reduced premium of less than $424 per year.

The co-payment will remain at 30 per cent per prescription to a maximum of $382 per year.

More details can be found on our website at the following link:

http://novascotia.ca/dhw/pharmacare/seniors-pharmacare.asp

If you have any questions you can contact us at the following numbers:

Metro Halifax: 902-429-6565

Toll Free: 1-800-544-6191

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## Nova Scotia Formulary Updates

### Criteria Updates

The criteria for Buprenorphine/Naloxone has been updated to the following, effective May 2, 2016:

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| Buprenorphine/ Naloxone | 2mg/0.5mg SL Tab | Various | DN | E (SF) | VAR |
| (Brand and generics) | 8mg/2mg SL Tab | Various | DN | E (SF) | VAR |
| Criteria | • for the treatment of opioid dependence for patients in whom methadone is contraindicated (e.g., patients at high risk of, or with, QT prolongation, or hypersensitivity to methadone)<br>• for the treatment of opioid dependence for appropriate patients ages 18-24 years<br><br>Note:<br>Physicians wishing to prescribe buprenorphine/naloxone for opioid use disorder must be properly informed in its use. The College's Methadone Maintenance Support Program Committee's recommended resource is the Centre for Addition and Mental Health (CAMH) document Buprenorphine/Naloxone for Opioid Dependence: Clinical Practice Guidelines. For further information, the College recommends the CAMH Buprenorphine-Assisted Treatment of Opioid Dependence: An Online Course for Front-Line Clinicians and the College's Methadone Maintenance Treatment Handbook, Section 3: Options Other than MMT for Opioid Dependence | | | | |

Criteria Updates Continued…

The following product has been reviewed by the pCODR Expert Review Committee (pERC) and will be listed with the following criteria, effective May 2, 2016.

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| Xalkori | 200mg Cap | 02384256 | DNP | E (SFC) | PFI |
| (crizotinib) | 250mg Cap | 02384264 | DNP | E (SFC) | PFI |
| Criteria | • as a first-line therapy for patients with ALK-positive advanced non-small cell lung cancer with ECOG performance status ≤ 2.<br>AND<br>• as a second-line therapy for patients with ALK-positive advanced non-small cell lung cancer with ECOG performance status ≤ 2. | | | | |

## New Exception Status Benefits

The following products have been reviewed by the Canadian Drug Expert Committee (CDEC) and will be listed as exception status benefits, with the following criteria, effective May 2, 2016.

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| Diacomit | 250mg Cap | 02398958 | DNP | E (SF) | BOX |
| (stiripentol) | 500mg Cap | 02398966 | DNP | E (SF) | BOX |
| | 250mg Pdr for Susp | 02398974 | DNP | E (SF) | BOX |
| | 500mg Pdr for Susp | 02398982 | DNP | E (SF) | BOX |
| Criteria | • for use in combination with clobazam and valproate as adjunctive therapy of refractory generalized tonic-clonic seizures in patients with severe myoclonic epilepsy in infancy (Dravet syndrome), whose seizures are not adequately controlled with clobazam and valproate alone.<br>• the patient must be under the care of a neurologist or a pediatrician. | | | | |

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| Jardiance | 10mg Tab | 02443937 | DNP | E (SFD) | BOE |
| (empagliflozin) | 25mg Tab | 02443945 | DNP | E (SFD) | BOE |
| Criteria | For the treatment of Type II diabetes for patients with:<br>• inadequate glycemic control on metformin and a sulfonylurea; and<br>• for whom insulin is not an option | | | | |

New Exception Status Benefits Continued…

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| Inspiolto Respimat<br>(tiotropium bromide monohydrate/olodaterol hydrochloride) | 2.5mcg/2.5mcg Inh Sol | 02441888 | DNP | E (SF) | BOE |
| Criteria | • for the treatment of moderate to severe chronic obstructive pulmonary disease (COPD), as defined by spirometry, in patients with an inadequate response to a long-acting beta-2 agonist (LABA) or long-acting anticholinergic (LAAC).<br><br>Notes:<br>• Moderate to severe COPD is defined by spirometry (post-bronchodilator) FEV1 < 60% predicted and FEV1/FVC ratio of < 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 regarding COPD severity must be provided for consideration (i.e. Medical Research Council (MRC) Dyspnea Scale score of at least Grade 3). MRC Grade 3 is described as: walks slower than people of same age on the level because of shortness of breath (SOB) from COPD or has to stop for breath when walking at own pace on the level.<br>• Inadequate response is defined as persistent symptoms after at least 2 months of long-acting beta-agonist (LABA) or long-acting anticholinergic therapy (LAAC). | | | | |

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| Firazyr<br>(icatibant) | 30mg/3mL single dose pre-filled syringes | 02425696 | DNP | E (SF) | SHI |
| Criteria | For the treatment of acute attacks of hereditary angioedema (HAE) in adults with lab confirmed c1-esterase inhibitor deficiency (type I or type II) under the following conditions:<br>• treatment of non-laryngeal attacks of at least moderate severity, or<br>• treatment of acute laryngeal attacks<br><br>Notes:<br>• Limited to a single dose for self-administration per attack<br>• Be prescribed by physicians with experience in the treatment of HAE<br><br>Claim Notes:<br>• Maximum of two doses on hand at any time. | | | | |

New Exception Status Benefits Continued…

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| Spiriva Respimat<br>(tiotropium bromide monohydrate) | 2.5µg/actuation Inh Sol | 02435381 | DNP | E (SF) | BOE |

**Criteria**

- for the treatment of moderate to severe chronic obstructive pulmonary disease (COPD) as defined by spirometry; OR
- for the treatment of COPD in patients with an inadequate response to short acting bronchodilators.
- combination therapy with a long-acting beta-2 agonist /inhaled corticosteroid (LABA/ICS) and a long acting anticholinergic (LAAC) inhaler will be considered in patients with: moderate to severe COPD, as defined by spirometry, a history of COPD exacerbation(s) and an inadequate response to LABA/ICS or LAAC.

Clinical Notes:

1. Moderate to severe COPD is defined by spirometry as a post bronchodilator FEV1 < 60% predicted and FEV1/FVC ratio of < 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 Score of at least Grade 3. MRC Grade 3 is described as: walks slower than people of same age on the level because of shortness of breath from COPD or has to stop for breath when walking at own pace on the level.
2. Inadequate response to short acting bronchodilators is defined as persistent symptoms, i.e., MRC of at least Grade 3, after at least 2 months of short acting bronchodilator at the following doses*:
   - 8 puffs per day of short acting beta-2 agonist; or
   - 12 puffs per day of ipratropium; or
   - 6 puffs per day of ipratropium plus salbutamol combination inhaler

   * Inadequate response to LABA/ICS or LAAC is defined as persistent symptoms after at least 2 months of therapy.
3. COPD exacerbation is defined as an increase in symptoms requiring treatment with antibiotics and/or systemic (oral or intravenous) corticosteroids.

Note:

- Coverage for LABA and LAAC as two separate inhalers will not be considered.
- Inhalers which combine a LABA/LAAC are also available as ESD benefits. These products have their own criteria which are listed in the NS Formulary.

New Exception Status Benefits Continued…

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| Jentadueto (linagliptin/metformin) | 2.5mg/500mg Tab | 02403250 | DNP | E (SFD) | BOE |
| | 2.5mg/850mg Tab | 02403269 | DNP | E (SFD) | BOE |
| | 2.5mg/1000mg Tab | 02403277 | DNP | E (SFD) | BOE |
| Criteria | For the treatment of Type II diabetes for patients:<br>• who are already stabilized on therapy with metformin, a sulfonylurea and linagliptin to replace the individual components of linagliptin and metformin; and<br>• for whom insulin is not an option. | | | | |

The following product has been reviewed by the pCODR Expert Review Committee (pERC) and will be listed as an exception status benefit, with the following criteria, effective May 2, 2016.

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| Bosulif (bosutinib) | 100mg Tab | 02419149 | DNP | E (SFC) | PFI |
| | 500mg Tab | 02419157 | DNP | E (SFC) | PFI |
| Criteria | • As a treatment option for patients with chronic, accelerated or blast phase Philadelphia chromosome positive (Ph+) chronic myelogenous leukemia (CML) which have resistance/disease progression or intolerance to prior tyrosine kinase inhibitor (TKI) therapy, and for whom subsequent treatment with imatinib, nilotinib and dasatinib is not clinically appropriate. | | | | |

## New Products

The following products are new listings to the Nova Scotia Formulary, effective May 2, 2016. The benefit status within the Nova Scotia Pharmacare Programs is indicated. Where applicable, existing criteria applies.

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| Coversyl | 2mg Tab | 02123274 | DNP | SF | SEV |
| Fragmin | 3500 IU/0.28 mL prefilled syringe | 02430789 | DNP | SFC | PFI |
| Ibavyr | 200mg Tab | 02439212 | DNP | E (SF) | PDP |
| Jakavi | 10mg Tab | 02434814 | DNP | E (SFC) | NVR |
| Lidodan | 2% Jelly | 02143879 | DNP | SFC | ODN |
| Mavik | 0.5mg Cap | 02231457 | DNP | SF | BGP |
| Nutropin AQ NuSpin | 5mg Inj | 02376393 | DNP | E (SF) | HLR |
| Nutropin AQ NuSpin | 10mg Inj | 02399091 | DNP | E (SF) | HLR |
| Nutropin AQ NuSpin | 20mg Inj | 02399083 | DNP | E (SF) | HLR |

## Changes in Benefit Status

The following product and category will be listed as full benefits, effective May 2, 2016.

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| Pentoxifylline | 400mg Tab | 02230090 | DNP | SF | AAP |
| Tizanidine | 4mg Tab | Various | DNP | SF | VAR |

## New Diabetic Supplies

The following products are new listings to the Nova Scotia Formulary, effective May 2, 2016. The benefit status within the Nova Scotia Pharmacare Programs is indicated.

| PRODUCT | DIN/PIN | PRODUCT NUMBER | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| First Canadian Health Lancet 28g X 0.36mm | 97799253 | 288082 | DNP | SFD | ARA |
| First Canadian Health Lancet 28g X 0.37mm | 97799292 | 288082-201 | DNP | SFD | ARA |
| First Canadian Health Lancet 33g X 0.19mm | 97799255 | 288591 | DNP | SFD | ARA |
| First Canadian Health Lancet 30g X 0.32mm | 97799254 | 288087 | DNP | SFD | ARA |
| First Canadian Health Spirit – Blood Glucose Test Strips (50) | 97799290 | 288144 | DNP | SFD | ARA |
| First Canadian Health Spirit – Blood Glucose Test Strips (100) | 97799291 | 288105 | DNP | SFD | ARA |

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## Nova Scotia Formulary Updates

### New Exception Status Benefits

The following product has been reviewed by the Canadian Drug Expert Committee (CDEC) and will be listed as an exception status benefit, with the following criteria, effective June 1, 2016

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| Inflectra (infliximab) | 100mg Pdr for Inj | 02419475 | DNP | E (SF) | HOS |

**Criteria**

*For infliximab-naïve patients whose infliximab therapy is initiated after June 1, 2016, Infectra will be the product approved for the following indications:*

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 3 months observation, 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 3 months observation and have had an inadequate response to an optimal dose or maximal tolerated dose of a DMARD.

Notes:

- Must be prescribed by a rheumatologist or prescriber with a specialty in rheumatology.

New Exception Status Benefits Continued…

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| Inflectra (infliximab) | 100mg Pdr for Inj | 02419475 | DNP | E (SF) | HOS |

**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")

**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.

- Initial coverage period 6 months, maximum dose 5mg/kg at 0, 2, and 6 weeks then every 6-8 weeks thereafter and not in combination with other anti-TNF agents.

Psoriasis:

For patients with severe, debilitating chronic plaque psoriasis (PsO) who meet all of the following criteria:

- Body Surface Area (BSA) involvement of >10% and/or significant involvement of the face, hands, feet or genital region;
- failure to respond to, contraindications to or intolerant of methotrexate and cyclosporine;
- failure to respond to, intolerant of or unable to access phototherapy; AND
- written request of a dermatologist or prescriber with a specialty in dermatology.

Continued coverage is dependent on evidence of improvement, specifically:

- ≥ 75% reduction in the Psoriasis Area and Severity Index (PASI) score; OR
- ≥ 50% reduction in PASI with a ≥ 5 point improvement in DLQI (Dermatology Life Quality Index); OR
- significant reduction in BSA involved, with consideration of important regions such as the face, hands, feet or genitals.

Concurrent use of biologics not approved.

Initial approval for a maximum of 12 weeks. Dosage restricted to infliximab 5mg/kg 0, 2 and 6 weeks then every 8 weeks.

Rheumatoid Arthritis:

- Refer to RA criteria included in this bulletin.

…New Exception Status Benefits continued on Page 6

## Criteria Updates – Rheumatoid Arthritis

The Atlantic Common Drug Review (ACDR) reviewed the Rheumatoid Arthritis criteria for biologics and based on updated evidence, effective June 1, 2016, the revised criteria will apply to the following drugs:

- abatacept Inj
- adalimumab Pen and Inj
- certolizumab pegol SC Inj
- etanercept Inj
- golimumab Autoinjector and Syringe
- infliximab Pdr for Inj
- tocilizumab IV Inj and SC Inj

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.
- 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.

Criteria Updates – Rheumatoid Arthritis Continued…

- Maximum Dosage Approved:
  - Abatacept Intravenous infusion: 500mg for patients <60 kg, 750mg for patients 60-100 kg and 1000mg for patients >100 kg, given at 0, 2, and 4 weeks then every 4 weeks thereafter. Subcutaneous injection: a single IV loading dose of up to 1,000mg may be given, followed by 125mg subcutaneous injection within a day, then once-weekly 125mg subcutaneous injections
  - Adalimumab: 40mg every two weeks with no dose escalation permitted
  - Certolizumab pegol: 400mg at weeks 0, 2 and 4 weeks, then 200mg every 2 weeks (or 400mg every 4 weeks) with no dose escalation permitted
  - Etanercept: 25mg twice a week or 50mg once a week with no dose escalation permitted
  - Golimumab: 50mg once a month with no dose escalation permitted
  - Infliximab (Remicade): 3mg/kg/dose at 0, 2 and 6 weeks, then every 8 weeks thereafter
  - Infliximab (Inflectra): 3mg/kg/dose at 0, 2 and 6 weeks, then every 8 weeks thereafter
  - Tocilizumab: 4mg/kg/dose once every 4 weeks followed by an increase to 8 mg/kg/dose based on clinical response

As per the Canadian Drug Expert Committee (CDEC) recommendation, tocilizumab IV will be listed to include the following criteria for the management of Polyarticular Juvenile Idiopathic Arthritis, effective June 1, 2016:

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| Actemra (tocilizumab) | 80mg/4mL Inj | 02350092 | DNP | E (SF) | HLR |
| | 200mg/10mL Inj | 02350106 | DNP | E (SF) | HLR |
| | 400mg/20mL Inj | 02350114 | DNP | E (SF) | HLR |
| Criteria | • 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).<br>Notes:<br>• Must be prescribed by, or in consultation with, a rheumatologist who is familiar with the use of biologic DMARDs in children.<br>• 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.<br>• Initial approval period: 16 weeks<br>• Renewal Approval: 1 year. Confirmation of continued response is required. | | | | |

## New Exception Status Benefits

The following product has been reviewed by the Canadian Drug Expert Committee (CDEC) and will be listed as an exception status benefit, with the following criteria, effective June 1, 2016.

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| Zaxine (rifaximin) | 550mg Tab | 02410702 | DNP | E (SF) | LUP |
| Criteria | For reducing the risk of overt hepatic encephalopathy (HE) recurrence if the following clinical criteria are met:<br>• patients are unable to achieve adequate control of HE recurrence with lactulose alone<br>• used in combination with a maximal tolerated dose of lactulose | | | | |

## New Interchangeable Categories

A Maximum Reimbursable Price (MRP) or Pharmacare Reimbursement Price (PRP) has been established for the following products. Benefit status is effective May 20, 2016.

| PRODUCT | DIN/PIN | PRESCRIBER | BENEFIT STATUS MAY 20, 2016 | MRP/PRP* JUNE 10, 2016 | MFR |
|---|---|---|---|---|---|
| **duloxetine 30mg cap** | | | | | |
| Apo-Duloxetine 30mg Cap | 02440423 | DNP | E (SF) | 0.4814 | APX |
| Auro-Duloxetine 30mg Cap | 02436647 | DNP | E (SF) | 0.4814 | ARO |
| Duloxetine DR 30mg Cap | 02437082 | DNP | E (SF) | 0.4814 | TEV |
| Jamp-Duloxetine 30mg Cap | 02451913 | DNP | E (SF) | 0.4814 | JPC |
| Mar-Duloxetine 30mg Cap | 02446081 | DNP | E (SF) | 0.4814 | MAR |
| MINT-Duloxetine 30mg Cap | 02438984 | DNP | E (SF) | 0.4814 | MNT |
| pms-Duloxetine 30mg Cap | 02429446 | DNP | E (SF) | 0.4814 | PMS |
| Ran-Duloxetine 30mg Cap | 02438259 | DNP | E (SF) | 0.4814 | RAN |
| Sandoz Duloxetine 30mg Cap | 02439948 | DNP | E (SF) | 0.4814 | SDZ |
| Cymbalta 30mg Cap | 02301482 | DNP | E (SF) | 0.4814 | LIL |
| **duloxetine 60mg cap** | | | | | |
| Apo-Duloxetine 60mg Cap | 02440431 | DNP | E (SF) | 0.9769 | APX |
| Auro-Duloxetine 60mg Cap | 02436655 | DNP | E (SF) | 0.9769 | ARO |
| Duloxetine DR 60mg Cap | 02437090 | DNP | E (SF) | 0.9769 | TEV |
| Jamp-Duloxetine 60mg Cap | 02451921 | DNP | E (SF) | 0.9769 | JPC |
| Mar-Duloxetine 60mg Cap | 02446103 | DNP | E (SF) | 0.9769 | MAR |
| MINT-Duloxetine 60mg Cap | 02438992 | DNP | E (SF) | 0.9769 | MNT |
| pms-Duloxetine 60mg Cap | 02429454 | DNP | E (SF) | 0.9769 | PMS |
| Ran-Duloxetine 60mg Cap | 02438267 | DNP | E (SF) | 0.9769 | RAN |
| Sandoz Duloxetine 60mg Cap | 02439956 | DNP | E (SF) | 0.9769 | SDZ |
| Cymbalta 60mg Cap | 02301490 | DNP | E (SF) | 0.9769 | LIL |

## Change in Benefit Status

The following categories will be listed as full benefits, effective May 20, 2016.

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| Indapamide | 1.25mg Tab | Various | DNP | SF | VAR |
| Indapamide | 2.5mg Tab | Various | DNP | SF | VAR |

## Change in Category Pricing

The following category will change from MLP to MRP, effective June 1, 2016.

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| Citalopram | 10mg Tab | Various | DNP | SFC | VAR |

## Palliative Care Drug Program Updates

As you may know, the Nova Scotia Palliative Care Drug Program is available for those who need assistance covering medications used in palliative care. This program ensures that the cost of medications does not create a financial barrier for those who wish to receive end-of-life care at home.

Over the past year the Department of Health and Wellness has been collaborating with Palliative Care teams and specialists to provide supports and education regarding the best use of the program. The goal of working collaboratively is to support the most effective use of this program.

Part of this work has resulted in additional documents and tools that may be helpful to you in your practice. This additional information can be found on our website at:

http://novascotia.ca/dhw/pharmacare/palliative-drug-program.asp

The information includes, but is not limited to a Formulary, a brief comparison chart reviewing the various Pharmacare Programs, and Frequently Asked Questions.

Claims are to continue to be submitted online as per other programs, using the patient identification number and a carrier ID of NS. Further information is available in the Pharmacists' Guide available at:

http://novascotia.ca/dhw/pharmacare/pharmacists-guide.asp

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## Nova Scotia Formulary Updates

### Changes in Benefit Status

Effective **September 1, 2016**, the following products will move to full benefit status and will no longer require special authorization.

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| Apidra (insulin glulisine) | 3mL Cartridge | 02279479 | DNP | SFD | SAV |
| Apidra (insulin glulisine) | SoloSTAR 3mL Prefilled Pen | 02294346 | DNP | SFD | SAV |
| Apidra (insulin glulisine) | 10mL Vial | 02279460 | DNP | SFD | SAV |

*An Exception Status Request Form for the other rapid acting insulins can be found at the back of this bulletin and will be available on the Pharmacare website at www.nspharmacare.ca.

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| Nabilone (Cesamet and generic brands) | 0.25mg Cap | Various | DN | SFC | VAR |
| Nabilone (Cesamet and generic brands) | 0.5mg Cap | Various | DN | SFC | VAR |
| Nabilone (Cesamet and generic brands) | 1mg Cap | Various | DN | SFC | VAR |

## New Exception Status Benefits

The following products have been reviewed by the pCODR Expert Review Committee (pERC) and will be listed with the following criteria, effective September 1, 2016.

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| Tafinlar (dabrafenib) | 50mg Cap | 02409607 | DNP | E (SFC) | NVR |
| | 75mg Cap | 02409615 | DNP | E (SFC) | NVR |
| Mekinist (trametinib) | 0.5mg Tab | 02409623 | DNP | E (SFC) | NVR |
| | 2mg Tab | 02409658 | DNP | E (SFC) | NVR |
| Criteria | • Dabrafenib-trametinib combination therapy as a first-line BRAF-mutation targeted treatment for patients with BRAF V600 mutation positive, unresectable or metastatic melanoma and who have an ECOG performance status of 0 or 1. Treatment should continue until disease progression. If brain metastases are present, patients should be asymptomatic or have stable symptoms.<br>• In the event that a patient is initiated on dabrafenib-trametinib combination therapy and has to discontinue one agent due to toxicity, dabrafenib or trametinib monotherapy as a BRAF-mutation targeted treatment for patients with BRAF V600 mutation positive, unresectable or metastatic melanoma and who have an ECOG performance status of 0 or 1, will be funded, should that be the chosen treatment option. Treatment should continue until disease progression. If brain metastases are present, patients should be asymptomatic or have stable symptoms. For clarity, initiation of treatment with dabrafenib or trametinib monotherapy will not be funded. | | | | |

## Criteria Update

The following product was reviewed for the management of asthma by the Canadian Drug Expert Committee (CDEC) and will be listed with the following additional criteria effective September 1, 2016.

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| Breo Ellipta (fluticasone furoate/vilanterol) | 100mcg/25mcg Pdr for Inh | 02408872 | DNP | E (SF) | GSK |
| | 200/25 mcg Pdr for Inh | 02444186 | DNP | E (SF) | GSK |
| Criteria | For the treatment of moderate to severe asthma in patients who:<br>• are compliant with inhaled corticosteroids at optimal doses; and<br>• require additional symptom control, (e.g., cough, awakening at night, missing activities such as school, work or social activities because of asthma symptoms); and<br>• require increasing amounts of short-acting beta2-agonists, indicative of poor control | | | | |

## New Product

The following product is a new strength to be added to the Nova Scotia Formulary, effective September 1, 2016. The benefit status within the Nova Scotia Pharmacare Programs is indicated and existing criteria will apply.

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| Revlimid (lenalidomide) | 20mg Cap | 02440601 | DNP | E (SFC) | CEL |

## Non Insured Products

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

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| Prezcobix (darunavir/cobicistat) | 800mg/150mg Tab | 02426501 | N/A | Non Insured | JAN |

The following products were reviewed and the recommendation was not to list as benefits in the Pharmacare Programs for the following indications.

| PRODUCT | STRENGTH | INDICATION | DIN | MFR |
|---|---|---|---|---|
| Afinitor (everolimus) | Various | Subependymal giant cell astrocytoma associated with tuberous sclerosis complex | Various | NVR |
| Constella (linaclotide) | 145mcg Cap<br>290mcg Cap | Irritable bowel syndrome with constipation | 02417162<br>02417170 | ATV<br>ATV |
| Daklinza (daclatasvir) | 30mg Tab<br>60mg Tab | Hepatitis C, chronic | 02444747<br>02444755 | BMS<br>BMS |
| Dymista (azelastine HCl and fluticasone propionate) | 137mcg/50mg Nasal Spray | Seasonal allergic rhinitis | 02432889 | MVL |
| Elelyso (taliglucerase alfa) | 200U/Vial Pdr for Inj | Gaucher disease | 02425637 | PFI |
| Juxtapid (lomitapide) | 5mg Cap<br>10mg Cap<br>20mg Cap | Homozygous familial hypercholesterolemia | 02420341<br>02420376<br>02420384 | AEG<br>AEG<br>AEG |
| Opsumit (macitentan) | 10mg Tab | Pulmonary Arterial Hypertension | 02415690 | ACT |
| Revolade (eltrombopag) | 25mg Tab<br>50mg Tab | Thrombocytopenia associated with chronic hepatitis C infection | 02361825<br>02361833 | GSK<br>GSK |
| Signifor (pasireotide diaspartate) | 0.3mg/mL Inj<br>0.6mg/mL Inj<br>0.9mg/mL Inj | Cushing Disease | 02413299<br>02413302<br>02413310 | NVR<br>NVR<br>NVR |

## New Ostomy Products

Effective September 1, 2016, a number of Coloplast ostomy products will be added as full benefits under the Nova Scotia Pharmacare Programs. The specific products and associated billing PINs (as per the OPINIONS website) can be found in the next update of the Nova Scotia Formulary, which will be available on the Nova Scotia Pharmacare website.

## Administration of Publicly-Funded Influenza Vaccine by Pharmacists for the 2016-2017 Influenza Season

### Who is eligible to have publicly-funded influenza vaccine administered by a pharmacist?

All individuals 5 years of age and over can have publicly-funded influenza vaccine administered by a pharmacist. As publicly-funded influenza vaccine is available free of charge, no individual is to be charged for the vaccine.

### Who is eligible to have the influenza vaccine administration fee publicly-funded?

Only residents with a valid Nova Scotia Health Card Number are eligible to have the influenza vaccine administration fee billed to Pharmacare. There are no copayments or deductibles associated with the administration of the influenza vaccine to residents with a valid Nova Scotia Health Card Number. All other individuals are responsible for paying the applicable administration fee.

### Which pharmacies are eligible to bill for the administration of publicly-funded influenza vaccine?

Pharmacies set up as providers to bill publicly-funded influenza vaccine administration fees last year are already set up for the 2016-2017 influenza season. However, all pharmacies are still required to contact their local Nova Scotia Health Authority public health office to confirm their email, dispensary telephone number, and their preferred method for being contacted by public health.

Pharmacies that have not yet been set up as a provider to bill publicly-funded influenza vaccine administration must:

1. Comply with the required training and application expectations set out by the *Pharmacist Extended Practice Regulations* and the NSCP's *Standards of Practice: Drug Administration*.
2. Sign the *Confirmation of Agreement Form for Pharmacist Administered Publicly Funded Seasonal Influenza Vaccine* (available in the Pharmacists' Guide) and submit it to Medavie Blue Cross. Medavie Blue Cross will confirm by email or facsimile that the pharmacy has been set up as a provider to bill influenza vaccine administration fees.
3. Provide their local public health office with their provider confirmation and any other information the public health office requires to issue influenza vaccine to the pharmacy.

### Where do pharmacies get publicly-funded influenza vaccine?

All publicly-funded influenza vaccine must be obtained from the local public health office. All providers are responsible for any transportation costs to obtain publicly-funded vaccine. Pharmacies should contact their local public health office to place their order for vaccine and to arrange pick-up. Review the packing protocol for transporting biologicals in the Nova Scotia Immunization Manual (located at: http://novascotia.ca/dhw/cdpc/documents/Immunization-Manual.pdf ) to ensure you have all the required equipment when you pick up your vaccine. Public health can only release vaccine in accordance with this protocol.

### When can pharmacists begin administering publicly-funded influenza vaccine?

Pharmacists may begin administering publicly-funded influenza vaccine as soon as they receive it.

Administration of Publicly-Funded Influenza Vaccine by Pharmacists for the 2016-2017 Influenza Season Continued…

### How do pharmacies bill Pharmacare for influenza vaccine administration fees?

Fees for the administration of publicly-funded influenza vaccine to Nova Scotia residents with a valid Nova Scotia Health Card must be billed to Pharmacare online. The electronic claim must contain the following in the patient's insurance field:

- Patient ID – *the patient's Nova Scotia Health Card Number*
- Carrier ID – *NS*

If a patient is already set up in the pharmacy system with Pharmacare coverage (e.g., Seniors' Pharmacare, Family Pharmacare), a separate patient file does not need to be created. Claims must be submitted using the DIN of the vaccine administered to the patient, unless the patient is pregnant or is a child receiving a second vaccine dose. The following Table provides direction related to submitting claims using a PIN for pregnant women or children receiving a second dose.

Claims are submitted with the administration fee in the professional fee field. Providers are not reimbursed for ingredient costs or markups for these claims as they are able to access publicly-funded vaccine at no charge.

### Claims Submission Field Content for Pharmacist-Administered Publicly Funded Influenza Vaccines

| CPhA Claim Standard Field # | CPhA Claim Standard Field Name | Content |
|---|---|---|
| D.56.03 | DIN/GP#/PIN | DINs<br>Fluzone Quadrivalent MDV 02432730<br>FluLaval Tetra 02420783<br><br>PIN for pregnant women<br>Fluzone Quadrivalent 93899895<br>FluLaval Tetra 93899893<br><br>PIN for second dose for children<br>Fluzone Quadrivalent 93899896<br>FluLaval Tetra 93899894 |
| D.58.03 | Quantity | 000001 (one) |
| D.61.03 | Prescriber ID | Pharmacists prescriber ID |
| D.66.03 | Drug Cost/Product Value | DDDDD (dollar value - not adjudicated) |
| D 67.03 | Cost Upcharge | DDDDD (dollar value - not adjudicated) |
| D.68.03 | Professional Fee | $12.00 |

### What documentation does a pharmacy need to retain for audit and other purposes?

Pharmacies must retain the signed patient Consent and Disclosure form for each claim reimbursed by Pharmacare. Pharmacies are advised to maintain a record of the quantity of influenza vaccine administered to individuals who do not have a valid Nova Scotia Health Card Number, as this information may be requested by public health.

Administration of Publicly-Funded Influenza Vaccine by Pharmacists for the 2016-2017 Influenza Season Continued...

### How do I report an adverse event following immunization (AEFI)?

It is possible that reactions may occur after administration of influenza vaccine, without a causal association to the vaccine. These reactions must be reported to your local Nova Scotia Health Authority public health office for the appropriate follow-up. Providers should document an AEFI using the Public Health Agency of Canada AEFI form (located at: http://www.phac-aspc.gc.ca/im/pdf/raefi-dmcisi-eng.pdf) and forward the form to the local public health office. The local public health office reviews these reports and enters them in their local database before they are forwarded to the Public Health Agency of Canada.

### What do I do if there is a break in the cold chain?

Cold chain refers to the process used to maintain optimal conditions during the transport, storage, and handling of vaccines, starting with the manufacturer and ending with the administration of the vaccine. When vaccines are exposed to temperatures of less than 2°C or more than 8°C, the result is a break in the cold chain. Vaccines affected by a break in the cold chain must be packaged separately, identified with a sticker reading "DO NOT USE," and stored in a refrigerator at between 2°C and 8°C separately from vaccines in current use. Contact your local public health office to determine whether or not they can be used.

# NOVA SCOTIA PROVINCIAL PHARMACARE PROGRAMS
## Request for Coverage of Rapid Acting Insulins

### PATIENT INFORMATION

| PATIENT SURNAME | PATIENT GIVEN NAME | HEALTH CARD NUMBER | DATE OF BIRTH |
|---|---|---|---|
| | | | |

PATIENT ADDRESS

### DRUG REQUESTED

**FULL BENEFIT – no form required:**
Apidra (insulin glulisine)

**EXCEPTION STATUS BENEFITS – complete all sections of the form below:**
☐ NovoRapid (insulin aspart)
☐ Humalog (insulin lispro)

### CRITERIA AND DIAGNOSTIC INFORMATION

**NovoRapid and Humalog Criteria:**
For the management of Type I or Type II diabetes mellitus in patients who are:
- undergoing intensive therapy, i.e. administering three or more injections of insulin per day including basal insulin, and
- testing blood glucose levels 4-6 times per day.

► Please identify previous/current treatment and frequency of dosing:

_____
_____
_____
_____
_____

► Please identify how often blood glucose is monitored per day:

_____

| PRESCRIBER NAME & ADDRESS: | | |
|---|---|---|
| LICENCE # | PRESCRIBER SIGNATURE | DATE |

**If you need assistance, please contact the Pharmacare Office at (902) 496-7001 or 1-800-305-5026**

**Please Return Form To**: Nova Scotia Pharmacare Programs
P.O. Box 500, Halifax, NS B3J 2S1
Fax: (902) 496-4440

**08/2016**

NOVA SCOTIA

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PHARMACISTS' EDITION

NOVA SCOTIA

# PharmacareNEWS

inside



# Nova Scotia Formulary Updates

## New Exception Status Benefits

The following product has been reviewed by the pCODR Expert Review Committee (pERC) and will be listed with the following criteria, effective **December 1, 2016.**

| Product | Strength | DIN | Prescriber | Benefit Status | MFR |
|---|---|---|---|---|---|
| **Iclusig (ponatinib)** | 15mg Tab | 02437333 | DNP | E (SFC) | PAL |
| | 45mg Tab | 02437341 | DNP | E (SFC) | PAL |
| Criteria | • For the treatment of patients with chronic phase, accelerated phase or blast phase chronic myeloid leukemia (CML) or Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) for whom other tyrosine kinase inhibitor (TKI) therapy is not appropriate, including CML or Ph+ ALL that is T315i mutation positive or where there is resistance or intolerance to prior TKI therapy. Funding should be for ECOG performance status 0-2. Treatment should continue until unacceptable toxicity or disease progression. | | | | |

The following product has been reviewed by the Atlantic Common Drug Review (ACDR) and will be listed with the following criteria, effective **December 1, 2016.**

| Product | Strength | DIN | Prescriber | Benefit Status | MFR |
|---|---|---|---|---|---|
| **Sodium Bicarbonate** | 500mg Tab | 80030520 | DNP | E (SF) | JPC |
| | 500mg Tab | 80022194 | DNP | E (SF) | SDZ |
| Criteria | • For patients with chronic kidney disease with a serum bicarbonate (CO2) <22 mmol/L. | | | | |

**New Exception Status Benefits Continued…**

The following products have been reviewed by the Common Drug Review (CDR) and will be listed with the following criteria, effective **December 1, 2016.**

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| **Ferriprox** | 100mg/mL Sol | 02436523 | DNP | E (SF) | APO |
| **(deferiprone)** | 1000mg Tab | 02436558 | DNP | E (SF) | APO |
| Criteria | • For the treatment of patients with transfusional iron overload due to thalassemia syndromes when current chelation therapy is inadequate. | | | | |

In order to allow for online adjudication the claim must be divided and processed as separate transactions. The following PINs are to be used to bill drug cost in excess of $9,999.99:

100mg/mL Sol

- 00904194 and 00904195

1000mg Tab

- 00904192 and 00904193

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| **Xolair** | 150mg sterile powder for reconstitution vials | 02260565 | DNP | E (SF) | NVR |
| **(omalizumab)** | | | | | |
| 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.<br><br>**Criteria Notes:**<br>• Prescribed by a specialist (allergist, immunologist, dermatologist, etc.) or other authorized prescriber with knowledge of CIU treatment.<br>• Initial approval period of 24 weeks at a maximum dose of 300mg every 4 weeks.<br>• 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.<br>• Continued coverage will be authorized if the patient has achieved:<br>  ○ complete symptom control for less than 12 consecutive weeks; or<br>  ○ partial response to treatment, defined as at least a ≥ 9.5 point reduction in baseline urticaria activity score over 7 days (UAS7) | | | | |

**New Exception Status Benefits Continued…**

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| **Cosentyx (secukinumab)** | 300mg dose kits (two subcutaneous injections of 150mg/1mL) | 02438070 | DNP | E (SF) | NVR |
| Criteria | For patients with severe, debilitating chronic plaque psoriasis who meet all of the following:<br>• Body surface area (BSA) involvement of >10% and/or significant involvement of the face, hands, feet or genitals;<br>• Failure to, contraindication to or intolerant of methotrexate and cyclosporine;<br>• Failure to, intolerant of or unable to access phototherapy;<br>• Written request of a dermatologist or prescriber with a specialty in dermatology.<br><br>Continued coverage is dependent on evidence of improvement, specifically:<br>• A >75% reduction in the Psoriasis Area and Severity Index (PASI) score; or<br>• A >50% reduction in PASI with a > 5 point improvement in DLQI (Dermatology Life Quality Index); or<br>• Significant reduction in BSA involved, with consideration of important regions such as the face, hands, feet or genitals.<br><br>Concurrent use of biologics not approved.<br>Initial approval for a maximum of 12 weeks.<br>Coverage may be approved as follows: initial dosing of 300 mg doses at Weeks 0, 1, 2 and 3, followed by monthly maintenance dosing of 300 mg doses starting at Week 4. | | | | |

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| **Ofev (nintedanib)** | 100mg Cap<br>150mg Cap | 02443066<br>02443074 | DNP<br>DNP | E (SF)<br>E (SF) | BOE<br>BOE |
| Criteria | **Initial approval criteria:**<br>Adult patients who have a diagnosis of mild to moderate idiopathic pulmonary fibrosis (IPF)* confirmed by a respirologist and a high-resolution CT scan within the previous 24 months.<br>• All other causes of restrictive lung disease (e.g. collagen vascular disorder or hypersensitivity pneumonitis) should be excluded.<br>• Patient is under the care of a physician with experience in IPF | | | | |

**New Exception Status Benefits Continued…**

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| **Ofev** | 100mg Cap | 02443066 | DNP | E (SF) | BOE |
| **(nintedanib)** | 150mg Cap | 02443074 | DNP | E (SF) | BOE |
| Criteria | • Initial approval period: 7 months (allow 4 weeks for repeat pulmonary function tests)<br>*Mild-moderate IPF is defined as: a forced vital capacity (FVC) ≥ 50% of predicted.<br>**Initial renewal criteria:**<br>Patients must NOT demonstrate progression of disease defined as an absolute decline in percent predicted FVC of ≥10% from initiation of therapy until renewal (initial 6 month treatment period). If a patient has experienced progression as defined above, then the results should be validated with a confirmatory pulmonary function test conducted 4 weeks later.<br>• Approval period: 6 months<br>**Second and Subsequent renewal criteria (at 12 months after initiation and thereafter):**<br>Patients must NOT demonstrate progression of disease defined as an absolute decline in percent predicted FVC of ≥10% within any 12 month period. If a patient has experienced progression as defined above, then the results should be validated with a confirmatory pulmonary function test conducted 4 weeks later.<br>• Approval period: 12 months<br>**Exclusion Criteria:**<br>Combination use of Ofev (nintedanib) and Esbriet (pirfenidone) will not be funded.<br>**Note:**<br>• Patients who have experienced intolerance or failure to Ofev (nintedanib) or Esbriet (pirfenidone) will be considered for the alternate agent provided that the patient continues to meet the above coverage criteria. | | | | |
| Decision Highlights | • The Manufacturer's Patient Access Program is called HeadStart™ and can be reached by phone at 1-844-473-6338. | | | | |

In order to allow for online adjudication the claim must be divided and processed as separate transactions. The following PIN is to be used to bill drug cost in excess of $9,999.99:

- 00904198

**New Exception Status Benefits Continued…**

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| **Lemtrada (alemtuzumab)** | 12 mg/1.2 mL (10mg/mL) concentrated solution for IV infusion in single-use vials | 02418320 | DNP | E (SF) | GZM |
| Criteria | For the management of adult patients with relapsing-remitting multiple sclerosis (RRMS), with active disease defined by clinical and imaging features, who have had an inadequate response to interferon beta or other disease-modifying therapies, if the following clinical criteria are met:<br>• At least two attacks (first episode or relapse) in the previous two years, with at least one attack in the previous year;<br>• At least one relapse while on at least six months of a disease modifying therapy within the last 10 years;<br>• An Expanded Disability Status Scale (EDSS) score of five (5) or less;<br>• Prescribed by a specialist with experience in the treatment of multiple sclerosis.<br><br>**Claim Note:**<br>A maximum of two years of therapy (i.e. two treatment courses; 8 vials) will be reimbursed. | | | | |

In order to allow for online adjudication the claim must be divided and processed as separate transactions. The following PIN is to be used to bill drug cost in excess of $9,999.99:

- 00904161

Please call the Nova Scotia Pharmacare Programs if additional PINs are required.

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| **Orencia (abatacept)** | 125mg/mL pre-filled syringe | 02402475 | DNP | E (SF) | BRI |
| Criteria | **Rheumatoid Arthritis (250mg/15mL vial and 125mg/mL pre-filled syringe):**<br>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:<br>• 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<br>• methotrexate in combination with at least two other DMARDs, such as hydroxychloroquine and sulfasalazine, for a minimum of 12 weeks | | | | |

**New Exception Status Benefits Continued…**

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| **Orencia (abatacept)** | 125mg/mL pre-filled syringe | 02402475 | DNP | E (SF) | BRI |
| Criteria | **Clinical Notes:**<br>• 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.<br>• 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.<br>• 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.<br>• Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above.<br>• 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.<br><br>**Claim Notes:**<br>• Must be prescribed by a rheumatologist.<br>• Combined use of more than one biologic DMARD will not be reimbursed.<br>• Initial Approval: 6 months<br>• Renewal Approval: 1 year. Confirmation of continued response is required.<br><br>**Maximum Dosage Approved:**<br>• Abatacept Intravenous infusion: 500mg for patients <60 kg, 750mg for patients 60-100 kg and 1000mg for patients >100 kg, given at 0, 2, and 4 weeks then every 4 weeks thereafter.<br>• Subcutaneous injection: a single IV loading dose of up to 1,000mg may be given, followed by 125mg subcutaneous injection within a day, then once-weekly 125mg subcutaneous injections. | | | | |

**New Exception Status Benefits Continued…**

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| **Xeljanz (tofacitinib)** | 5mg Tab | 02423898 | DNP | E (SF) | PFI |

Criteria

**Rheumatoid Arthritis:**

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 ≥ 20mg weekly (≥15mg if patient is ≥ 65 years of age) for a minimum of 12 weeks, followed by methotrexate in combination with at least two other DMARDs, such as hydroxychloroquine and sulfasalazine, for a minimum of 12 weeks; OR
- Initial use of triple DMARD therapy with methotrexate in combination with at least two other DMARDs such as hydroxychloroquine and sulfasalazine, for a minimum of 24 weeks.

**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 may take up to 24 weeks; however coverage of tofacitinib can be considered if no improvement is seen after 12 weeks of triple DMARD use.
- If the patient is intolerant to triple DMARD therapy, then dual therapy with DMARDs (methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) 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 or contraindications to treatments as defined in product monographs. The nature of intolerance(s) must be clearly documented.
- Must be prescribed by a rheumatologist.
- Combined use with biologic DMARD will not be reimbursed.

## Criteria Updates

The following products were reviewed by the Common Drug Review (CDR) and will be listed with the following new criteria effective **December 1, 2016.**

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| **Esbriet (pirfenidone)** | 267mg Cap | 02393751 | DNP | E (SF) | HLR |
| Criteria | **Initial approval criteria:**<br>Adult patients who have a diagnosis of mild to moderate idiopathic pulmonary fibrosis (IPF)* confirmed by a respirologist and a high-resolution CT scan within the previous 24 months.<br>• All other causes of restrictive lung disease (e.g. collagen vascular disorder or hypersensitivity pneumonitis) should be excluded.<br>• Patient is under the case of a physician with experience in IPF<br>• Initial approval period: 7 months (allow 4 weeks for repeat pulmonary function tests)<br>*Mild-moderate IPF is defined as: a forced vital capacity (FVC) ≥ 50% of predicted.<br><br>**Initial renewal criteria:**<br>Patients must NOT demonstrate progression of disease defined as an absolute decline in percent predicted FVC of ≥10% from initiation of therapy until renewal (initial 6 month treatment period). If a patient has experienced progression as defined above, then the results should be validated with a confirmatory pulmonary function test conducted 4 weeks later.<br>• Approval period: 6 months<br><br>**Second and Subsequent renewal criteria (at 12 months after initiation and thereafter):**<br>Patients must NOT demonstrate progression of disease defined as an absolute decline in percent predicted FVC of ≥10% within any 12 month period. If a patient has experienced progression as defined above, then the results should be validated with a confirmatory pulmonary function test conducted 4 weeks later.<br>• Approval period: 12 months<br><br>**Exclusion Criteria:**<br>Combination use of Esbriet (pirfenidone) and Ofev (nintedanib) will not be funded. | | | | |
| Decision Highlights | • The Manufacturer's Patient Access Program is called the Inspiration™ Program and can be reached by phone at 1-855-547-3227. | | | | |

In order to allow for online adjudication the claim must be divided and processed as separate transactions. The following PIN is to be used to bill drug cost in excess of $9,999.99:

- 00904113

**Criteria Updates Continued…**

The following product was reviewed by the Common Drug Review (CDR) and will be listed with the following additional criteria effective **December 1, 2016.**

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| **Inflectra (infliximab)** | 100mg/vial, sterile, lyophilized powder for solution | 02419475 | DNP | E (SF) | HOS |

Criteria

***For infliximab-naïve patients whose infliximab therapy is initiated after December 1, 2016, Inflectra will be the product approved for the following indications:***

**Ulcerative Colitis:**

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 more than one biologic DMARD will not be reimbursed.
- Initial Approval: 16 weeks.
- Renewal Approval: 1 year.

**Criteria Updates Continued…**

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| **Inflectra (infliximab)** | 100mg/vial, sterile, lyophilized powder for solution | 02419475 | DNP | E (SF) | HOS |
| Criteria | **Crohn's Disease:**<br>As per current Crohn's Disease criteria. Please refer to the Anti-Tumor Necrosis Factor (TNF) Agents criteria in the Nova Scotia Formulary online at http://novascotia.ca/dhw/pharmacare/documents/Criteria-for-Exception-Status-Coverage.pdf<br>Initial approval is for three infusions of infliximab of 5mg/kg/dose at 0, 2 and 6 week intervals.<br>**Psoriatic Arthritis:**<br>As per current Psoriatic Arthritis criteria. Please refer to the Anti-Tumor Necrosis Factor (TNF) Agents criteria in the Nova Scotia Formulary online at http://novascotia.ca/dhw/pharmacare/documents/Criteria-for-Exception-Status-Coverage.pdf<br>Initial approval for a maximum of 3 months. Dosage restricted to infliximab 5mg/kg 0, 2 and 6 weeks then every 8 weeks. | | | | |

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| **Eliquis (apixaban)** | 2.5mg Tab<br>5mg Tab | 02377233<br>02397714 | DNP<br>DNP | E (SF)<br>E (SF) | BRI<br>BRI |
| Criteria | **Deep Vein Thrombosis/Pulmonary Embolism:**<br>**Inclusion Criteria:**<br>• For the treatment of deep vein thrombosis (DVT) or pulmonary embolism (PE)<br>• Approval Period: Up to six (6) months<br>**Notes:**<br>• The recommended dose of apixaban for patients initiating DVT or PE treatment is 10mg twice daily for 7 days, followed by 5mg twice daily (for treatment up to 6 months).<br>• Drug plan coverage for apixaban for the treatment of DVT or PE is an alternative to heparin/warfarin for up to six months. When used for greater than 6 months, apixaban is more costly than heparin/warfarin. As such, patients with an intended duration of therapy greater than 6 months should be considered for initiation on heparin/warfarin.<br>• Since renal impairment can increase bleeding risk, it is important to monitor renal function regularly. Other factors that increase bleeding risks should also be assessed and monitored (see apixaban product monograph) | | | | |

**Criteria Updates Continued…**

The following product was reviewed by the pCODR Expert Review Committee (pERC) and will be listed with the following additional criteria effective **December 1, 2016.**

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| **Revlimid (lenalidomide)** | Various | Various | DNP | E (SFC) | CEL |
| Criteria | • As a first-line treatment option for newly diagnosed patients with multiple myeloma who are not eligible for autologous stem cell transplantation. Treatment should be in combination with dexamethasone for patients with ECOG performance status 0-2, and until disease progression.<br>**Notes:**<br>Celgene will ensure that the Product will be prescribed and dispensed only by physicians and pharmacists, respectively, who are registered with and agree in writing to adhere to the guidelines of the Company's RevAid® Program, details of which Program are available at https://revaid.ca/revaid. | | | | |

The following products were reviewed by the Atlantic Common Drug Review (ACDR) and will be listed with the following new criteria effective **December 1, 2016.**

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| **Donepezil** | Various | Various | DNP | E (SF) | VAR |
| **Galantamine** | Various | Various | DNP | E (SF) | VAR |
| **Rivastigmine** | Various | Various | DNP | E (SF) | VAR |
| Criteria | For the treatment of patients with mild to moderate dementia who meet the following criteria:<br>• A Mini-Mental Statement Examination (MMSE) score of 10 to 30<br>AND<br>• A Functional Assessment Staging Test (FAST) score of 4 to 5<br>• Initial requests for reimbursement will be considered for a 4 month approval; subsequent requests may be considered for a maximum 12 months approval. | | | | |
| Decision Highlights | • The committee made this recommendation because the types of dementia are not clearly differentiated in the clinical setting; therefore, there is no need to specify the types in the criteria. Also, the criteria addressing switching within 4 months between cholinesterase inhibitors was removed, as switching may be required at various times during therapy. | | | | |

**Criteria Updates Continued…**

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| **Renagel (Sevelamer hydrochloride)** | 800mg Tab | 02244310 | DNP | E (SF) | SAV |
| Criteria | For the treatment of hyperphosphatemia (>1.8 mmol/L) in patients with end-stage renal disease (eGFR < 15 mL/min) who have:<br>• Inadequate control of phosphate levels on a calcium based phosphate binder, or<br>• Hypercalcemia (corrected for albumin), or<br>• Calciphylaxis (calcific arteriolopathy)<br><br>**Claim Notes:**<br>• Must be prescribed by a nephrologist or other prescriber within the Provincial Dialysis Program.<br>• Initial Approval: 6 months.<br>• Renewal Approval: 1 year. Confirmation of improvement of phosphate levels is required (lab values must be provided). | | | | |

## New Products

The following products are new listings to the Nova Scotia Formulary, effective **December 1, 2016**. The benefit status within the Nova Scotia Pharmacare Programs is indicated.

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| Arnuity Ellipta | 100mcg Pdr for Inh | 02446561 | DNP | SF | GSK |
| Arnuity Ellipta | 200mcg Pdr for Inh | 02446588 | DNP | SF | GSK |
| Biltricide | 600mg Tab | 02230897 | DNP | SF | BAY |
| Jamp-Nystatin | 100,000iu/mL Oral Susp | 02433443 | DNP | SFC | JPC |
| Naropin | 5mg/mL Inj | 02229415 | DNP | SFC | AZE |
| Naropin | 10mg/mL Inj | 02229418 | DNP | SFC | AZE |
| Pms-Sennosides | 8.6 mg Tab | 00896411 | DNP | C | PMS |
| Ropivacaine | 5mg/mL Inj | 02347822 | DNP | SFC | HOS |
| Ropivacaine | 10mg/mL Inj | 02347830 | DNP | SFC | HOS |

## Change of Benefit Status

Effective **December 1, 2016,** the following products will move to full benefit status and will no longer require special authorization.

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| NovoRapid (Insulin Aspart) | 100iu/mL Penfill Ins | 02244353 | DNP | SFD | NNO |
| NovoRapid (Insulin Aspart) | 100iu/mL Vial Ins | 02245397 | DNP | SFD | NNO |
| NovoRapid (Insulin Aspart) | 100iu/mL Flextouch | 02377209 | DNP | SFD | NNO |
| Olanzapine | 2.5mg Tab | Various | DNP | SF | VAR |
| Olanzapine | 5mg Tab | Various | DNP | SF | VAR |
| Olanzapine | 7.5mg Tab | Various | DNP | SF | VAR |
| Olanzapine | 10mg Tab | Various | DNP | SF | VAR |
| Olanzapine | 15mg Tab | Various | DNP | SF | VAR |
| Olanzapine | 20mg Tab | Various | DNP | SF | VAR |
| Olanzapine ODT | 5mg Tab | Various | DNP | SF | VAR |
| Olanzapine ODT | 10mg Tab | Various | DNP | SF | VAR |
| Olanzapine ODT | 15mg Tab | Various | DNP | SF | VAR |
| Olanzapine ODT | 20mg Tab | Various | DNP | SF | VAR |

## Non Insured Product

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| LoLo (ethinyl estradiol/norethindrone) | 10mcg/1mg Tab | 02417456 | N/A | **Non Insured** | WNC |

## Delisted Product

Effective **December 1, 2016**, Fosrenol will be delisted as a benefit under the Nova Scotia Pharmacare Programs. Those with coverage currently will be grandparented.

| PRODUCT | STRENGTH | DIN | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| Fosrenol (lanthanum) | 250mg Tab | 02287145 | N/A | **Delisted** | SHI |
| Fosrenol (lanthanum) | 500mg Tab | 02287153 | N/A | **Delisted** | SHI |
| Fosrenol (lanthanum) | 750mg Tab | 02287161 | N/A | **Delisted** | SHI |
| Fosrenol (lanthanum) | 1000mg Tab | 02287188 | N/A | **Delisted** | SHI |

## New Ostomy Products

Effective **December 1, 2016** a number of Hollister ostomy products will be added as full benefits under the Nova Scotia Pharmacare Programs. The specific products and associated billing PINs (as per the OPINIONS website) can be found in the next update of the Nova Scotia Formulary, which will be available on the Nova Scotia Pharmacare website.

## New Diabetic Products

The following products will be new listings to the Nova Scotia Formulary, effective **December 1, 2016**. The benefit status and reimbursement price within the Nova Scotia Pharmacare Programs is indicated.

| PRODUCT | DIN/PIN | PRODUCT NUMBER | PRESCRIBER | BENEFIT STATUS | MFR |
|---|---|---|---|---|---|
| Droplet Lancet 28G | 97799232 | 7106 | DNP | SFD | SFA |
| Droplet Lancet 30G | 97799233 | 7167 | DNP | SFD | SFA |
| Droplet Lancet 33G | 97799234 | 7206 | DNP | SFD | SFA |
| Droplet Pen Needles 10mm/29G | 97799238 | 8084 | DNP | SFD | SFA |
| Droplet Pen Needles 12mm/29G | 97799235 | 8085 | DNP | SFD | SFA |
| Droplet Pen Needles 5mm/31G | 97799239 | 8156 | DNP | SFD | SFA |
| Droplet Pen Needles 6mm/31G | 97799237 | 8082 | DNP | SFD | SFA |
| Droplet Pen Needles 8mm/31G | 97799236 | 8085 | DNP | SFD | SFA |
| Droplet Pen Needles 4mm/32G | 97799243 | 8081 | DNP | SFD | SFA |
| Droplet Pen Needles 5mm/32G | 97799242 | 8153 | DNP | SFD | SFA |
| Droplet Pen Needles 6mm/32G | 97799241 | 8154 | DNP | SFD | SFA |
| Droplet Pen Needles 8mm/32G | 97799240 | 8155 | DNP | SFD | SFA |

## Reminder: Claims Submission for Therapeutic Substitution Service - Proton Pump Inhibitors (PPIs)

Pharmacists must submit electronic claims for therapeutic substitution services to the Pharmacare Programs for reimbursement provided all of the criteria for coverage are met (this criteria can be found in the Pharmacists' Guide).

The following steps **must be** completed on the same day in the following order for the pharmacy to be reimbursed for the service:

- The original claim for the prescription as written by the prescriber is submitted to Pharmacare and then reversed.
- A claim for therapeutic substitution is submitted using PIN 93899912. (This PIN is specific for therapeutic substitutions within the PPI category).
- The record of therapeutic substitution must reference the prescription numbers for the original claim and modified claim.
- The claim for the new prescription with the changes made is submitted to Pharmacare.

*Please see the Pharmacists' Guide for a table depicting all CPhA Claims Standard field content.

## Reminder: Publicly-Funded Influenza Vaccine by Pharmacist

**Reminder: Claim Submissions for Publicly-Funded Influenza Vaccine by Pharmacist**

The last Pharmacare News Bulletin (Volume 16-05) contained the table below, which indicated claim submission content, which must be included for adjudication of the influenza vaccine. To ensure claims are adjudicated correctly, all influenza claims must be adjudicated using a **quantity of 1**, as well as the correct DIN and/or PIN.

Effective **December 1, 2016** reports will be generated by Nova Scotia Pharmacare to identify claims adjudicated with an improper quantity (<1) and incorrect PINS (i.e. PIN for pregnant women, used to adjudicate claim for male). These reports will be provided to pharmacies and the indicated claims must be reversed and resubmitted correctly. Any claims that have been identified on these reports, which are not corrected, may be subject to audit and possible recovery of administration fees.

**Claims Submission Field Content for Pharmacist-Administered Publicly Funded Influenza Vaccines**

| CPhA Claim Standard Field # | CPhA Claim Standard Field Name | Content |
|---|---|---|
| D.56.03 | DIN/GP#/PIN | **DINs**<br>Fluzone Quadrivalent MDV 02432730<br>FluLaval Tetra 02420783<br>**PIN for pregnant women**<br>Fluzone Quadrivalent 93899895<br>FluLaval Tetra 93899893<br>**PIN for second dose for children**<br>Fluzone Quadrivalent 93899896<br>FluLaval Tetra 93899894 |
| D.58.03 | Quantity | **000001 (one)** |
| D.61.03 | Prescriber ID | Pharmacists prescriber ID |
| D.66.03 | Drug Cost/Product Value | DDDDD (dollar value - not adjudicated) |
| D 67.03 | Cost Upcharge | DDDDD (dollar value - not adjudicated) |
| D.68.03 | Professional Fee | $12.00 |

**Reminder: How to adjudicate claims for individuals without a valid Nova Scotia Health Card Number?**

Only residents with a valid Nova Scotia Health Card Number are eligible to have the influenza vaccine administration fee billed to Pharmacare. Individuals who do not have a valid Nova Scotia Health Card Number are responsible for paying the applicable administration fee.

Pharmacies are advised to maintain a record of the quantity of influenza vaccine administered to individuals who do not have a valid Nova Scotia Health Card Number, as this information may be requested by public health.

## Home Care Acute Care Drugs

The Department of Health, Risk Mitigation – Continuing Care Branch oversees the payment for Home Care Acute Care drugs. The process at this time is that each pharmacy receives an authorization form that has been completed by a care coordinator or referral assistant, fills the prescription and bills appropriately. Billing should be done first through private insurance (except Pharmacare) and any remaining co-pays are then submitted to the local Nova Scotia Health Authority, Continuing Care Zone financial office. Continuing Care in turn processes these invoices and submits them to the DHW. It has been noted that in some cases pharmacies are not sending the original prescription receipt. Please be advised that only the original receipt will be processed on a go forward basis.

## Nova Scotia Insulin Pump Program Annual Renewal

The Nova Scotia Insulin Pump Program (NSIPP) offers financial assistance toward the cost of insulin pumps and supplies. Beneficiaries of this program are required to renew their enrollment each year.

Eligibility for renewal and enrolment:

- Must be a permanent resident of Nova Scotia with a valid Nova Scotia Health Card
- Must be 25 years of age or younger
- Must meet medical criteria as determined by the program

Currently the program year runs from January 01 to December 31. For more information to renew or apply visit: http://novascotia.ca/dhw/NSIPP/