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PHYSICIANS' EDITION

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Nova Scotia Formulary Updates

Changes in Benefit Status

The Atlantic Expert Advisory Committee (AEAC) recommended that the following categories be listed as full benefits effective December 29, 2014.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
alendronate	10mg Tab	Various	DNP	SFC	VAR
alendronate	70mg Tab	Various	DNP	SFC	VAR
alendronate/ cholecalciferol	70mg/5600iu Tab	Various	DNP	SFC	VAR
risedronate	5mg	Various	DNP	SFC	VAR
risedronate	35mg	Various	DNP	SFC	VAR

Decision Highlights

It is anticipated that prescribers will continue to investigate fracture risk prior to initiating bisphosphonate therapy. This typically starts with BMD testing. Indications for BMD testing are clearly specified on the provincial BMD requisition. The BMD reports indicate the patient's 10 year fracture risk which should guide management decisions, i.e. treat those at high risk on their BMD reports.

Both benefits and risks must be considered prior to initiating bisphosphonate treatment. The bisphosphonates have been linked to adverse events such as osteonecrosis of the jaw and atypical femoral fractures. Low risk patients are never indicated for treatment and moderate risk patients are rarely indicated for treatment (only in exceptional cases, see the OC 2010 Guidelines; http://www.osteoporosis.ca/health-care-professionals/guidelines/).

Changes in Benefit Status Continued...

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
rizatriptan	5mg Tab	Various	DNP	SF	VAR
rizatriptan	5mg ODT/Wafer	Various	DNP	SF	VAR
rizatriptan	10mg Tab	Various	DNP	SF	VAR
rizatriptan	10mg ODT/Wafer	Various	DNP	SF	VAR
zolmitriptan	2.5mg Tab	Various	DNP	SF	VAR
zolmitriptan	2.5mg ODT	Various	DNP	SF	VAR
Decision Highlights	The Atlantic Expert Advisory Committee (AEAC) recommended the least expensive agents be available as full benefits without the need for special authorization. • zolmitriptan 2.5mg (Zomig and Zomig Rapid Melt and generic equivalents), AND • rizatriptan 5mg and 10mg (Maxalt and Maxalt RPD and generic equivalents) This will help reduce the administrative burden for practitioners while also encouraging the use of the least expensive agents. The current quantitative maximum of 18 doses per 3 months will remain in place for all agents.				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
leflunomide	10mg Tab	Various	DNP	SF	VAR
leflunomide	20mg Tab	Various	DNP	SF	VAR

New Exception Status Benefits

The following products have been reviewed by the pCODR Expert Review Committee (pERC) and were listed as exception status benefits, with the following criteria, effective December 29, 2014.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Giotrif® (afatinib dimaleate)	20mg Tab	02415666	DNP	E	BOE
	30mg Tab	02415674		E	BOE
	40mg Tab	02415682		E	BOE
Criteria	• for first line treatment of patients with EGFR mutation positive advanced or metastatic adenocarcinoma of the lung and with an ECOG performance status 0 or 1 • Note: Use of afatinib precludes the use of any other EGFR inhibitor as a subsequent line of therapy.				

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Stivarga® (regorafenib)	40mg Tab	02403390	DNP	E	BAY
Criteria	• For patients with metastatic and/or unresectable gastrointestinal stromal tumors (GIST) who have had disease progression on, or intolerance to, imatinib and sunitinib; AND has ECOG ≤ 1				

The following products have been reviewed by the Canadian Drug Expert Committee (CDEC) and were listed as exception status benefits, with the following criteria, effective December 29, 2014.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Galexos® (simeprevir)	150mg Cap	02416441	DNP	E	JAN
Criteria	In combination with peginterferon alfa and ribavirin, for the treatment of chronic hepatitis C genotype 1 infection in adults with compensated liver disease if the following clinical criteria and conditions are met: • Detectable levels of hepatitis C virus (HCV) RNA in the last six months; AND • A fibrosis stage of F2, F3, or F4 Conditions: • Patients should have their HCV strain tested for NS3 Q80K polymorphism Dosage: 150 mg once daily for 12 weeks in combination with peginterferon alfa and ribavirin. Response-guided therapy (RGT) for treatment naïve patients or treatment experienced patients as per Product Monograph Treatment Futility Rule as per Product Monograph Renewals are not considered. Exclusion Criteria: • Patients with the NS3 Q80K polymorphism • Patients who have received a prior treatment with boceprevir or telaprevir in combination with pegINF/RBV and did NOT receive an adequate response • Patients not genotype 1 • Fibrosis stage less than F2 (Metavir scale or equivalent) • Decompensated liver disease • Patients less than 18 years old • Simeprevir monotherapy • Simeprevir in combination with sofosbuvir				

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Aubagio® (teriflunomide)	14mg Tab	02416328	DNP	E	GZM
Criteria	For the treatment of patients with relapsing remitting multiple sclerosis (RRMS) who meet all of the following criteria: • requested and followed by a neurologist experienced in the management of RRMS, and • recent expanded disability status scale (EDSS) score of 5.5 or less (i.e. patients must be able to ambulate at least 100 metres without assistance) Exclusions: • not funded in combination with other disease modifying therapies • not funded in patients with an EDSS > 5.5 • not funded in patients < 18 years of age Renewals: • EDSS score < 5.5 (i.e. patients must be able to ambulate at least 100 metres without assistance). Date and details of the most recent neurological examination and EDSS score must be provided (exam must have occurred within the last 90 days), and • Patients must be stable or have experienced no more than 1 disabling attack/relapse in the past year.				

The following products were listed as exception status benefits effective December 29, 2014.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Erivedge® (vismodegib)	150mg Cap	02409267	DNP	E	HLR
Criteria	• As a single agent for the treatment of measurable metastatic BCC, OR • For the treatment of locally advanced BCC (including basal cell nevus syndrome i.e. Gorlin syndrome who are 18 years of age and older) in patients who are inappropriate for surgery and radiotherapy based on a discussion/evaluation with other members of the multi-disciplinary team. • Patient has ECOG ≤ 2				

New Exception Status Benefits Continued…

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

Criteria

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%

Initial Coverage Duration and Maximum Dosage approved:

- initial coverage period 12 weeks, maximum dose 400mg at weeks 0, 2 and 4, then 200mg every 2 weeks (or 400mg every 4 weeks)

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[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.

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Jetrea® (ocriplasmin)	2.5 mg/ml Inj	02410818	DNP	E	ALC
Criteria	For the treatment of symptomatic vitreomacular adhesion (VMA) if the following clinical criteria and conditions are met: • Diagnosis of VMA should be confirmed through optical coherence tomography • Patient does not have any of the following: large diameter macular holes (> 400 micrometre), high myopia (> 8 dioptre spherical correction or axial length > 28 millimetre), aphakia, history of retinal detachment, lens zonule instability, recent ocular surgery or intraocular injection (including laser therapy), proliferative diabetic retinopathy, ischemic retinopathies, retinal vein occlusions, exudative age-related macular degeneration, or vitreous hemorrhage Conditions: • Ocriplasmin should be administered by a retinal specialist or by a qualified ophthalmologist experienced in intravitreal injections • Treatment with ocriplasmin should be limited to a single injection per eye (i.e., retreatments are not covered)				

New Products

The following products were listed as benefits under the Nova Scotia Pharmacare Programs effective December 29, 2014. Any established criteria apply.

PRODUCT	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Clopixol-Depot 200mg/mL Inj	02230406	DNP	SF	VLH
Levemir FlexTouch 100 IU/mL Pre-Filled Pen	02412829	DNP	E	NNO

Criteria Updates

The following product was listed with the following new criteria effective December 29, 2014.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Dovobet® (calcipotriol and betamethasone dipropionate)	50mcg/g/0.5 mg/g	02319012	DNP	E	LEO
Criteria	• for the treatment of body and scalp psoriasis after failure of a topical steroid and a vitamin D analogue as single agents				

Criteria Updates Continued…

The following product was reviewed by the pCODR Expert Review Committee (pERC) and was listed with the following new criteria effective December 29, 2014.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Revlimid® (lenalidomide)	5mg Cap 10mg Cap 15mg Cap 25mg Cap	02304899 02304902 02317699 02317710	DNP	E	CEL
Criteria	Newly Diagnosed Multiple Myeloma Post-Autologous Stem Cell Transplant (NDMM post-ASCT) For the maintenance treatment of patients with newly diagnosed multiple myeloma, following autologous stem-cell transplantation (ASCT): • In patients with stable disease or better, with no evidence of disease progression; • treat until progression or development of unacceptable toxicity requiring discontinuation of lenalidomide; • initial dose 10 mg lenalidomide PO daily, AND • dose adjustments (5-15 mg) may be necessary based on individual patient characteristics/responses 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 product was listed with the following new criteria effective December 29, 2014.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Gilenya® (fingolimod)	0.5mg Cap	02365480	DNP	E	NVR
Criteria	For the treatment of patients with relapsing remitting multiple sclerosis (RRMS) who meet all of the following criteria: • have failed to respond to a full and adequate course of at least one disease modifying therapy (DMT) publicly insured in Nova Scotia as an initial therapy, or has contraindications/intolerance to at least two initial therapies. • one or more clinically disabling relapses in the previous year. • significant increase in T2 lesion load compared with that from a previous MRI scan (i.e. 3 or more new lesions) or at least one gadolinium-enhancing lesion. • requested and followed by a neurologist experienced in the management of RRMS • recent expanded disability status scale (EDSS) score of 5.5 or less (i.e. patients must be able to ambulate at least 100 meters without assistance).				

Legend

PRESCRIBER CODES	BENEFIT STATUS	MANUFACTURER CODES
D - Physician / Dentist	S - Seniors' Pharmacare	ALC - Alcon Canada Inc.
N - Nurse Practitioner	F - Community Services Pharmacare	BAY - Bayer Inc.
P - Pharmacist	- Family Pharmacare	BOE - Boehringer Ingelheim (Canada) Ltd.
M - Midwife	C - Drug Assistance for Cancer Patients	
O - Optometrist	D - Diabetes Assistance Program	CEL - Celgene
	E - Exception status applies	GZM - Genzyme Canada Inc.
		HLR - Hoffmann-LaRoche Ltd.
		JAN - Janssen-Ortho Inc.
		LEO - Leo Pharma Inc.
		NNO - Novo Nordisk Canada Inc.
		NVR - Novartis Pharmaceuticals Canada Inc.
		UCB - UCB Pharma Canada Inc.
		VAR - *Various Manufacturers*
		VLH - Lundbeck Canada Inc.

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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 April 1, 2015.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Harvoni® (ledipasvir/ sofosbuvir)	90mg/400mg Tab	02432226	DNP	E	GIL

Criteria

- For treatment-naïve and treatment-experienced adult patients with chronic hepatitis C genotype 1 infection, with compensated liver disease, (including compensated cirrhosis)[1] according to the following criteria:
  - Prescribed by a hepatologist or other specialist with expertise in the treatment of hepatitis C
  - Lab-confirmed hepatitis C genotype 1
  - Patient has a quantitative HCV RNA value within the last 6 months
  - Fibrosis stage F2 or greater (Metavir scale or equivalent)

Duration of therapy reimbursed:

Genotype 1 Patient Population	Duration of therapy
Treatment naïve, non-cirrhotic, viral load < 6 M IU/mL	8* weeks
Treatment naïve, non-cirrhotic, viral load ≥ 6 M IU/mL OR Treatment naïve, cirrhotic OR Treatment-experienced[2], non-cirrhotic	12 weeks
Treatment-experienced[2], cirrhotic	24 weeks

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Harvoni® (ledipasvir/sofosbuvir)	90mg/400mg Tab	02432226	DNP	E	GIL
Criteria	Exclusion criteria: • Patients currently being treated with another HCV antiviral agent • Patients who have received a previous trial of ledipasvir/sofosbuvir (Re-treatment requests will not be considered) NOTES: 1. Compensated cirrhosis is defined as cirrhosis with a Child Pugh Score =A (5-6). 2. Treatment experienced is defined as those who failed prior therapy with an interferon-based regimen, including regimens containing an HCV protease inhibitor. 3. HIV-HCV co-infected patients with Genotype 1 may be considered as per criteria listed above. 4. Treatment of decompensated HCV may be considered for coverage on an exceptional case by case basis.				

** For this population cohort, evidence has shown that the SVR rates with the 8-week and 12-week treatment regimens are similar. Treatment regimens of up to 12 weeks are recognized as a Health Canada approved treatment option. Patients may be considered for 12 weeks of coverage if they have borderline or severe fibrosis (F3-4) or if they are co-infected with HIV.*

The original prescription and refills will be limited to a maximum of 28 days supply at a time.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Sovaldi® (sofosbuvir)	400mg Tab	02418355	DNP	E	GIL
Criteria	• For the treatment of adult patients with chronic hepatitis C infection with compensated liver disease, (including compensated cirrhosis)[1] as follows: Genotype 1 [for 12 weeks in combination with Pegylated interferon (PegIFN)/Ribavirin (RBV)]: • Treatment-naive patients OR Genotype 2 (for 12 weeks in combination with RBV): • Treatment-naïve patients in whom interferon (IFN) is medically contraindicated[2] OR • PegIFN/RBV treatment-experienced[3] patients				

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Sovaldi® (sofosbuvir)	400mg Tab	02418355	DNP	E	GIL
	OR Genotype 3 (for 24 weeks in combination with RBV): • Treatment-naïve patients in whom interferon (IFN) is medically contraindicated[2] OR • PegIFN/RBV treatment-experienced[3] patients AND Who meet ALL of the following: • Prescribed by a hepatologist or other specialist with expertise in the treatment of hepatitis C. • Lab-confirmed hepatitis C genotype 1, 2, or, 3 • Patient has a quantitative HCV RNA value within the last 6 months • Fibrosis stage F2 or greater (Metavir scale or equivalent) Exclusion criteria: • Patients currently being treated with another HCV antiviral agent; • Patients who have previously received a treatment course of sofosbuvir (Re-treatment requests will not be considered). NOTES: 1. Compensated cirrhosis is defined as cirrhosis with a Child Pugh Score = A (5-6) 2. Medical contraindication to IFN is defined as hypersensitivity to peginterferon or interferon alfa-2a or 2b, polyethylene glycol or any component of the formulation resulting in discontinuation of therapy; OR presence of significant clinical comorbidities which are deemed to have a high risk of worsening with IFN treatment. Details are required regarding patient's contraindications and/or risk of worsening significant comorbidities. 3. Treatment-experienced patients (with Genotype 2 or 3) are defined as patients who have previously been treated with PegIFN/RBV and did NOT receive adequate response. 4. HIV-HCV co-infected patients may be considered as per criteria listed above. 5. Treatment of decompensated HCV may be considered for coverage on an exceptional case by case basis.				

The original prescription and refills will be limited to a maximum of 28 days supply at a time.

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
BREO® ELLIPTA® (fluticasone furoate/vilanterol (as trifenatate))	100mcg/25mcg dry powder for inh	02408872	DNP	E	GSK

Criteria

- For the treatment of chronic obstructive pulmonary disease (COPD), if symptoms persist after 2-3 months of short-acting bronchodilator therapy (i.e., salbutamol at a maximum dose of 8 puffs/day or ipratropium at maximum dose of 12 puffs/day).
- Coverage can be provided without a trial of short-acting agent if:
  - there is spirometric evidence of at least moderate to severe airflow obstruction, (postbronchodilator values FEV1 < 60% and FEV1/FVC ratio < 0.7), and significant symptoms (MRC score of 3-5*)
- Combination therapy with tiotropium and a long-acting beta$_2$ agonist/inhaled corticosteroid will only be considered if:
  - there is spirometric evidence of at least moderate to severe airflow obstruction (postbronchodilator values FEV1 < 60% and FEV1/FVC ratio < 0.7), and significant symptoms (MRC score of 3-5*) *and*
  - there is evidence of one or more moderate-to-severe exacerbations per year, on average, for 2 consecutive years requiring antibiotics and/or systemic (oral or intravenous) corticosteroids
- If spirometry cannot be obtained, reasons must be clearly explained and other evidence regarding severity of condition must be provided for consideration (MRC scale). Spirometry reports from any point in time will be accepted.

*Canadian Thoracic Society COPD Classification By Symptom/Disability:

Moderate (MRC 3-4):	Shortness of breath from COPD causing the patient to stop after walking about 100 meters (or after a few minutes) on the level.
Severe (MRC 5):	Shortness of breath from COPD resulting in the patient being too breathless to leave the house or breathless after undressing, or the presence of chronic respiratory failure or clinical signs of right heart failure.

MRC= Medical Research Council Dyspnea Scale

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Onglyza® (saxagliptin)	2.5mg Tab 5mg Tab	02375842 02333554	DNP DNP	E E	AZE AZE
Criteria	• For the treatment of Type II diabetes for patients with: o inadequate glycemic control on metformin and a sulfonylurea; and o for whom insulin is not an option.				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Komboglyze® (saxagliptin and metformin)	2.5mg/500mg Tab 2.5mg/850mg Tab 2.5mg/1000mg Tab	02389169 02389177 02389185	DNP DNP DNP	E E E	AZE AZE AZE
Criteria	• For the treatment of Type II diabetes for patients: o who are already stabilized on therapy with metformin, a sulfonylurea and saxagliptin to replace the individual components of saxagliptin and metformin; and o for whom insulin is not an option.				

The following products will be listed as exception status benefits, with the following criteria, effective April 1, 2015.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Ibavyr® (ribavirin)	400mg Tab 600mg Tab	02425890 02425904	DNP DNP	E E	PDP PDP
Criteria	• For use within a combination therapy regimen for the treatment of chronic hepatitis C, in accordance with the specific eligibility criteria for approved agents.				

The original prescriptions and refills will be limited to a maximum of 28 days supply at a time.

New Product

The following product is a new listing to the Nova Scotia Formulary, effective April 1, 2015. The benefit status within the Nova Scotia Pharmacare Programs is indicated.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Trelstar® (triptorelin)	22.5mg Inj	02412322	DNP	SFC	ATV

Legend

PRESCRIBER CODES	BENEFIT STATUS	MANUFACTURER CODES
D - Physician / Dentist	S - Seniors' Pharmacare	ATV - Actavis Pharma Company
N - Nurse Practitioner	F - Community Services Pharmacare	AZE - AstraZeneca Canada Inc.
P - Pharmacist	- Family Pharmacare	GIL - Gilead Sciences Inc.
M - Midwife	C - Drug Assistance for Cancer Patients	GSK - GlaxoSmithKline Inc.
O - Optometrist	D - Diabetes Assistance Program	PDP - Pendopharm, Division of Pharmascience Inc.
	E - Exception status applies	

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New Exception Status Benefits

The following products have been reviewed by the Atlantic Common Drug Review (ACDR) and will be listed as exception status benefits, with the following criteria, effective May 4, 2015.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
DexIron® (iron dextran)	50mg/mL Inj	02205963	DNP	E	MYL
Criteria	• For the treatment of iron deficiency anemia in patients intolerant to oral iron replacement products OR • For patients who have not responded to adequate therapy with oral iron. NOTE: • Given the safety concerns associated with IV iron, it is expected that the patients will be carefully screened and will have tried various oral iron options before being eligible for IV iron. • Details regarding oral iron tried, length of therapy, and outcome must be provided.				

New Exception Status Benefits Continued...

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Feraheme® (ferumoxytol)	30mg/mL Inj	02377217	DNP	E	TAK
Criteria	• For the treatment of iron deficiency anemia in home hemodialysis, peritoneal dialysis and predialysis chronic kidney disease patients. o Coverage must be requested by a practitioner with a specialty in nephrology. o Coverage will only be considered if the dose required is ferumoxytol 510mg to avoid wastage and unnecessary costs. NOTE: • Given the safety concerns with IV iron, patients should be closely monitored for signs and symptoms of hypersensitivity reactions including monitoring of blood pressure and pulse during and for at least 30 minutes following each infusion of Feraheme®. IV iron product monographs recommend IV irons should only be administered when personnel and therapies are immediately available for the treatment of anaphylaxis and other hypersensitivity reactions. • Ferumoxytol is contraindicated in some patients, including those with hypersensitivities to this product, any allergies to other parenteral iron products, and in individuals with any known drug allergy. • Ferumoxytol may affect the diagnostic ability of MRI for up to 3 months.				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Ferrlecit® (sodium ferric gluconate)	12.5mg/mL Inj	02243333	DNP	E	SAV
Criteria	• For the treatment of iron deficiency anemia in patients intolerant to oral iron replacement products OR • For patients who have not responded to adequate therapy with oral iron. NOTE: • Given the safety concerns associated with IV iron, it is expected that the patients will be carefully screened and will have tried various oral iron options before being eligible for IV iron. • Details regarding oral iron tried, length of therapy, and outcome must be provided.				

New Exception Status Benefits Continued…

The following product was reviewed by the Canadian Drug Expert Committee (CDEC) and will be listed as an exception status benefit, with the following criteria, effective May 4, 2015.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Oralair®	300 Unit IR S/L Tab	02381893	DNP	E	STA
(grass pollen allergen extract)	100 Unit IR S/L Tab	02381885	DNP	E	STA
Criteria	• For the seasonal treatment of grass pollen allergic rhinitis in patients that have not adequately responded to, or tolerated, conventional pharmacotherapy. NOTE: • Treatment with 5-GPAE must be prescribed and initiated by physicians with adequate training and experience in the treatment of respiratory allergic diseases. • Treatment should be initiated four (4) months before onset of pollen season and should only be continued until the end of the season. • Treatment should not be taken for more than three (3) consecutive years.				

The following product was reviewed by the pCODR Expert Review Committee (pERC) and will be listed as an exception status benefit, with the following criteria, effective May 4, 2015.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Pomalyst®	1mg Cap	02419580	DNP	E	CEL
(pomalidomide)	2mg Cap	02419599	DNP	E	CEL
	3mg Cap	02419602	DNP	E	CEL
	4mg Cap	02419610	DNP	E	CEL
Criteria	• For patients with relapsed and/or refractory multiple myeloma who have previously failed at least two treatments, including both bortezomib and lenalidomide and demonstrated disease progression on the last treatment. • Pomalidomide may be an option in rare instances where bortezomib is not tolerated or contraindicated but in all cases, patients should have failed lenalidomide. NOTE: • Pomalidomide must be prescribed and dispensed only by physicians and pharmacists who are registered with and agree in writing to adhere to the guidelines of the Company's RevAid® Program. Details are available at https://revaid.ca/revaid.				

*The original prescription and refills will be limited to a maximum of 28 days supply at a time.

Criteria Update

The following product was reviewed by the Atlantic Common Drug Review (ACDR) and will be listed with the following new criteria effective May 4, 2015.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Venofer® (iron sucrose)	20mg/mL Inj	02243716	DNP	E	MYL
Criteria	• For the treatment of iron deficiency anemia in patients intolerant to oral iron replacement products OR • For patients who have not responded to adequate therapy with oral iron. NOTE: • Given the safety concerns associated with IV iron, it is expected that the patients will be carefully screened and will have tried various oral iron options before being eligible for IV iron. • Details regarding oral iron tried, length of therapy, and outcome must be provided.				

Notification of ASA 325mg Delisting

Effective July 1, 2015, the benefit status of ASA 325mg will change from a full benefit to non-insured status. This change will align the coverage of ASA 325mg with ASA 81mg, which is currently a non-benefit. ASA 325mg is an over-the-counter medication which is available at a very low cost for patients who require this therapy.

New Ostomy Products

Effective May 13, 2015, a number of Convatec 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 on 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	CEL - Celgene
N - Nurse Practitioner	F - Community Services Pharmacare	MYL - Mylan Pharmaceuticals ULC.
P - Pharmacist	- Family Pharmacare	SAV - Sanofi-Aventis Canada Inc.
M - Midwife	C - Drug Assistance for Cancer Patients	STA - Stallergene Canada Inc.
O - Optometrist	D - Diabetes Assistance Program	TAK - Takeda Canada Inc.
	E - Exception status applies	

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New Benefits

Based on a review by the Atlantic Common Drug Review (ACDR), effective June 29, 2015, the following products were listed as full benefits under the Nova Scotia Pharmacare Programs.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Dutasteride	0.5mg Cap	Multiple	DNP	SF	VAR
Finasteride	5mg Tab	Multiple	DNP	SF	VAR

New Exception Status Benefits

The following products have been reviewed by the Canadian Drug Expert Committee (CDEC) and were listed as exception status benefits, with the following criteria, effective June 29, 2015.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Myrbetriq® (mirabegron)	25mg ER Tab	02402874	DNP	E (SF)	ASL
	50mg ER Tab	02402882	DNP	E (SF)	ASL
Criteria	• For the treatment of overactive bladder (OAB) with symptoms of urgency, urgency incontinence, and urinary frequency if the patient has had an intolerance or inadequate response to an adequate trial of an anticholinergic therapy. • Not to be used in combination with other pharmacological treatments of OAB.				

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Adempas® (riociguat)	0.5mg Tab	02412764	DNP	E (SF)	BAY
	1.0mg Tab	02412772	DNP	E (SF)	BAY
	1.5mg Tab	02412799	DNP	E (SF)	BAY
	2.0mg Tab	02412802	DNP	E (SF)	BAY
	2.5mg Tab	02412810	DNP	E (SF)	BAY
Criteria	• For the treatment of inoperable chronic thromboembolic pulmonary hypertension (CTEPH, World Health Organization [WHO] Group 4) or persistent or recurrent CTEPH after surgical treatment in adult patients (≥18 years of age) with WHO Functional Class (FC) II or III pulmonary hypertension (PH). • Adempas® should be prescribed by a clinician with experience in the diagnosis and treatment of CTEPH.				

The original prescription and refills will be limited to a maximum of 28 days supply at a time.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Ultibro® Breezhaler® (indacaterol/ glycopyrronium)	110mcg/50mcg Cap	02418282	DNP	E (SF)	NVR
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) FEV_1 < 60% predicted and FEV_1/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-agonist (LABA) or long-acting anticholinergic therapy (LAAC).				

New Products

The following products are new listings to the Nova Scotia Formulary, effective June 29, 2015. The benefit status within the Nova Scotia Pharmacare Programs is indicated. Where applicable, existing criteria applies.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
ACT-Amlodipine	2.5mg Tab	02297477	DNP	SF	ATV
Innohep®	8,000IU/0.4mL Inj	02429462	DNP	SFC	LEO
Innohep®	12,000IU/0.6mL Inj	02429470	DNP	SFC	LEO
Innohep®	16,000IU/0.8mL Inj	02429489	DNP	SFC	LEO
Jamp Bisacodyl	5mg Supp	02410893	DNP	C	JPC
Jamp Bisacodyl	10mg Supp	02361450	DNP	C	JPC
Jaydess® IUD	13.5mg Insert	02408295	DNP	F	BAY
Latuda®	20mg Tab	02422050	DNP	E	SEP
Latuda®	60mg Tab	02413361	DNP	E	SEP

Non Insured Products

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

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Tivicay® (dolutegravir)	50mg Tab	02414945	N/A	Not Insured	VIV
Triumeq® (dolutegravir/abacavir/lamivudine)	50mg/600mg/300mg Tab	02430932	N/A	Not Insured	VIV

Other Funding Decisions

Tykerb (lapatinib) was reviewed by pCODR and it was determined that the criteria will not be expanded to include the use of lapatinib in combination with letrozole for the treatment of postmenopausal patients with hormone receptor positive metastatic breast cancer, whose tumours overexpress the ErB2 (HER2) receptor, and who are suitable for endocrine therapy. The criteria for Tykerb (lapatinib) will remain as it is currently listed.

New Diabetic and Ostomy Products

Effective June 29, 2015, a number of new Hollister CeraPlus ostomy products as well as, FORA Test n' Go diabetic supplies were added as full benefits under the Nova Scotia Pharmacare Programs. The specific products can be found in the most recent update of the Nova Scotia Formulary, which is available on the Nova Scotia Pharmacare website.

Legend

PRESCRIBER CODES	BENEFIT STATUS	MANUFACTURER CODES
D - Physician / Dentist	S - Seniors' Pharmacare	ASL - Astellas Pharma Canada Inc.
N - Nurse Practitioner	F - Community Services Pharmacare	ATV - Actavis Pharma Company
P - Pharmacist	- Family Pharmacare	BAY - Bayer Inc.
M - Midwife	C - Drug Assistance for Cancer Patients	JPC - Jamp Pharma Corporation
O - Optometrist	D - Diabetes Assistance Program	LEO - Leo Pharma Inc.
	E - Exception status applies	SEP - Sunovion Pharmaceuticals Canada Inc.
		VAR - *various manufacturers*
		VIV - ViiV Health Care Inc.

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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 September 1, 2015.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Holkira™ Pak (ombitasvir/ paritaprevir/ ritonavir and dasabuvir)	12.5/75/50mg and 250mg Tab	02436027	DNP	E (SF)	ABV

Criteria

- For treatment-naïve and treatment-experienced adult patients with chronic hepatitis C genotype 1 infection, with compensated liver disease, (including compensated cirrhosis)[1] according to the following criteria:
  - Prescribed by a hepatologist or other specialist with expertise in the treatment of hepatitis C;
  - Lab-confirmed hepatitis C genotype 1, sub-type 1a and 1b required;
  - Patient has a quantitative HCV RNA value within the last 6 months;
  - Fibrosis stage F2 or greater (Metavir scale or equivalent);

Duration of therapy reimbursed:

Genotype 1 Patient Population	Duration of Therapy
Treatment naïve and experienced Genotype 1b, non-cirrhotic**	12 Weeks
Treatment naïve and experienced Genotype 1a, non-cirrhotic	12 Weeks in combination with ribavirin (Moderiba)

New Exception Status Benefits Continued...

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Holkira™ Pak (ombitasvir/paritaprevir/ ritonavir and dasabuvir)	12.5/75/50mg and 250mg Tab	02436027	DNP	E (SF)	ABV

Criteria

Genotype 1 Patient Population	Duration of Therapy
Treatment naïve and experienced Genotype 1b, cirrhotic	12 Weeks in combination with ribavirin (Moderiba)
Treatment naïve and experienced (prior relapsers and prior partial responders) Genotype 1a, cirrhotic	12 Weeks in combination with ribavirin (Moderiba)
Treatment experienced genotype 1a, with cirrhosis AND who have had a previous null response to PegIFN and RBV	24 Weeks in combination with ribavirin (Moderiba)

***Holkira Pak with ribavirin is recommended in patients with an unknown genotype 1 subtype or with mixed genotype 1 infection.*

Exclusion criteria:

- Patients currently being treated with another HCV antiviral agent
- Patients who have received a previous trial of Holkira Pak (Re-treatment requests will NOT be considered)
- Decompensated patients
- No funding for other genotypes except as noted in the above funding criteria for genotype 1
- Patients who have received previous NS3/4A protease inhibitor-based regimens (boceprevir, telaprevir, and simeprevir-based regimens)
- Patients who have received previous sofosbuvir-based regimens (including ledispavir/sofosbuvir)

Notes:

1. Compensated cirrhosis is defined as cirrhosis with a Child Pugh Score =A (5-6)
2. Treatment experienced patients are defined as those who have previously been treated with PegINF/RBV and did NOT receive adequate response.
3. HIV-HCV co-infected patients with genotype 1 may be considered as per criteria listed above

The original prescription and refills will be limited to a maximum of 28 days supply at a time.

New Exception Status Benefits Continued...

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Moderiba™ (ribavirin)	200mg Tab	02436396	DNP	E (SF)	ABV
	400mg Tab	02436418	DNP	E (SF)	ABV
	600mg Tab	02436426	DNP	E (SF)	ABV
Criteria	• For use in chronic hepatitis C patients, genotype 1, who have been approved for coverage of Holkira Pak				
Decision Highlights	• The manufacturer will provide ribavirin (Moderiba) free of charge to all patients, regardless of whether they choose to participate in the patient assistance program or not. Any inquiries should be directed to AbbVie Care at 1-844-471-CARE (2273).				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Abilify Maintena™ (aripiprazole)	300mg prolonged release injectable suspension	02420864	DNP	E (SF)	OTS
	400mg prolonged release injectable suspension	02420872	DNP	E (SF)	OTS
Criteria	• For the maintenance treatment of schizophrenia in adult patients who are stabilized on oral aripiprazole, and who have: o problems with compliance with oral treatments or o inadequate control or significant side-effects (e.g. EPS or TD) from one or more conventional depot antipsychotic agents				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Invokana™ (canagliflozin)	100mg Tab	02425483	DNP	E (SF)	JAN
	300mg Tab	02425491	DNP	E (SF)	JAN
Criteria	• For the treatment of Type II diabetes for patients with: o inadequate glycemic control on metformin and a sulfonylurea; and o for whom insulin is not an option Note: • 200mg is not a recognized dose; as such a dose of two 100mg tablets will not be funded.				

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Anoro™ Ellipta® (umeclidinium (as bromide) and vilanterol (as trifenatate))	62.5mcg/25mcg dry powder for oral inh	02418401	DNP	E (SF)	GSK
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
Inspra®	25mg Tab	02323052	DNP	E (SF)	PFI
(eplerenone)	50mg Tab	02323060	DNP	E (SF)	PFI
Criteria	• For patients >55 years with mild to moderate HF on standard HF treatments with EF≤ 30% (or ≤35% if QRS duration >130ms) and recent (6 months) hospitalization for CV disease or with elevated BNP or NT-proBNP levels. Notes: • Requests will be considered from practitioners with a specialty in cardiology. • Patients must be on optimal therapy with an angiotensin-converting–enzyme (ACE) inhibitor, an angiotensin-receptor blocker (ARB), or both and a beta-blocker (unless contraindicated) at the recommended dose or maximal tolerated dose.				

New Exception Status Benefits Continued…

The following product will be added as an exception status benefit effective September 1, 2015.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Vyvanse® (lisdexamfetamine dimesylate)	10mg Cap	02439603	DNP	E (F)	SHI
	20mg Cap	02347156	DNP	E (F)	SHI
	30mg Cap	02322951	DNP	E (F)	SHI
	40mg Cap	02347164	DNP	E (F)	SHI
	50mg Cap	02322978	DNP	E (F)	SHI
	60mg Cap	02347172	DNP	E (F)	SHI
Criteria	• For the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients age 6 to 25 years who: o Demonstrate significant and problematic disruptive behaviour or who have problems with inattention that interfere with learning; and o Have been tried on methylphenidate (immediate release or long-acting formulation) or dexamphetamine with unsatisfactory results. Notes: • Requests will be considered from specialists in pediatric psychiatry, pediatricians or general practitioners with expertise in ADHD. • The maximum dose reimbursed is 60mg daily.				

Non Insured Products

The following products were reviewed by the Canadian Drug Expert Committee (CDEC) and were not recommended to be listed as benefits under the Nova Scotia Pharmacare Program.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Nesina™ (alogliptin benzoate)	6.25mg Tab	02417189	N/A	Not Insured	TAK
	12.5mg Tab	02417197	N/A	Not Insured	TAK
	25mg Tab	02417200	N/A	Not Insured	TAK
Kazano™ (alogliptin benzoate and metformin)	12.5mg/500mg Tab	02417219	N/A	Not Insured	TAK
	12.5mg/850mg Tab	02417227	N/A	Not Insured	TAK
	12.5mg/1000mg Tab	02417235	N/A	Not Insured	TAK
Decision Highlights	• The single randomized controlled study reviewed had several significant limitations. Therefore, the comparative clinical benefit of these products relative to other less costly oral agents is uncertain.				

Legend

PRESCRIBER CODES	BENEFIT STATUS	MANUFACTURER CODES
D - Physician / Dentist	S - Seniors' Pharmacare	ABV - AbbVie Corporation
N - Nurse Practitioner	F - Community Services Pharmacare	GSK - GlaxoSmithKline Inc.
P - Pharmacist	- Family Pharmacare	JAN - Janssen-Ortho Inc.
M - Midwife	C - Drug Assistance for Cancer Patients	OTS - Otsuka Canada Pharmaceuticals
O - Optometrist	D - Diabetes Assistance Program	PFI - Pfizer Canada Inc.
	E - Exception status applies	SHI - Shire Canada Inc.
		TAK - Takeda Canada Inc.

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New Exception Status Benefits

The following product has been reviewed by the Common Drug Review (CDR) and was listed as an exception status benefit, with the following criteria, effective November 2, 2015.

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

Criteria

Initial Request:

For the treatment of Relapsing-Remitting Multiple Sclerosis (RRMS) who meet all the following criteria:

- The patient's physician is a neurologist experienced in the management of relapsing-remitting multiple sclerosis (RRMS); AND
- The patient;
  - Has a current EDSS less than or equal to 5.0; AND
  - Has failed to respond to a full and adequate course* (at least six months) of at least ONE disease modifying therapy OR has contraindications/intolerance to at least TWO disease modifying therapies; AND
  - Has had ONE of the following types of relapses in the past year:
    - The occurrence of one relapse with partial recovery during the past year AND has at least ONE gadolinium-enhancing lesion on brain MRI, OR

* Failure to respond to a full and adequate course is defined as a trial of at least one approved first line therapy for a minimum of 6 months AND experienced at least one disabling relapse (attack) while on this therapy.

New Exception Status Benefits Continued...

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Tysabri® (natalizumab)	300mg/15mL Vial	02286386	DNP	E (SF)	BIG
Criteria	significant increase in T2 lesion load compared to a previous MRI; OR ▪ The occurrence of two or more relapses with partial recovery during the past year; OR ▪ The occurrence of two or more relapses with complete recovery during the past year AND has at least ONE gadolinium-enhancing lesion on brain MRI, OR significant increase in T2 lesion load compared to a previous MRI. • Approval period: 1 year Requirements for Initial Requests: • The patient's physician provides documentation setting out the details of the patient's most recent neurological examination within ninety (90) days of the submitted request. This must include a description of any recent attacks, the dates, and the neurological findings. • MRI reports do NOT need to be submitted with the initial request Renewal: • Date and details of the most recent neurological examination and EDSS scores must be provided (exam must have occurred within the last 90 days) AND • Patients must be stable or have experienced no more than 1 disabling attack/relapse in the past year; AND • Recent Expanded Disability Status Scale (EDSS) score less than or equal to 5.0.				

The original prescription and refills will be limited to a maximum of 28 days supply at a time.

The following product has been reviewed by the pCODR Expert Review Committee (pERC) and was listed as an exception status benefit, with the following criteria, effective November 2, 2015.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Imbruvica® (ibrutinib)	140mg Cap	02434407	DNP	E (SFC)	JAN
Criteria	As a treatment option for patients with relapsed and/or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic leukemia (SLL) who have received at least one prior therapy and are considered inappropriate for treatment or retreatment with a fludarabine-based regimen, including : • Patients who received prior fludarabine-based treatment and had a progression free interval of less than three years • Patients who received prior fludarabine-based treatment and had a progression free interval of greater than three years, but are now considered unfit for				

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Imbruvica® (ibrutinib)	140mg Cap	02434407	DNP	E (SFC)	JAN
Criteria	fludarabine-based retreatment due to age ≥ 70, or age ≥ 65 and the presence of comorbidities (Cumulative Illness Rating Scale [CIRS] ≥ 6 or creatinine clearance <70ml/min) • Patients who did not receive prior fludarabine-based treatment because they were considered unfit, and who relapsed after at least two cycles of alkylator-based therapy, regardless of the progression free interval after that therapy				

The original prescription and refills will be limited to a maximum of 28 days supply at a time.

Criteria Updates

The following product has been reviewed by the Atlantic Common Drug Review (ACDR) and was listed with the following new criteria effective November 2, 2015.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Valganciclovir (Valcyte and generics)	450mg Tab	Various	DNP	E (SFC)	VAR
Criteria	• For the treatment of cytomegalovirus (CMV) retinitis in HIV-positive patients, upon the request of an infectious disease specialist or prescriber with a specialty in infectious disease • For the prevention of CMV disease post solid organ transplantation in patients at high-risk (D+ / R-) (i.e., donor positive/recipient negative). Coverage will be for a maximum of 90 days • For the treatment of patients with CMV infection who have received a solid organ transplant.				

The following products were reviewed by the pCODR Expert Review Committee (pERC) and were listed with the following new criteria effective November 2, 2015.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Xtandi® (enzalutamide)	40mg Tab	02407329	DNP	E (SFC)	ASL
Criteria	Asymptomatic or Mildly Symptomatic Patients • As a single agent treatment for asymptomatic or mildly symptomatic metastatic CRPC patients after failure of androgen deprivation therapy (including an LHRH agonist/antagonist or orchiectomy) who have not received prior chemotherapy for metastatic CRPC, ECOG PS 0-1 and no risk for seizures.				

Criteria Updates Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Xtandi® (enzalutamide)	40mg Tab	02407329	DNP	E (SFC)	ASL
Criteria	• Enzalutamide would be an **alternative** to abiraterone and **not sequential** therapy in this asymptomatic or mildly symptomatic patient population. Symptomatic (post-docetaxel chemotherapy) Patients: • As a **single agent treatment** for metastatic CRPC patients with ECOG PS 0-2, no risk for seizures and progression **after previous treatment with docetaxel.** • Enzalutamide would be an **alternative** to abiraterone and **not sequential** therapy in this symptomatic post docetaxel chemotherapy setting. Retreatment: • Use of enzalutamide in the post docetaxel setting is **not permitted** if previously used in the pre-chemotherapy setting.				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Zytiga® (abiraterone acetate)	250mg Tab	02371065	DNP	E (SFC)	JAN
Criteria	Asymptomatic or Mildly Symptomatic Patients: • In **combination with prednisone** for **asymptomatic or mildly symptomatic** metastatic CRPC patients after failure of androgen deprivation therapy (including an LHRH agonist/antagonist or orchiectomy) who have not received prior chemotherapy for metastatic CRPC and have ECOG PS 0 or 1. • Abiraterone would be an **alternative** to enzalutamide and **not sequential** therapy in this asymptomatic or mildly symptomatic patient population. Symptomatic (post-docetaxel chemotherapy) Patients: • In **combination with prednisone** for metastatic CRPC patients with ECOG PS of 0-2 and progression after previous treatment with docetaxel. • Abiraterone would be an **alternative** to enzalutamide and **not sequential** therapy in this symptomatic post docetaxel chemotherapy setting. Retreatment: • Use of abiraterone in the post-docetaxel setting is **not permitted** if previously used in the pre-chemotherapy setting.				

Criteria Update: Exception Status Criteria for Certain Chronic Obstructive Pulmonary Disease (COPD) Medications

Effective November 2, 2015, the criteria for all listed long-acting beta-2 agonists (LABA), long-acting anticholinergics (LAAC), and long- acting beta-2 agonists/Inhaled corticosteroid (LABA/ICS) was updated to the criteria listed below. Also, the Request for Coverage form has been updated and can be found on our website at www.nspharmacare.ca.

- 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.

NOTE:

- Coverage for LABA and LAAC as two separate inhalers will not be considered.

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.

Treatment of COPD

Please note that inhaled corticosteroids in combination with long-acting $beta_2$ agonists (LABA/ICS) have been associated with an increased risk of pneumonia in patients with COPD. Guidelines recommend their use in moderate to severe COPD patients who are experiencing frequent exacerbations, not controlled by long-acting bronchodilators. For patients with moderate to severe COPD who are *not* experiencing frequent exacerbations, long-acting $beta_2$ agonists or long-acting anticholinergics are recommended.

Global strategy for the diagnosis, management and prevention of COPD 2015

http://www.goldcopd.org/uploads/users/files/GOLD_Report_2015_Sept2.pdf

NOTE: 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.

Update to Days Supply Limits for Kalydeco® Prescriptions

Effective November 2, 2015, if a beneficiary has coverage for Kalydeco®, the original prescription and refills will be limited to a **maximum of 28 days supply** at a time.

New Ostomy Products

Effective November 2, 2015, a number of new Hollister ostomy products were 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 is available on the Nova Scotia Pharmacare website.

New Products

The following products are new listings to the Nova Scotia Formulary, effective November 2, 2015. The benefit status within the Nova Scotia Pharmacare Programs is indicated.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Combivent Respimat	100/20mcg Sol	02419106	DNP	SFC	BOE
Nuvaring	11.4mg/2.6mg	02253186	DNP	F	FRS
ODAN-Sodium Chloride	5% Oph Oint	80046696	DNP	SF	ODN
ODAN-Sodium Chloride	5% Oph Sol	80046737	DNP	SF	ODN

Legend

PRESCRIBER CODES	BENEFIT STATUS	MANUFACTURER CODES
D - Physician / Dentist	S - Seniors' Pharmacare	ASL - Astellas Pharma Canada Inc.
N - Nurse Practitioner	F - Community Services Pharmacare	BIG - Biogen Idec Canada Inc.
P - Pharmacist	- Family Pharmacare	BOE - Boehringer Ingelheim (Canada) Ltd.
M - Midwife	C - Drug Assistance for Cancer Patients	FRS - Merck Canada Ltd.
O - Optometrist	D - Diabetes Assistance Program	JAN - Janssen-Ortho Inc.
	E - Exception status applies	ODN - Odan Laboratories Ltd.
		VAR - *Various manufacturers*