JANUARY 2016 • VOLUME 16-01
PHYSICIANS' EDITION

NOVA SCOTIA

PharmacareNEWS

inside

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.

NOVA SCOTIA

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: Tocilizumab IV • 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% • maximum dose: 800 mg every 4 weeks [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. [2] Traditional agents include methotrexate, IM gold, sulfasalazine, hydroxychloroquine, azathioprine, chloroquine, penicillamine and cyclosporine. *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: • inadequate glycemic control on metformin and a sulfonylurea; and • 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: • who are already stabilized on therapy with metformin, a sulfonylurea and sitagliptin to replace the individual components of sitagliptin and metformin; and • 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: For the treatment of adult patients with active psoriatic arthritis who meet all of the following: • have at least three active and tender joints; • have not responded to an adequate trial with two DMARDs or have an intolerance or contraindication to DMARDs. Notes: Must be prescribed by 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% Initial Coverage Duration and Maximum Dosage approved: • initial coverage period 3 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.				

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

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.

Legend

PRESCRIBER CODES	BENEFIT STATUS	MANUFACTURER CODES
D - Physician / Dentist	S - Seniors' Pharmacare	ALC - Alcon Canada Inc.
N - Nurse Practitioner	F - Community Services Pharmacare	FRS - Merck Canada Ltd.
P - Pharmacist	- Family Pharmacare	HLR - Hoffmann-LaRoche Limited
M - Midwife	C - Drug Assistance for Cancer Patients	JAN - Janssen-Ortho Inc.
O - Optometrist	D - Diabetes Assistance Program	UCB - UCB Pharma Canada Inc.
	E - Exception status applies	VAR - *various manufacturers*

FEBRUARY 2016 • VOLUME 16-02
PHYSICIANS' EDITION

NOVA SCOTIA

PharmacareNEWS

inside

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® (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: o are under the care of a physician experienced in the treatment of epilepsy, and o are currently receiving two or more antiepileptic drugs, and o in whom all other antiepileptic drugs are ineffective or not appropriate Notes: • 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	DRX
Insupen Pen Needle, 4mm, 32g	97799399	22620	DNP	SFD	DRX

Legend

PRESCRIBER CODES	BENEFIT STATUS	MANUFACTURER CODES
D - Physician / Dentist	S - Seniors' Pharmacare	AZE - AstraZeneca Canada Inc.
N - Nurse Practitioner	F - Community Services Pharmacare	DRX - Domrex Pharma Inc.
P - Pharmacist	- Family Pharmacare	GSK - GlaxoSmithKline Inc.
M - Midwife	C - Drug Assistance for Cancer Patients	SNV - Sunovion Pharmaceuticals Canada Inc.
O - Optometrist	D - Diabetes Assistance Program	
	E - Exception status applies	VLN - Valeant Canada Limited

APRIL 2016 • VOLUME 16-03
PHYSICIANS' EDITION

NOVA SCOTIA

PharmacareNEWS

inside

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) • for the treatment of opioid dependence for appropriate patients ages 18-24 years Note: 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. AND • 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. • 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: • inadequate glycemic control on metformin and a sulfonylurea; and • for whom insulin is not an option				

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Inspiolto Respimat (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). Notes: • 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. • 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 (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: • treatment of non-laryngeal attacks of at least moderate severity, or • treatment of acute laryngeal attacks Notes: • Limited to a single dose for self-administration per attack • Be prescribed by physicians with experience in the treatment of HAE Claim Notes: • Maximum of two doses on hand at any time.				

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Spiriva Respimat (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 2.5mg/850mg Tab 2.5mg/1000mg Tab	02403250 02403269 02403277	DNP DNP DNP	E (SFD) E (SFD) E (SFD)	BOE BOE BOE
Criteria	For the treatment of Type II diabetes for patients: • who are already stabilized on therapy with metformin, a sulfonylurea and linagliptin to replace the individual components of linagliptin and metformin; and • 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 500mg Tab	02419149 02419157	DNP DNP	E (SFC) E (SFC)	PFI 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

Legend

PRESCRIBER CODES

- D - Physician / Dentist
- N - Nurse Practitioner
- P - Pharmacist
- M - Midwife
- O - Optometrist

BENEFIT STATUS

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

MANUFACTURER CODES

- AAP - AA Pharma Inc.
- ARA - ARA Pharmaceuticals Inc.
- BGP - BGP Pharma Inc
- BOE - Boehringer Ingelheim (Canada) Ltd.
- BOX - Biocodex S.A.
- HLR - Hoffmann-LaRoche Limited
- NVR - Novartis Pharmaceuticals Canada Inc.
- ODN - Odan Laboratories Ltd.
- PDP - PendoPharm, Division of Pharmascience Inc.
- PFI - Pfizer Canada Inc.
- SEV - Servier Canada Inc.
- SHI - Shire Canada Inc.
- VAR - *various manufacturers*

MAY 2016 • VOLUME 16-04
PHYSICIANS' EDITION

NOVA SCOTIA

PharmacareNEWS

inside

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 5

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). Notes: • Must be prescribed by, or in consultation with, a rheumatologist who is familiar with the use of biologic DMARDs in children. • Intravenous infusion: Approvals will be for 10mg/kg for patients <30kg or 8mg/kg for patients ≥ 30kg, to a maximum of 800mg, administered every four weeks. • Initial approval period: 16 weeks • 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: • patients are unable to achieve adequate control of HE recurrence with lactulose alone • used in combination with a maximal tolerated dose of lactulose				

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

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.

Legend

PRESCRIBER CODES	BENEFIT STATUS	MANUFACTURER CODES
D - Physician / Dentist	S - Seniors' Pharmacare	HLR - Hoffmann-LaRoche Limited
N - Nurse Practitioner	F - Community Services Pharmacare	HOS - Hospira Healthcare Corporation
P - Pharmacist	- Family Pharmacare	LUP - Lupin Pharma Canada Limited
M - Midwife	C - Drug Assistance for Cancer Patients	VAR - *Various manufacturers*
O - Optometrist	D - Diabetes Assistance Program	
	E - Exception status applies	

SEPTEMBER 2016 • VOLUME 16-05
PHYSICIANS' EDITION

NOVA SCOTIA

PharmacareNEWS

inside

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. • 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: • are compliant with inhaled corticosteroids at optimal doses; and • require additional symptom control, (e.g., cough, awakening at night, missing activities such as school, work or social activities because of asthma symptoms); and • 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 290mcg Cap	Irritable bowel syndrome with constipation	02417162 02417170	ATV ATV
Daklinza (daclatasvir)	30mg Tab 60mg Tab	Hepatitis C, chronic	02444747 02444755	BRI BRI
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 10mg Cap 20mg Cap	Homozygous familial hypercholesterolemia	02420341 02420376 02420384	AEG AEG AEG
Opsumit (macitentan)	10mg Tab	Pulmonary Arterial Hypertension	02415690	ACT
Revolade (eltrombopag)	25mg Tab 50mg Tab	Thrombocytopenia associated with chronic hepatitis C infection	02361825 02361833	GSK GSK
Signifor (pasireotide diaspartate)	0.3mg/mL Inj 0.6mg/mL Inj 0.9mg/mL Inj	Cushing Disease	02413299 02413302 02413310	NVR NVR 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.

Legend

PRESCRIBER CODES	BENEFIT STATUS	MANUFACTURER CODES
D - Physician / Dentist	S - Seniors' Pharmacare	ACT - Actelion Pharmaceuticals Canada Inc.
N - Nurse Practitioner	F - Community Services Pharmacare	AEG - Aegerion Phamaceuticals (Canada) Ltd.
P - Pharmacist	- Family Pharmacare	BRI - Bristol-Myers Squibb Canada Inc.
M - Midwife	C - Drug Assistance for Cancer Patients	CEL - Celgene
O - Optometrist	D - Diabetes Assistance Program	GSK - GlaxoSmithKline Inc.
	E - Exception status applies	JAN - Janssen-Ortho Inc.
		MVL - Meda Valeant Pharma Canada
		NVR - Novartis Pharmaceuticals Canada Inc.
		PFI - Pfizer Canada Inc.
		SAV - Sanofi-Aventis Canada Inc.
		VAR - *various manufacturers*

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

NOVEMBER 2016 • VOLUME 16-06
PHYSICIANS' 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.				

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.
	
	Criteria Notes:
	• Prescribed by a specialist (allergist, immunologist, dermatologist, etc.) or other authorized prescriber with knowledge of CIU treatment.
	• Initial approval period of 24 weeks at a maximum dose of 300mg every 4 weeks.
	• 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.
	• Continued coverage will be authorized if the patient has achieved:
	  ○ complete symptom control for less than 12 consecutive weeks; or
	  ○ 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: • Body surface area (BSA) involvement of >10% and/or significant involvement of the face, hands, feet or genitals; • Failure to, contraindication to or intolerant of methotrexate and cyclosporine; • Failure to, intolerant of or unable to access phototherapy; • Written request of a dermatologist or prescriber with a specialty in dermatology. Continued coverage is dependent on evidence of improvement, specifically: • A >75% reduction in the Psoriasis Area and Severity Index (PASI) score; or • A >50% reduction in PASI with a > 5 point improvement in DLQI (Dermatology Life Quality Index); or • Significant reduction in BSA involved, with consideration of important regions such as the face, hands, feet or genitals. Concurrent use of biologics not approved. Initial approval for a maximum of 12 weeks. 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 150mg Cap	02443066 02443074	DNP DNP	E (SF) E (SF)	BOE BOE
Criteria	**Initial approval criteria:** 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. • All other causes of restrictive lung disease (e.g. collagen vascular disorder or hypersensitivity pneumonitis) should be excluded. • 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) *Mild-moderate IPF is defined as: a forced vital capacity (FVC) ≥ 50% of predicted. **Initial renewal criteria:** 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. • Approval period: 6 months **Second and Subsequent renewal criteria (at 12 months after initiation and thereafter):** 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. • Approval period: 12 months **Exclusion Criteria:** Combination use of Ofev (nintedanib) and Esbriet (pirfenidone) will not be funded. **Note:** • 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.				

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: • At least two attacks (first episode or relapse) in the previous two years, with at least one attack in the previous year; • At least one relapse while on at least six months of a disease modifying therapy within the last 10 years; • An Expanded Disability Status Scale (EDSS) score of five (5) or less; • Prescribed by a specialist with experience in the treatment of multiple sclerosis. **Claim Note:** A maximum of two years of therapy (i.e. two treatment courses; 8 vials) will be reimbursed.				

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):** 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				

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:** • 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. **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.				

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:** 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. • All other causes of restrictive lung disease (e.g. collagen vascular disorder or hypersensitivity pneumonitis) should be excluded. • Patient is under the case of a physician with experience in IPF • Initial approval period: 7 months (allow 4 weeks for repeat pulmonary function tests) *Mild-moderate IPF is defined as: a forced vital capacity (FVC) ≥ 50% of predicted. **Initial renewal criteria:** 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. • Approval period: 6 months **Second and Subsequent renewal criteria (at 12 months after initiation and thereafter):** 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. • Approval period: 12 months **Exclusion Criteria:** 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.				

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:** 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 Initial approval is for three infusions of infliximab of 5mg/kg/dose at 0, 2 and 6 week intervals. **Psoriatic Arthritis:** 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 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 5mg Tab	02377233 02397714	DNP DNP	E (SF) E (SF)	BRI BRI
Criteria	**Deep Vein Thrombosis/Pulmonary Embolism:** **Inclusion Criteria:** • For the treatment of deep vein thrombosis (DVT) or pulmonary embolism (PE) • Approval Period: Up to six (6) months **Notes:** • 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). • 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. • 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. **Notes:** 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: • A Mini-Mental Statement Examination (MMSE) score of 10 to 30 AND • A Functional Assessment Staging Test (FAST) score of 4 to 5 • 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: • Inadequate control of phosphate levels on a calcium based phosphate binder, or • Hypercalcemia (corrected for albumin), or • Calciphylaxis (calcific arteriolopathy) **Claim Notes:** • Must be prescribed by a nephrologist or other prescriber within the Provincial Dialysis Program. • Initial Approval: 6 months. • 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 Diabetic and Ostomy Products

Effective **December 1, 2016,** a number of new Droplet lancets and pen needles 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 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/

Legend

Prescriber Codes		Benefit Status	
D	- Physician / Dentist	S	- Seniors' Pharmacare
N	- Nurse Practitioner	F	- Community Services Pharmacare
P	- Pharmacist		- Family Pharmacare
M	- Midwife	C	- Drug Assistance for Cancer Patients
O	- Optometrist	D	- Diabetes Assistance Program
		E	- Exception status applies

Manufacturer Codes			
AZE	- AstraZeneca Canada Inc.	NNO	- Novo Nordisk Canada Inc.
APO	- ApoPharma Inc.	NVR	- Novartis Pharmaceuticals Canada Inc.
BAY	- Bayer Inc.	PAL	- Paladin Labs Inc.
BOE	- Boehringer Ingelheim (Canada) Ltd.	PFI	- Pfizer Canada Inc.
BRI	- Bristol-Myers Squibb Canada Inc.	PMS	- Pharmascience Inc.
CEL	- Celgene	SAV	- Sanofi-Aventis Canada Inc.
GSK	- GlaxoSmithKline Inc.	SDZ	- Sandoz Canada Incorporated
GZM	- Genzyme Canada Inc.	SHI	- Shire Canada Inc.
HLR	- Hoffman-LaRoche Limited	VAR	- *Various*
HOS	- Hospira Healthcare Corporation	WNC	- Warner Chilcott Canada Co
JPC	- Jamp Pharma Corporation		