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PHYSICIANS' EDITION

NOVA SCOTIA

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Nova Scotia Formulary Updates

New Exception Status Benefits

The following products have been listed with the following criteria, effective **February 1, 2019**.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Procysbi	25mg Cap	02464705	DNP	E (SF)	HRZ
(cysteamine bitartrate)	75mg Cap	02464713	DNP	E (SF)	HRZ
Criteria	• For the treatment of infantile nephropathic cystinosis with documented cystinosin (lysosomal cystine transporter) gene mutation. **Claim Notes:** • Must be prescribed by, or in consultation with, a prescriber with experience in the diagnosis and management of cystinosis • Claims for Procysbi 75mg capsule that exceed the maximum claim amount of $9,999.99 must be divided and submitted as separate transactions using the following PINs: o 00904354 o 00904355				

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Nucala (mepolizumab)	144mg/Vial Pws Inj (100mg/mL when reconstituted)	02449781	DNP	E (SF)	GSK

Criteria

- For the adjunctive treatment of severe eosinophilic asthma in adult patients who are inadequately controlled with high-dose inhaled corticosteroids and one or more additional asthma controller(s) (e.g., a long-acting beta-agonist), and have a blood eosinophil count of ≥ 0.15 x 10^9 /L at initiation of treatment with mepolizumab or ≥ 0.3 x 10^9 /L in the past 12 months, if one of the following clinical criteria are met:
  - Patients who have experienced two or more clinically significant asthma exacerbations in the past 12 months and who show reversibility (at least 12% and 200 mL) on spirometry, **or**
  - Are treated with daily oral corticosteroids (OCS).

Stopping Criteria:

- Failure to achieve a decrease in any clinically significant exacerbations at 12 months; **or**
- Failure to achieve a decrease in the daily maintenance OCS dose at 12 months.

Clinical Notes:

- Significant clinical exacerbation is defined as worsening of asthma such that the treating physician elected to administer systemic glucocorticoids for at least 3 days or the patient visited an emergency department or was hospitalized.
- A decrease in the daily maintenance OCS dose is defined as a decrease of at least 25%.

Claim Notes:

- Must be prescribed by a respirologist, clinical immunologist or allergist.
- Approvals will be for a maximum of 100mg every four weeks.
- Initial approval: 1 year.
- Renewal approval: 1 year.

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Ocaliva	5mg Tab	02463121	DNP	E (SF)	INT
(obeticholic acid)	10mg Tab	02463148	DNP	E (SF)	INT

Criteria

Initiation Criteria:

- For the treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA, or as monotherapy in adults unable to tolerate UDCA, where the following criteria are met:
  - A confirmed diagnosis of PBC, defined as:
    - Positive antimitochondrial antibodies (AMA); **or**
    - Liver biopsy results consistent with PBC.
  - The patient is under the care of a gastroenterologist or hepatologist or other prescriber with a specialty in gastroenterology or hepatology.

    AND
  - The patient has received UDCA for a minimum of 12 months and has experienced an inadequate response to UDCA and can benefit from the addition of obeticholic acid. An inadequate response is defined as:
    - alkaline phosphatase (ALP) ≥ 1.67 x upper limit of normal (ULN) **and/or**
    - bilirubin > ULN and < 2 x ULN **and/or**
    - evidence of compensated cirrhosis

    OR
  - The patient has experienced documented and unmanageable intolerance to UDCA and can benefit from switching therapy to obeticholic acid.

Renewal Criteria:

- The patient continues to benefit from treatment with obeticholic acid as evidenced by:
  - A reduction in the ALP level to less than 1.67 x ULN; **or**
  - A 15% reduction in the ALP level compared with values before beginning treatment with obeticholic acid.

Claim Note:

- Duration of approval: 12 months

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Ravicti **(glycerol phenylbutyrate)**	1.1g/mL Oral Liquid	02453304	DNP	E (SF)	HRZ
Criteria	• For the chronic management of patients with urea cycle disorders (UCDs). **Clinical Note:** • Diagnosis must be confirmed by blood, enzymatic, biochemical or genetic testing. **Claim Notes:** • Must be prescribed by, or in consultation with, a prescriber experienced in the treatment of UCDs. • Claims that exceed the maximum claim amount of $9,999.99 must be divided and submitted as separate transactions using the following PINs: o 00904360 o 00904361				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Taltz **(ixekizumab)**	80mg/mL Autoinjector 80mg/mL Prefilled Syringe	02455102 02455110	DNP DNP	E (SF) E (SF)	LIL LIL
Criteria	**Psoriasis** • For patients with severe, debilitating chronic plaque psoriasis who meet all of the following: o Body surface area (BSA) involvement of >10% and/or significant involvement of the face, hands, feet or genitals; o Failure to, contraindication to or intolerant of methotrexate and cyclosporine; o Failure to, intolerant of or unable to access phototherapy; o Written request of a dermatologist or prescriber with a specialty in dermatology. • Continued coverage is dependent on evidence of improvement, specifically: o A >75% reduction in the Psoriasis Area and Severity Index (PASI) score; or o A >50% reduction in PASI with a >5-point improvement in DLQI (Dermatology Life Quality Index); or o Significant reduction in BSA involved, with consideration of important regions such as the face, hands, feet or genitals.				

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Taltz	80mg/mL Autoinjector	02455102	DNP	E (SF)	LIL
(ixekizumab)	80mg/mL Prefilled Syringe	02455110	DNP	E (SF)	LIL
Criteria	**Clinical Notes:** • Treatment should be discontinued if a response has not been demonstrated after 12 weeks. **Claim Notes:** • Concurrent use of biologics not approved. • Initial approval for a maximum of 12 weeks. Renewal approval: 1 year. • Approvals will be for 160 mg at week 0, followed by 80 mg at weeks 2, 4, 6, 8, 10, and 12 then 80 mg every four weeks. **Psoriatic Arthritis** • For the treatment of patients with predominantly axial psoriatic arthritis who are refractory, intolerant or have contraindications to the sequential use of at least two NSAIDs at maximal tolerated dose for a minimum of two weeks each. • For the treatment of patients with predominantly peripheral psoriatic arthritis who are refractory, intolerant or have contraindications to: o The sequential use of at least two NSAIDs at maximal tolerated dose for a minimum of two weeks each; **and** o Methotrexate (oral or parenteral) at a dose of ≥ 20mg weekly (≥15mg if patient is ≥65 years of age) for a minimum of 8 weeks; **and** o Leflunomide for a minimum of 10 weeks or sulfasalazine for a minimum of 3 months **Clinical Notes:** • For patients who do not demonstrate a clinical response to oral methotrexate, or who experience gastrointestinal intolerance, a trial of parenteral methotrexate must be considered. • Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above. • Intolerant is defined as demonstrating serious adverse effects to treatments. The nature of intolerance(s) must be clearly documented. **Claim Notes:** • Must be prescribed by a rheumatologist. • Combined use of more than one biologic DMARD will not be reimbursed. • Initial approval for a maximum of 12 weeks. • Approvals will be for 160mg at week 0, followed by 80mg every 4 weeks. • Renewal Approval: 1 year. Confirmation of continued response is required.				

Criteria Update: Psoriatic Arthritis

The psoriatic arthritis criteria for the following products has been updated effective **February 1, 2019**:

- Cimzia (certolizumab pegol)
- Enbrel (etanercept)
- Humira (adalimumab)
- Inflectra and Remicade (infliximab)
- Simponi (golimumab)

Please see the full criteria for psoriatic arthritis under the ixekizumab (Taltz) listing on Page 5.

Prescriber Identification on Exception Status Request

Please ensure the prescriber information section is complete when submitting exception status drug request forms. The following information must be included:

- Prescriber name
- License number
- Signature

If the above information is not included and clearly legible, responses may be prevented or delayed.

Legend

PRESCRIBER CODES	BENEFIT STATUS	MANUFACTURER CODES
D - Physician / Dentist	S - Seniors' Pharmacare	GSK - GlaxoSmithKline Inc.
N - Nurse Practitioner	F - Community Services Pharmacare	HRZ - HZNP Canada Limited
P - Pharmacist	- Family Pharmacare	INT - Intercept Pharma Canada Inc.
M - Midwife	C - Drug Assistance for Cancer Patients	LIL - Eli Lilly Canada Inc.
O - Optometrist	D - Diabetes Assistance Program	
	E - Exception status applies	

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New Exception Status Benefits

The following products have been listed with the following criteria, effective **April 1, 2019**.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Brivlera (brivaracetam)	10mg Tab	02452936	DNP	E (SF)	UCB
	25mg Tab	02452944	DNP	E (SF)	UCB
	50mg Tab	02452952	DNP	E (SF)	UCB
	75mg Tab	02452960	DNP	E (SF)	UCB
	100mg Tab	02452979	DNP	E (SF)	UCB
Criteria	• For the adjunctive treatment of refractory partial-onset seizures (POS) in patients who are currently receiving two or more antiepileptic drugs, and who have had an inadequate response or intolerance to at least three other antiepileptic drugs. **Claim Notes:** • The patient must be under the care of a physician experienced in the treatment of epilepsy. • Any combination of lacosamide, perampanel, eslicarbazepine, levetiracetam or brivaracetam will not be reimbursed.				

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Entresto	24.3mg/25.7mg Tab	02446928	DNP	E (SF)	NVR
(sacubitril/valsartan)	48.6mg/51.4mg Tab	02446936	DNP	E (SF)	NVR
	97.2mg/102.8mg Tab	02446944	DNP	E (SF)	NVR

Criteria

- For the treatment of heart failure (HF) with reduced ejection fraction in patients with New York Heart Association (NYHA) class II or III HF to reduce the incidence of cardiovascular (CV) death and HF hospitalization, if ALL of the following clinical criteria are met:
    - Reduced left ventricular ejection fraction (LVEF) (< 40%);
    - Patient has NYHA class II to III symptoms despite at least four weeks of treatment with stable doses of all of the following medications:
        - an angiotensin-converting enzyme inhibitor (ACEI) or an angiotensin II receptor antagonist (ARB);
        - a beta blocker;
        - other recommended therapies, including an aldosterone antagonist (if tolerable);
- Plasma B-type natriuretic peptide (BNP) ≥ 150 pg/mL or N-terminal prohormone B-type natriuretic peptide (NT-proBNP) ≥ 600 pg/mL; or plasma BNP ≥ 100 pg/mL or NT-proBNP ≥ 400 pg/mL levels if the patient has been hospitalized for HF within the past 12 months. If BNP testing is not accessible the reasons must be clearly outlined.

Clinical Note:

- Initiation and up-titration should be conducted by a prescriber experienced with the treatment of heart failure
- For patients who have not received four weeks of therapy with a beta blocker or aldosterone antagonist due to an intolerance or contraindication, details must be provided.

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Lynparza (olaparib)	50mg Cap	02454408	DNP	E (SFC)	AZE
	100mg Tab	02475200	DNP	E (SFC)	AZE
	150mg Tab	02475219	DNP	E (SFC)	AZE
Criteria	• As monotherapy maintenance treatment for patients with platinum-sensitive, relapsed, BRCA-mutated (germline or somatic), high grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who have completed at least two previous lines of platinum-based chemotherapy and are in radiologic response (complete or partial) to their most recent platinum-based chemotherapy regimen as per the SOLO-2 trial. • Patients must have received at least four cycles of their most recent platinum-based chemotherapy before starting treatment with olaparib. **Clinical Notes:** • Maintenance therapy with olaparib should begin within eight weeks of the last dose of platinum-based chemotherapy. • Platinum-sensitive disease is defined as disease progression occurring at least six months after completion of platinum-based chemotherapy. • Patients should have a good performance status. • Treatment should continue until unacceptable toxicity or disease progression. • Patients who are unable to tolerate platinum-based chemotherapy (due to allergic reaction) and otherwise meet criteria, will be assessed on a case by case basis to determine eligibility for treatment with olaparib.				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Pheburane (sodium phenylbutyrate)	483mg/g Oral Granules	02436663	DNP	E (SF)	MDU
Criteria	• For the treatment of patients with urea cycle disorders (UCDs). **Clinical Note:** • Diagnosis must be confirmed by blood, enzymatic, biochemical or genetic testing. **Claim Note:** • Must be prescribed by, or in consultation with, a physician experienced in the treatment of UCDs.				

New Product

Effective **April 1, 2019,** the following new product has been added to the Nova Scotia Formulary. The benefit status within the Pharmacare Programs is indicated.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Actikerall	0.5%/10% Sol	02428946	DNP	SF	CIP

Non Insured Product

The following product will not be insured in the Pharmacare Programs, however, it is funded through the Nova Scotia Cystic Fibrosis Program.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Quinsair	240mg/2.4mL Inh Sol	02442302	N/A	**Non Insured**	HRZ

Correspondence Address Updates

If your mailing address has changed, prescribers must contact Provider Coordinators at MSIProvidercoordinators@medavie.bluecross.ca or 1-866-553-0585 to ensure accurate and timely responses to your exception status drug requests.

Legend

PRESCRIBER CODES	BENEFIT STATUS	MANUFACTURER CODES
D - Physician / Dentist	S - Seniors' Pharmacare	AZE - AstraZeneca Canada Inc.
N - Nurse Practitioner	F - Community Services Pharmacare	CIP - Cipher Pharmaceuticals Inc.
P - Pharmacist	- Family Pharmacare	HRZ - HZNP Canada Limited
M - Midwife	C - Drug Assistance for Cancer Patients	MDU - Medunik Canada Inc.
O - Optometrist	D - Diabetes Assistance Program	NVR - Novartis Pharmaceuticals Canada Inc.
	E - Exception status applies	UCB - UCB Pharma Canada Inc.

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Nova Scotia Formulary Updates

New Exception Status Benefits

The following products have been listed with the following criteria, effective **May 1, 2019**.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Movapo (apomorphine)	30mg/3mL Prefilled Pen	02459132	DNP	E (SF)	PAL
Criteria	• For the acute, intermittent treatment of hypomobility "off" episodes ("end-of-dose wearing off" and unpredictable "on/off" episodes) in patients with advanced Parkinson's disease (PD), if the following criteria are met: ○ Apomorphine should only be used as adjunctive therapy in patients who are receiving optimized PD therapy (levodopa and derivatives and dopaminergic agonists) and still experiencing "off" episodes. **Clinical Notes:** • Patients should be under the care of a physician with experience in the diagnosis and management of PD. • If the patient is not a good candidate for treatment with dopaminergic agonists, please provide detail as to why (i.e., those with cognitive impairment and impulsivity).				

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Enstilar **(calcipotriol/betamethasone dipropionate)**	50mcg/g/ 0.5mg/g Aer Foam	02457393	DNP	E (SF)	LEO
Criteria	• For the treatment of body and scalp psoriasis after failure of a topical steroid and a vitamin D analogue as single agents.				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Ilaris **(canakinumab)**	150mg/1mL Sol for Inj 150 mg/mL Pdr for Sol	02460351 02344939	DNP DNP	E (SF) E (SF)	NVR NVR
Criteria	• For the treatment of active systemic juvenile idiopathic arthritis, in patients 2 years of age or older, who have an inadequate response or intolerance to systemic corticosteroids (with or without methotrexate) and tocilizumab. **Clinical Note:** • Intolerance is defined as a serious adverse effect as described in the product monograph. The nature of the intolerance(s) must be clearly documented. **Claim Notes:** • Must be prescribed by, or in consultation with, a rheumatologist, who is familiar with the use of biologic DMARDs in children. • Combined used of more than one biologic DMARD will not be reimbursed. • Approvals will be for 4 mg/kg for patients > 9 kg, to a maximum of 300mg, administered every four weeks. • Initial approval period: 16 weeks. • Renewal approval period: 1 year. Confirmation of continued response is required.				

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Praluent (alirocumab)	75 mg/mL Prefilled Syringe	02453754	DNP	E (SF)	SAV
	75 mg/mL Prefilled Pen	02453819	DNP	E (SF)	SAV
	150 mg/mL Prefilled Syringe	02453762	DNP	E (SF)	SAV
	150 mg/mL Prefilled Pen	02453835	DNP	E (SF)	SAV
Repatha (evolocumab)	140mg/mL Prefilled Syringe	02446057	DNP	E (SF)	AGA
	120mg/mL Automated Mini Doser	02459779	DNP	E (SF)	AGA
Criteria	For the treatment of heterozygous familial hypercholesterolemia (HeFH) in adult patients who require additional lowering of low-density lipoprotein cholesterol (LDL-C) if the following criteria are met: • Definite or probable diagnosis of HeFH using the Simon Broome or Dutch Lipid Network criteria or genetic testing; and • Patient is unable to reach LDL-C target (less than 2.0 mmol/L or at least a 50% reduction in LDL-C from untreated baseline) despite confirmed adherence to at least 3 months of continuous treatment with: o high-dose statin (e.g., atorvastatin 80 mg, rosuvastatin 40 mg) in combination with ezetimibe; or o ezetimibe alone if high dose statin is not possible due to rhabdomyolysis, contraindication or intolerance **Initial renewal criteria:** • A reduction in LDL-C of at least 40% from baseline or has reached a target LDL-C less than 2.0 mmol/L. **Subsequent renewal criteria:** • The patient continues to maintain a reduction in LDL- C of at least 40% from baseline or has reached a target LDL-C less than 2.0 mmol/L. **Clinical Notes:** • LDL-C levels must be provided. • Intolerance to high dose statin will be considered if patient has developed documented, myopathy or abnormal biomarkers (i.e. creatinine kinase greater than 5 times the upper limit of normal) after trial of at least two statins and o for each statin, dose reduction was attempted rather than statin discontinuation, and intolerance was reversible upon statin discontinuation, but reoccurred with statin re-challenge where clinically appropriate; and o at least one statin was initiated at the lowest daily starting dose; and o other known causes of intolerance or abnormal biomarkers have been ruled out.				

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Praluent (alirocumab)	75 mg/mL Prefilled Syringe	02453754	DNP	E (SF)	SAV
	75 mg/mL Prefilled Pen	02453819	DNP	E (SF)	SAV
	150 mg/mL Prefilled Syringe	02453762	DNP	E (SF)	SAV
	150 mg/mL Prefilled Pen	02453835	DNP	E (SF)	SAV
Repatha (evolocumab)	140mg/mL Prefilled Syringe	02446057	DNP	E (SF)	AGA
	120mg/mL Automated Mini Doser	02459779	DNP	E (SF)	AGA
Criteria	**Clinical Notes Continued:** • For patients who cannot take a statin due to an intolerance or contraindication, details must be provided (ie. confirmed rhabdomyolysis, active liver disease, unexplained persistent elevations of serum transaminases exceeding three times the upper limit of normal). • For patients who cannot take ezetimibe due to an intolerance or contraindication, details must be provided. **Claim Notes:** • Initial approval: 6 months • Renewal approval: 1 year **Maximum dosage approved:** alirocumab • 300mg every 4 weeks evolocumab • 140mg every 2 weeks or 420mg monthly				

New Products

Effective **May 1, 2019,** the following new products have been added to the Nova Scotia Formulary. The benefit status within the Pharmacare Programs is indicated.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Kyleena IUS	19.5mg/insert	02459523	DNP	F	BAY
Tresiba Flextouch	100U/mL Prefilled Pen	02467879	DNP	SFD	NNO
Tresiba Flextouch	200U/mL Prefilled Pen	02467887	DNP	SFD	NNO

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
Odefsey	200mg/25mg/25mg Tab	02461463	N/A	**Non Insured**	GIL

Criteria Update

The following indications have been added to existing criteria effective **May 1, 2019**:

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Cosentyx	150mg/mL Prefilled Pen Inj	02438070	DNP	E (SF)	NVR
(secukinumab)	150mg/mL Prefilled Syringe Inj	02438070	DNP	E (SF)	NVR

Criteria

Psoriatic Arthritis

- For the treatment of patients with predominantly axial psoriatic arthritis who are refractory, intolerant or have contraindications to the sequential use of at least two NSAIDs at maximal tolerated dose for a minimum of two weeks each.
- For the treatment of patients with predominantly peripheral psoriatic arthritis who are refractory, intolerant or have contraindications to:
    - The sequential use of at least two NSAIDs at maximal tolerated dose for a minimum of two weeks each; and
    - Methotrexate (oral or parenteral) at a dose of ≥ 20mg weekly (≥15mg if patient is ≥65 years of age) for a minimum of 8 weeks; and
    - Leflunomide for a minimum of 10 weeks or sulfasalazine for a minimum of 3 months

Clinical Notes:

- For patients who do not demonstrate a clinical response to oral methotrexate, or who experience gastrointestinal intolerance, a trial of parenteral methotrexate must be considered.
- Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above.
- Intolerant is defined as demonstrating serious adverse effects to treatments. The nature of intolerance(s) must be clearly documented.

Claim Notes:

- Must be prescribed by a rheumatologist.
- Combined use of more than one biologic DMARD will not be reimbursed.
- Approvals will be for a maximum of 150mg given at weeks 0, 1, 2, 3, and 4, then monthly. Requests for 300mg monthly will be considered for patients who have previously had an inadequate response to TNF-inhibitors.

Criteria Update Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Cosentyx	150mg/mL Prefilled Pen Inj	02438070	DNP	E (SF)	NVR
(secukinumab)	150mg/mL Prefilled Syringe Inj	02438070	DNP	E (SF)	NVR

Criteria

Claim Notes Continued:

- Initial approval: 6 months.
- Renewal Approval: 1 year. Confirmation of continued response is required.

Ankylosing Spondylitis

- For the treatment of 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 or in whom NSAIDs are contraindicated, or
    - Have peripheral symptoms and who have failed to respond, or have contraindications to, the sequential use of at least 2 NSAIDs at the optimum dose for a minimum period of 3 months and have had an inadequate response to an optimal dose or maximal tolerated dose of a DMARD.
- Requests for renewal must include information demonstrating 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").

Clinical Note:

- Patients with recurrent uveitis (2 or more episodes within 12 months) as a complication to axial disease do not require a trial of NSAIDs alone.

Claim Notes:

- Must be prescribed by a rheumatologist or prescriber with a specialty in rheumatology.
- Combined use of more than one biologic DMARD will not be reimbursed.
- Approvals will be for 150mg given at weeks 0, 1, 2, 3, and 4, then monthly.
- Initial Approval: 6 months.
- Renewal Approval: 1 year.

Legend

PRESCRIBER CODES	BENEFIT STATUS	MANUFACTURER CODES
D - Physician / Dentist	S - Seniors' Pharmacare	AGA - Amgen Canada Inc.
N - Nurse Practitioner	F - Community Services Pharmacare	BAY - Bayer Inc.
P - Pharmacist	- Family Pharmacare	GIL - Gilead Sciences Inc.
M - Midwife	C - Drug Assistance for Cancer Patients	LEO - Leo Pharma Inc.
O - Optometrist	D - Diabetes Assistance Program	NNO - Novo Nordisk Canada Inc.
	E - Exception status applies	NVR - Novartis Pharmaceuticals Canada Inc.
		PAL - Paladin Labs Inc.
		SAV - Sanofi-Aventis Canada Inc.

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New Exception Status Benefits

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

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Siliq (brodalumab)	210mg/ 1.5 mL Prefilled Syringe	02473623	DNP	E (SF)	BSL

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.

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Siliq (brodalumab)	210mg/1.5 mL Prefilled Syringe	02473623	DNP	E (SF)	BSL
Criteria	**Clinical Notes:** • Treatment should be discontinued if a response has not been demonstrated after 12 weeks. **Claim Notes:** • Concurrent use of biologics not approved. • Initial approval for a maximum of 12 weeks. Renewal approval: 1 year. • Approvals will be for 210mg at week 0, 1, 2, followed by 210mg every two weeks.				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Maviret (glecaprevir/ pibrentasvir)	100mg/40mg Tab	02467550	DNP	E (SF)	ABV

Criteria: For treatment-naïve or treatment-experienced adult patients with chronic hepatitis C virus (HCV) who meet the following criteria:

	Approval Period
Genotypes 1, 2, 3, 4, 5 or 6 • Treatment-naïve	8 weeks (12 weeks with cirrhosis)
Genotypes 1, 2, 4, 5 or 6 • Treatment-experienced with regimens containing peginterferon/ribavirin (PR) and/or sofosbuvir (SOF)	8 weeks (12 weeks with cirrhosis)
Genotype 1 • NS5A inhibitor treatment-naïve and treatment-experienced with regimens containing: - Boceprevir/PR; or - Simeprevir (SMV)/SOF; or - SMV/PR; or - Telaprevir/PR	12 weeks
Genotype 1 • NS3/4A inhibitor treatment-naïve and treatment-experienced with regimens containing: - Daclatasvir (DCV)/SOF; or - DCV/PR; or - Ledipasvir/SOF	16 weeks

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Maviret (glecaprevir/ pibrentasvir)	100mg/40mg Tab	02467550	DNP	E (SF)	ABV
Criteria					**Approval Period**
	Genotype 3 • Treatment-experienced with regimens containing PR and/or SOF				16 weeks
	The following information is also required: • Lab-confirmed hepatitis C genotype 1, 2, 3, 4, 5 or 6 • Quantitative HCV RNA value within the last 6 months • Fibrosis stage **Clinical Note:** • Acceptable methods for the measurement of fibrosis score include Fibrotest, liver biopsy, transient elastography (FibroScan®), serum biomarker panels (such as AST-to-Platelet Ratio Index or Fibrosis-4 score) either alone or in combination. **Claim Notes:** • Must be prescribed by a hepatologist, gastroenterologist, or infectious disease specialist (or other physician experienced in treating a patient with hepatitis C infection). • Claims will be limited to a 28-day supply.				

Legend

PRESCRIBER CODES	BENEFIT STATUS	MANUFACTURER CODES
D - Physician / Dentist	S - Seniors' Pharmacare	ABV - AbbVie Corporation
N - Nurse Practitioner	F - Community Services Pharmacare - Family Pharmacare	BSL - Bausch Health, Canada Inc.
P - Pharmacist	C - Drug Assistance for Cancer Patients	
M - Midwife	D - Diabetes Assistance Program	
O - Optometrist	E - Exception status applies	

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New Exception Status Benefit

The following product has been listed with the following criteria, effective **immediately**.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Lixiana (edoxaban)	15mg Tab	02458640	DNP	E (SF)	SEV
	30mg Tab	02458659	DNP	E (SF)	SEV
	60mg Tab	02458667	DNP	E (SF)	SEV

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
- **[Criteria Code 36]** will be used to allow the 30mg or 60mg strengths to pay (max 30 tablets), which will allow patients to start therapy while awaiting ESD approval for the six months of therapy.

Notes:

- The recommended dose of edoxaban for patients initiating DVT or PE treatment is 60mg once daily following the initial use of a parenteral anticoagulant for five to ten days. A reduced dose of edoxaban 30mg once daily is recommended for patients with one or more of the following clinical factors: moderate renal impairment (creatinine clearance (CrCl) 30-50 mL/min, low body weight ≤60kg, or concomitant use of P-glycoprotein (P-gp) inhibitors except amiodarone and verapamil.
- Drug plan coverage for edoxaban is an alternative to heparin/warfarin for up to 6 months. When used greater than 6 months, edoxaban is more costly than heparin/warfarin. As such, patient with an intended

New Exception Status Benefit Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Lixiana (edoxaban)	15mg Tab	02458640	DNP	E (SF)	SEV
	30mg Tab	02458659	DNP	E (SF)	SEV
	60mg Tab	02458667	DNP	E (SF)	SEV

Criteria

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 monitor (see edoxaban product monograph).

Non-Valvular Atrial Fibrillation (AF)

Inclusion Criteria:

- At-risk patients with non-valvular atrial fibrillation (AF) who require edoxaban for the prevention of stroke and systemic embolism AND in whom:
    - anticoagulation is inadequate following at least a 2-month trial on warfarin; OR
    - anticoagulation with warfarin is contraindicated or not possible due to inability to regularly monitor via International Normalized Ratio (INR) testing (i.e. no access to INR testing services at a laboratory, clinic, pharmacy, and at home).

Exclusion Criteria:

- Patients with impaired renal function (CrCL or estimated glomerular filtration rate < 30mL/min) OR hemodynamically significant rheumatic valvular heart disease, especially mitral stenosis; OR prosthetic heart valves.

Notes:

- At risk patients with non-valvular atrial fibrillation are defined as those with a CHADS2 score of ≥ 1. Prescribers may consider an antiplatelet regimen or oral anticoagulation for patients with CHADS2 score of ≥ 1.
- Inadequate anticoagulation is defined as INR testing results that are outside the desired INR range for at least 35% of the tests during the monitoring period (i.e. adequate anticoagulation is defined as INR test results that are within the desired INR range for at least 65% of the tests during the monitoring period).
- A reasonable trial on warfarin is defined as at least two months of therapy.
- The usual recommended dose is 60mg once daily. A reduced dose of edoxaban 30mg once daily is recommended for patients with one or more of the following clinical factors: moderate renal impairment (creatinine clearance (CrCl) 30-50 mL/min, low body weight ≤60kg, or concomitant use of P-glycoprotein (P-gp) inhibitors except amiodarone and verapamil.
- Since renal impairment can increase bleeding risk, renal function should be regularly monitored. Other factors that increase bleeding risk should also be assessed and monitored (see edoxaban Product Monograph).
- There is currently no data to support that edoxaban provides adequate anticoagulation in patients with rheumatic valvular disease or those with prosthetic heart valves, so edoxaban is not recommended in these populations.

Criteria Updates

The following criteria has been updated effectively **immediately**:

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Inlyta (axitinib)	1mg Tab 5mg Tab	02389630 02389649	DNP DNP	E (SFC) E (SFC)	PFI PFI
Criteria	• As second line therapy for the treatment of patients with metastatic renal cell carcinoma after failure of prior therapy with either a cytokine or tyrosine kinase inhibitor. **Renewal Criteria:** • Written confirmation that the patient has responded to treatment and there is no evidence of disease progression. **Clinical Notes:** • Patients must have a good performance status. • Treatment should be discontinued upon disease progression or unacceptable toxicity. **Claim Notes:** • Sequential use of axitinib and everolimus will not be reimbursed. Exceptions may be considered in cases of intolerance or contraindication without disease progression. • Initial approval period: 6 months. • Renewal period: 1 year.				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Prolia (denosumab)	60mg/mL Prefilled Syringe	02343541	DNP	E (SFC)	AGA

Criteria	• For the treatment of osteoporosis in postmenopausal women and in men who meet the following criteria:
	  ○ Have a contraindication to oral bisphosphonates; and
	  ○ High risk for fracture, or refractory or intolerant to other available osteoporosis therapies.
	Clinical Notes:
	• Refractory is defined as a fragility fracture or evidence of a decline in bone mineral density below pre-treatment baseline levels, despite adherence for one year to other available osteoporosis therapies.
	• High fracture risk is defined as:
	  ○ Moderate 10-year fracture risk (10% to 20%) as defined by the Canadian Association of Radiologists and Osteoporosis Canada (CAROC) tool or the World Health Organization's Fracture Risk Assessment (FRAX) tool with a prior fragility fracture; or
	  ○ High 10-year fracture risk (≥ 20%) as defined by the CAROC or FRAX tool.				

New Products

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

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Eligard	7.5mg Inj Kit	02248239	DNP	SFC	SAV
Eligard	30mg Inj Kit	02248999	DNP	SFC	SAV

Midwife Prescriptions

Please be advised that Pharmacare will now accept claims for prescriptions for oral contraceptives when written by midwives who have approved provider status with Medavie Blue Cross.

Legend

PRESCRIBER CODES	BENEFIT STATUS	MANUFACTURER CODES
D - Physician / Dentist	S - Seniors' Pharmacare	AGA - Amgen Canada Inc.
N - Nurse Practitioner	F - Community Services Pharmacare - Family Pharmacare	PFI - Pfizer Canada Inc.
P - Pharmacist	C - Drug Assistance for Cancer Patients	SAV - Sanofi-Aventis Canada Inc.
M - Midwife	D - Diabetes Assistance Program	SEV - Servier Canada Inc.
O - Optometrist	E - Exception status applies	

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New Exception Status Benefits

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

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Galafold (migalastat)	123mg Cap	02468042	DNP	E (SF)	AMT

Criteria

- Adults with confirmed diagnosis of Fabry Disease (alpha-galactosidase [alpha-Gal A]) and who have an alpha-Gal A mutation, determined to be amenable by an in vitro assay; and
- For use in patients with an amenable mutation and who are otherwise eligible for enzyme replacement therapy (ERT) for the treatment of Fabry Disease as determined through the Canadian Fabry Disease Initiative (CFDI).
- Not for use in pediatrics (i.e. patients < 18 years of age).

Clinical Note:

- Galafold will not be used concomitantly with any ERT.

Claim Note:

- Claims for Galafold 123mg capsule that exceed the maximum claim amount of $9,999.99 must be divided and submitted as separate transactions using the DIN first and then the following PINs:
  - 00904406
  - 00904407

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Cycle-Nitisinone (nitisinone)	2mg Tab	02458616	DNP	E (SF)	CYC
	5mg Tab	02458624	DNP	E (SF)	CYC
	10mg Tab	02458632	DNP	E (SF)	CYC
Orfadin (nitisinone)	2mg Cap	02459698	DNP	E (SF)	BVT
	5mg Cap	02459701	DNP	E (SF)	BVT
	10mg Cap	02459728	DNP	E (SF)	BVT
	20mg Cap	02459736	DNP	E (SF)	BVT
Criteria	• For the treatment of adult and pediatric patients with hereditary tyrosinemia type 1 (HT-1) in combination with dietary restriction of tyrosine and phenylalanine. **Clinical Note:** • For use in patients with an established diagnosis of HT-1. **Claim Notes:** • Must be prescribed by a physician experienced in the diagnosis and management of HT-1. • Claims for nitisinone 10mg tablet/capsule and 20mg capsule that exceed the maximum claim amount of $9,999.99 must be divided and submitted as separate transactions using the DIN first and then the following PINs: o Nitisinone 10mg Tab ▪ 00904442 ▪ 00904443 ▪ 00904444 o Orfadin 10mg Cap ▪ 00904434 ▪ 00904435 ▪ 00904436 o Orfadin 20mg Cap ▪ 00904437 ▪ 00904438 ▪ 00904439				

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Revestive (teduglutide)	5mg Pws for Inj	02445727	DNP	E (SF)	SHI

Criteria	• For the ongoing treatment of adult patients with Short Bowel Syndrome (SBS) who have all of the following:
	  ○ SBS as a result of major intestinal resection (e.g., volvulus, vascular disease, cancer, Crohn's disease, injury)
	  ○ dependency on parenteral nutrition (PN) for a least 12 months
	  ○ prior to initiating teduglutide, PN required at least three times weekly to meet caloric, fluid and electrolyte needs, due to ongoing malabsorption and stable PN frequency and volume for at least one month
	Renewal Criteria:
	• Has maintained at least a 20% reduction in PN volume from baseline at 12 months.
	Clinical Note:
	• PN is defined as the parenteral delivery of lipids, protein and/or carbohydrates to address caloric needs, and intravenous fluids which addresses fluid and electrolyte needs of patients.
	Claim Notes:
	• Must be prescribed by a gastroenterologist or an internal medicine specialist with a specialty in gastroenterology.
	• Approval period: 1 year.
	• Claims for Revestive 5mg powder for injection that exceed the maximum claim amount of $9,999.99 must be divided and submitted as separate transactions using the DIN first and then the following PINs:
	  ○ 00904402
	  ○ 00904403
	  ○ 00904422				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Dysport Therapeutic (abobotulinum toxin A)	300U Vial 500U Vial	02460203 02456117	DNP DNP	E (SF) E (SF)	IPS IPS
Criteria	• For the treatment of cervical dystonia (spasmodic torticollis) in adults. • For the treatment of upper and lower limb focal spasticity in adults. • For the treatment of lower limb spasticity in pediatric patients 2 years of age and older.				

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Rydapt (midostaurin)	25mg Cap	02466236	DNP	E (SFC)	NVR
Criteria	• For the treatment of adult patients with newly diagnosed FMS-like tyrosine kinase 3 (FLT3)-mutated acute myeloid leukemia when used in combination with standard cytarabine and daunorubicin (7+3) induction and cytarabine consolidation chemotherapy. Patients should be deemed fit to receive standard induction and consolidation chemotherapy. **Clinical Notes:** • Midostaurin is not funded as maintenance therapy. • Midostaurin may be used in combination with other 7+3 induction regimens (i.e. cytarabine and idarubicin) **Claim Note:** • Claims for Rydapt 25mg capsule that exceed the maximum claim amount of $9,999.99 must be divided and submitted as separate transactions using the DIN first and then the following PIN: • 00904390				

Criteria Update

The following indication has been added to existing criteria effective **immediately**:

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Jakavi (ruxolitinib)	5mg Tab	02388006	DNP	E (SFC)	NVR
	10mg Tab	02434814	DNP	E (SFC)	NVR
	15mg Tab	02388014	DNP	E (SFC)	NVR
	20mg Tab	02388022	DNP	E (SFC)	NVR

Criteria	• For the treatment of patients with polycythemia vera who have demonstrated resistance or intolerance to hydroxyurea (HU).
	Renewal Criteria:
	• Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.
	Clinical Notes:
	1. Patients must have a good performance status.
	2. Treatment should be discontinued upon disease progression or unacceptable toxicity.
	3. Resistance is considered if, after at least 3 months of HU therapy at the maximum tolerated dose, patients experience at least one of the following:
	  • Need for phlebotomy to maintain hematocrit (HCT) < 45%
	  • Uncontrolled myeloproliferation (i.e., platelet count > 400 x 10^9/L and white blood cell count > 10 x 10^9/L)				

Criteria Update Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Jakavi (ruxolitinib)	5mg Tab	02388006	DNP	E (SFC)	NVR
	10mg Tab	02434814	DNP	E (SFC)	NVR
	15mg Tab	02388014	DNP	E (SFC)	NVR
	20mg Tab	02388022	DNP	E (SFC)	NVR
Criteria	• Failure to reduce massive splenomegaly by greater than 50%, as measured by palpation 4. Intolerance to HU is considered if patients experience at least one of the following: • Absolute neutrophil count < 1.0 x 10^9/L, platelet count < 100 x 10^9/L or hemoglobin < 100g/L at the lowest dose of HU required to achieve a response (a response to HU is defined as HCT < 45% without phlebotomy, and/or all of the following: platelet count < 400 x 10^9/L, white blood cell count < 10 x 10^9/L, and nonpalpable spleen). • Presence of leg ulcers or other unacceptable HU-related non-hematological toxicities (defined as grade 3 or 4 or, more than one week of grade 2) such as mucocutaneous manifestations, gastrointestinal symptoms, pneumonitis, or fever. • Toxicity requiring permanent discontinuation of HU, interruption of HU until toxicity resolved, or hospitalization due to HU toxicity. **Claim Notes:** • Initial approval period: 6 months • Renewal approval period: 1 year				

Non Insured Product

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
Juluca	50mg/25mg Tab	02475774	N/A	**Not Insured**	VIV

Legend

PRESCRIBER CODES	BENEFIT STATUS	MANUFACTURER CODES
D - Physician / Dentist	S - Seniors' Pharmacare	AMT - Amicus Therapeutic Canada Inc.
N - Nurse Practitioner	F - Community Services Pharmacare - Family Pharmacare	BVT - Biovitrum
P - Pharmacist	C - Drug Assistance for Cancer Patients	CYC - Cycle Pharmaceuticals Ltd.
M - Midwife	D - Diabetes Assistance Program	IPS - Ipsen Biopharmaceuticals Canada Inc.
O - Optometrist	E - Exception status applies	NVR - Novartis Pharmaceuticals Inc.
		SHI - Shire Pharma Canada ULC
		VIV - ViiV Healthcare ULC

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New Exception Status Benefits

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

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Spinraza (nusinersen)	12mg/5mL Vial	02465663	DNP	E (SF)	BIG
Criteria	• For patients diagnosed with 5q Spinal Muscular Atrophy (SMA) under the care of a specialist with experience in the diagnosis and management of SMA, if the following clinical criteria are met: ○ Genetic documentation of 5q SMA homozygous gene deletion, homozygous mutation, or compound heterozygote, AND ○ Patients who: ▪ are pre-symptomatic with two or three copies of SMN2, OR ▪ have had disease duration of less than six months, two copies of SMN2, and symptom onset after the first week after birth and on or before seven months of age, OR ▪ are under the age of 18 with symptom onset after six months of age, AND ○ Patient is not currently requiring permanent invasive ventilation*, AND				

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Spinraza (nusinersen)	12mg/5mL Vial	02465663	DNP	E (SF)	BIG
Criteria	○ A baseline assessment using an age-appropriate scale (the Hammersmith Infant Neurological Examination [HINE] Section 2, Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders [CHOP INTEND], or Hammersmith Functional Motor Scale-Expanded [HFMSE]) must be completed prior to initiation of nusinersen treatment. Other patients with SMA type 2 or 3 who are over the age of 18 may be considered on a case by case basis. • For continued coverage, the patient must meet the following criteria: ○ There is demonstrated achievement or maintenance of motor milestone function (as assessed using age-appropriate scales: the [HINE] Section 2), CHOP INTEND, or HFMSE) since treatment initiation in patients who were pre-symptomatic at the time of treatment initiation; OR ○ There is demonstrated maintenance of motor milestone function (as assessed using age-appropriate scales: the HINE Section 2, CHOP INTEND, or HFMSE) since treatment initiation in patients who were symptomatic at the time of treatment initiation; AND ○ Patient does not require permanent invasive ventilation*. • Treatment should be discontinued if, prior to the fifth dose or every subsequent dose of nusinersen, the above renewal criteria are not met. * Permanent invasive ventilation is defined as the use of tracheostomy and a ventilator due to progression of SMA that is not due to an identifiable and reversible cause.				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Venclexta (venetoclax)	10mg Tab	02458039	DNP	E (SFC)	ABV
	50mg Tab	02458047	DNP	E (SFC)	ABV
	100mg Tab	02458055	DNP	E (SFC)	ABV
	Starter Kit	02458063	DNP	E (SFC)	ABV
Criteria	• As a **single agent treatment option** for patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) who have received at least one prior therapy, **and** who have failed a B-cell receptor inhibitor (BCRi). Treatment should be continued until disease progression or unacceptable toxicity. **Clinical Note**: • Patients who have intolerance or a contraindication to a B-cell receptor inhibitor (BCRi) will be eligible for treatment with venetoclax. Intolerance to BCRi would be determined by the clinician.				

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Akynzeo (netupitant/palono-setron)	300mg/0.5mg Cap	02468735	DNP	E (SFC)	PFR
Criteria	• In combination with dexamethasone for the prevention of acute and delayed nausea and vomiting in patients receiving: o highly emetogenic chemotherapy, OR o moderately emetogenic chemotherapy who have had inadequate symptom control using a 5-HT3 antagonist and dexamethasone in a previous cycle. **Clinical Notes:** • Highly emetogenic chemotherapy (HEC) may include, but is not limited to: cisplatin regimens, anthracycline and cyclophosphamide combination regimens, and regimens containing carmustine, mechlorethamine, streptozocin, dacarbazine and cyclophosphamide ≥ 1500mg/m^2. • Patients who receive carboplatin-based regimens with AUC ≥ 4 are also eligible to receive netupitant/palonosetron in combination with dexamethasone for primary prevention of acute and delayed nausea and vomiting.				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Alecensaro (alectinib)	150mg Cap	02458136	DNP	E (SFC)	HLR
Criteria	• For the **first line treatment** of patients with locally advanced or metastatic anaplastic lymphoma kinase (ALK) positive non-small cell lung cancer (NSCLC). • For the treatment of patients with locally advanced or metastatic anaplastic lymphoma kinase (ALK) positive non-small cell lung cancer (NSCLC) who have disease progression on, or intolerance to crizotinib. **Claim Notes:** • Patients should have a good performance status and treatment should be continued until disease progression or unacceptable toxicity. • If alectinib is chosen as first-line therapy, ceritinib is not funded as a subsequent line of therapy. • Alectinib is not funded following two prior ALK inhibitor therapies (e.g. crizotinib followed by ceritinib) • Claims for Alecensaro 150mg capsule that exceed the maximum claim amount of $9,999.99 must be divided and submitted as separate transactions using the DIN first and then the following PIN: o 00904400				

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Fasenra (benralizumab)	30mg/mL Prefilled Syringe	02473232	DNP	E (SF)	AZE

Criteria

- For the adjunctive treatment of severe eosinophilic asthma in adult patients who are inadequately controlled with high dose inhaled corticosteroids and one or more additional asthma controller(s) (e.g., long-acting beta-agonist), and meets one of the following criteria:
  - blood eosinophil count of ≥ 0.3 x 10^9/L within the past 12 months and has experienced two or more clinically significant asthma exacerbations in the past 12 months, OR
  - blood eosinophil count of ≥ 0.15 x 10^9/L and is receiving maintenance treatment with oral corticosteroids (OCS).

Initial Discontinuation Criteria:

- Baseline asthma control questionnaire score has not improved at 12 months since the initiation of treatment, OR
- No decrease in the daily maintenance OCS dose in the first 12 months of treatment, OR
- Number of clinically significant asthma exacerbations has increased within the previous 12 months.

Subsequent Discontinuation Criteria:

- Baseline asthma control questionnaire score achieved after the first 12 months of therapy has not been maintained subsequently, OR
- Reduction in the daily maintenance OCS dose achieved after the first 12 months of treatment is not maintained subsequently, OR
- Number of clinically significant asthma exacerbations has increased within the previous 12 months.

Clinical Notes:

1. A baseline and annual assessment of asthma symptom control using a validated asthma control questionnaire must be provided.
2. High-dose inhaled corticosteroids is defined as greater than or equal to 500 mcg of fluticasone propionate or equivalent daily dose.
3. A clinically significant asthma exacerbation is defined as worsening of asthma such that the treating physician elected to administer systemic glucocorticoids for at least 3 days or the patient visited an emergency department or was hospitalized.

Claim Notes:

- Must be prescribed by a respirologist, clinical immunologist, allergist or internist with experience in treating severe eosinophilic asthma.
- Combined use of benralizumab with other biologics used to treat asthma will not be reimbursed.
- Approvals will be for a maximum of 30 mg every four weeks for 12 weeks, then every eight weeks thereafter.
- Initial approval period: 1 year.
- Renewal approval period: 1 year.

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Renflexis (infliximab)	100mg Pws for Inj	02470373	DNP	E (SF)	FRS
Criteria	**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: o have axial symptoms[1] 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 o 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. 1. 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. **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: o a decrease of at least 2 points on the BASDAI scale, compared with the pre-treatment score; OR o 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"). • 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. **For patients whose infliximab therapy is initiated after June 1, 2016, an infliximab biosimilar will be the product approved.** **Psoriatic Arthritis:** • For the treatment of patients with predominantly axial psoriatic arthritis who are refractory, intolerant or have contraindications to the sequential use of at least two NSAIDs at maximal tolerated dose for a minimum of two weeks each. • For the treatment of patients with predominantly peripheral psoriatic arthritis who are refractory, intolerant or have contraindications to: o The sequential use of at least two NSAIDs at maximal tolerated dose for a minimum of two weeks each; AND o Methotrexate (oral or parenteral) at a dose of ≥ 20mg weekly (≥15mg if patient is ≥65 years of age) for a minimum of 8 weeks; AND o Leflunomide for a minimum of 10 weeks or sulfasalazine for a minimum of 3 months.				

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Renflexis (infliximab)	100mg Pws for Inj	02470373	DNP	E (SF)	FRS
Criteria	**Clinical Notes:** • For patients who do not demonstrate a clinical response to oral methotrexate, or who experience gastrointestinal intolerance, a trial of parenteral methotrexate must be considered. • Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above. • Intolerant is defined as demonstrating serious adverse effects to treatments. The nature of intolerance(s) must be clearly documented. **Claim Notes:** • Must be prescribed by a rheumatologist. • Combined use of more than one biologic DMARD will not be reimbursed. • Renewal approval: 1 year. Confirmation of continued response required. **For patients whose infliximab therapy is initiated after December 1, 2016, an infliximab biosimilar will be the product approved.** **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: o 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 o 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.				

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Renflexis (infliximab)	100mg Pws for Inj	02470373	DNP	E (SF)	FRS

Criteria

- 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:
    - Infliximab: 3mg/kg/dose at 0, 2 and 6 weeks, then every 8 weeks thereafter.

For patients whose infliximab therapy is initiated after June 1, 2016, an infliximab biosimilar will be the product approved.

Psoriasis:

- For patients with severe, debilitating chronic plaque psoriasis 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;
    - 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.

Clinical Note:

- Treatment should be discontinued if a response has not been demonstrated after 12 weeks.

Claim Note:

- Concurrent use of biologics not approved.

For patients whose infliximab therapy is initiated after June 1, 2016, an infliximab biosimilar will be the product approved.

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Renflexis (infliximab)	100mg Pws for Inj	02470373	DNP	E (SF)	FRS
Criteria	**Ulcerative Colitis:** • For the treatment of patients with moderately to severely active ulcerative colitis who have a partial Mayo score > 4, and a rectal bleeding subscore ≥ 2 and are: o 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 o 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: o a decrease in the partial Mayo score ≥ 2 from baseline, AND o 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. **For patients whose infliximab therapy is initiated after December 1, 2016, an infliximab biosimilar will be the product approved.** **For pediatric patients whose infliximab therapy is initiated after October 1, 2019, an infliximab biosimilar will be the product approved.**				

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Renflexis (infliximab)	100mg Pws for Inj	02470373	DNP	E (SF)	FRS

Criteria	**Crohn's Disease:**
	• For treatment of Crohn's disease in patients with moderate to severe active disease refractory to 5-ASA products AND glucocorticoids (e.g., prednisone) AND immunosuppressive therapy (azathioprine or 6-mercaptopurine or methotrexate)[1].
	  ○ Initial approval of infliximab will be for a single infusion of 5mg/kg/dose. A second infusion may be warranted in patients not responding to the first infusion or in patients responding initially but then worsening before maintenance therapy is effective. Request for approval beyond induction therapy will be considered on a case by case basis.
	  ○ In patients with fistulizing disease who have actively draining perianal or enterocutaneous fistula(e) that have recurred or persisted despite a course of appropriate antibiotic therapy (e.g., metronidazole +/-ciprofloxacin for a minimum of 3 weeks) AND immunosuppressive therapy (azathioprine or 6-mercaptopurine or methotrexate)[1].
	  ○ Initial approval is for three infusions of infliximab of 5mg/kg/dose at 0, 2 and 6 week intervals.
	1. Patients who are very ill and not candidates for surgery may qualify for infliximab therapy without a trial of AZA, 6-MP or MTX, as they may require a more rapid onset of response.
	Note:
	• Requires a written request by a gastroenterologist or physician with a specialty in gastroenterology.
	For patients whose infliximab therapy is initiated after December 1, 2016, an infliximab biosimilar will be the product approved.
	For pediatric patients whose infliximab therapy is initiated after October 1, 2019, an infliximab biosimilar will be the product approved.				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Rexulti (brexpiprazole)	0.25mg Tab	02461749	DNP	E (SF)	OTS
	0.5mg Tab	02461757	DNP	E (SF)	OTS
	1mg Tab	02461765	DNP	E (SF)	OTS
	2mg Tab	02461773	DNP	E (SF)	OTS
	3mg Tab	02461781	DNP	E (SF)	OTS
	4mg Tab	02461803	DNP	E (SF)	OTS
Criteria	• For the treatment of schizophrenia and related psychotic disorders (not dementia related) in adult patients with a history of intolerance or inadequate response to at least one less expensive antipsychotic agent, or who have a contraindication to less expensive agents.				

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Zykadia (ceritinib)	150mg Cap	02436779	DNP	E (SFC)	NVR
Criteria	• For the treatment of patients with locally advanced or metastatic anaplastic lymphoma kinase (ALK) positive non-small cell lung cancer (NSCLC) who experience disease progression on, or intolerance to crizotinib. **Claim Notes:** • Patients should have a good performance status and treatment should be continued until disease progression or unacceptable toxicity. • If alectinib is chosen as first-line therapy, ceritinib is not funded as a subsequent line of therapy. • Disease progression on any other ALK inhibitor in the second-line setting after crizotinib, precludes the use of ceritinib as a subsequent line of therapy.				

Criteria Updates

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

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Emend (aprepitant)	80mg Cap	02298791	DNP	E (SFC)	FRS
	125mg Cap	02298805	DNP	E (SFC)	FRS
	Tri-Pack Cap	02298813	DNP	E (SFC)	FRS

Criteria	• In combination with a 5-HT3 antiemetic and dexamethasone for the prevention of acute and delayed nausea and vomiting in patients receiving:
	  ○ highly emetogenic chemotherapy, OR
	  ○ moderately emetogenic chemotherapy who have had inadequate symptom control using a 5-HT3 antagonist and dexamethasone in a previous cycle.
	Clinical Notes:
	• Highly emetogenic chemotherapy (HEC) may include, but is not limited to: cisplatin regimens, anthracycline and cyclophosphamide combination regimens, and regimens containing carmustine, mechlorethamine, streptozocin, dacarbazine and cyclophosphamide ≥ 1500mg/m^2.
	• Patients who receive carboplatin-based regimens with AUC ≥ 4 are also eligible to receive aprepitant in combination with a 5-HT3 antiemetic and dexamethasone for the primary prevention of acute and delayed nausea and vomiting.				

Criteria Update Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Nucala (mepolizumab)	100mg/mL Pws Inj	02449781	DNP	E (SF)	GSK

Criteria

- For the adjunctive treatment of severe eosinophilic asthma in adult patients who are inadequately controlled with high dose inhaled corticosteroids and one or more additional asthma controller(s) (e.g., long-acting beta-agonist), and meets one of the following criteria:
  - blood eosinophil count of ≥ 0.3 x 10^9/L within the past 12 months and has experienced two or more clinically significant asthma exacerbations in the past 12 months, OR
  - blood eosinophil count of ≥ 0.15 x 10^9/L and is receiving maintenance treatment with oral corticosteroids (OCS).

Initial Discontinuation Criteria:

- Baseline asthma control questionnaire score has not improved at 12 months since the initiation of treatment, OR
- No decrease in the daily maintenance OCS dose in the first 12 months of treatment, OR
- Number of clinically significant asthma exacerbations has increased within the previous 12 months.

Subsequent Discontinuation Criteria:

- Baseline asthma control questionnaire score achieved after the first 12 months of therapy has not been maintained subsequently, OR
- Reduction in the daily maintenance OCS dose achieved after the first 12 months of treatment is not maintained subsequently, OR
- Number of clinically significant asthma exacerbations has increased within the previous 12 months.

Clinical Notes:

1. A baseline and annual assessment of asthma symptom control using a validated asthma control questionnaire must be provided.
2. High-dose inhaled corticosteroids is defined as greater than or equal to 500 mcg of fluticasone propionate or equivalent daily dose.
3. A clinically significant asthma exacerbation is defined as worsening of asthma such that the treating physician elected to administer systemic glucocorticoids for at least 3 days or the patient visited an emergency department or was hospitalized.

Claim Notes:

- Must be prescribed by a respirologist, clinical immunologist, allergist or internist with experience in treating severe eosinophilic asthma.
- Combined use of mepolizumab with other biologics used to treat asthma will not be reimbursed.
- Approvals will be for a maximum of 100 mg every four weeks.
- Initial approval period: 1 year.
- Renewal approval period: 1 year.

Changes in Benefit Status

Effective **immediately,** the following products have moved to full benefit status and no longer require exception status approval.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Ezetimibe	10mg Tab	Various	DNP	SF	VAR
Montelukast	4mg Chewtab	Various	DNP	SF	VAR
Montelukast	4mg Granules	Various	DNP	SF	VAR
Montelukast	5mg Chewtab	Various	DNP	SF	VAR
Montelukast	10mg Tab	Various	DNP	SF	VAR

Effective **immediately,** the following products have moved to non-benefit status and will no longer be covered under the Nova Scotia Pharmacare Programs.

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Choledyl Expectorant	500mg/100mg/5mL	00476374	**Not Insured**	ERF
Ridaura	3mg Cap	01916823	**Not Insured**	XPI
Soframycin Nasal Spray	12.5mg/0.05mg/2.5mg/mL	02224860	**Not Insured**	ERF

New Products

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

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Amlodipine	2.5mg Tab	02419556	DNP	SF	AHI
Amlodipine	2.5 mg Tab	02385783	DNP	SF	SIV
pharma-Amlodipine	2.5mg Tab	02469022	DNP	SF	PMS
Citalopram	10mg Tab	02387948	DNP	SFC	SIV
Teva-Citalopram	10mg Tab	02312336	DNP	SFC	TEV
Esbriet	267mg Tab	02464489	DNP	E (SF)	HLR
Esbriet	801mg Tab	02464500	DNP	E (SF)	HLR
Mint-Hydrochlorothiazide	12.5mg Tab	02425947	DNP	SF	MNT
Sterile Water for Inj	N/A	02299186	DNP	SF	TLG

Legend

PRESCRIBER CODES	BENEFIT STATUS	MANUFACTURER CODES
D - Physician / Dentist	S - Seniors' Pharmacare	ABV - AbbVie Corporation
N - Nurse Practitioner	F - Community Services Pharmacare	AHI - Accord Health Inc.
P - Pharmacist	- Family Pharmacare	AZE - AstraZeneca Canada Inc.
M - Midwife	C - Drug Assistance for Cancer Patients	BIG - Biogen Idec Canada Inc.
O - Optometrist	D - Diabetes Assistance Program	ERF - ERFA Canada Inc.
	E - Exception status applies	FRS - Merck Canada Ltd.
		GSK - GlaxoSmithKline Inc.
		HLR - Hoffmann-LaRoche Limited
		MNT - Mint Pharmaceuticals Inc.
		NVR - Novartis Pharmaceutical Canada Inc.
		OTS - Otsuka Canada Pharmaceuticals
		PFR - Purdue Pharma
		PMS - Pharmascience Inc.
		SIV - Sivem Pharmaceuticals
		TEV - Teva Canada Ltd.
		TLG - Teligent Canada
		VAR - *various manufacturers*
		XPI - Xediton Pharmaceuticals Inc.

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New Exception Status Benefits

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

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Kisqali (ribociclib)	200mg Tab	02473569	DNP	E (SFC)	NVR
Criteria	• In combination with an aromatase inhibitor (AI) (i.e. letrozole, anastrozole or exemestane) for the treatment of post-menopausal women with estrogen receptor (ER) positive, human epidermal growth factor receptor 2 (HER 2) negative advanced breast cancer who have not received any prior treatment for metastatic disease. **Clinical Notes** • Treatment should continue until unacceptable toxicity or disease progression. • Patients should have a good performance status and not be resistant to prior (neo) adjuvant aromatase inhibitor therapy (i.e. have the potential to benefit from first-line endocrine based therapy), without active or uncontrolled metastases to the central nervous system.				

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Tagrisso	40mg Tab	02456214	DNP	E (SFC)	AZE
(osimertinib)	80mg Tab	02456222	DNP	E (SFC)	AZE
Criteria	• For the treatment of patients with locally advanced or metastatic epidermal growth factor receptor (EGFR) T790M mutation-positive non-small cell lung cancer (NSCLC) who have progressed on EGFR tyrosine kinase inhibitor (TKI) therapy, or as initial therapy in patients with a de novo EGFR T790M mutation. **Clinical Note:** • Treatment may be continued until there is evidence of disease progression or the development of unacceptable toxicity.				

Criteria Updates

The following indications have been added to existing criteria effective **immediately:**

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Actemra	80mg/4mL Inj	02350092	DNP	E (SF)	HLR
(tocilizumab)	200mg/10mL Inj	02350106	DNP	E (SF)	HLR
	400mg/20mL Inj	02350114	DNP	E (SF)	HLR
	162mg/0.9mL SC Inj	02424770	DNP	E (SF)	HLR
	162mg/0.9mL Autoinjector	02483327	DNP	E (SF)	HLR
Criteria	**Giant Cell Arteritis** • For the treatment of Giant Cell Arteritis (GCA) in adult patients who are receiving prednisone at initiation of therapy, or with relapse. **Notes:** • Patients should be under the care of a physician with the experience of diagnosis and management of GCA. • Duration of therapy with tocilizumab should be limited to 52 weeks per treatment course. • Discontinuation of tocilizumab should be considered at 12 weeks if there is no response to therapy.				

Criteria Updates Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Stivarga (regorafenib)	40mg Tab	02403390	DNP	E (SFC)	BAY

Criteria	**Hepatocellular Carcinoma (HCC)**
	• For the treatment of patients with unresectable hepatocellular carcinoma (HCC) who have experienced disease progression on sorafenib and meet all of the following criteria:
	  ○ ECOG performance status of 0 or 1.
	  ○ Child-Pugh class status of A.
	  ○ Tolerated sorafenib at a dose of at least 400mg per day for at least 20 days of the last 28-day cycle.
	Clinical Note:
	• Treatment should continue until disease progression or unacceptable toxicity.				

Delisted Products

Effective **immediately**, the following products have moved to non-benefit status and will no longer be covered under the Nova Scotia Pharmacare Programs.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Ibavyr	200mg Tab	02439212	N/A	**Not Insured**	PDP
Ibavyr	400mg Tab	02425890	N/A	**Not Insured**	PDP
Ibavyr	600mg Tab	02425904	N/A	**Not Insured**	PDP

New Product

The following new product has been added to the Nova Scotia Formulary, effective **immediately.** The benefit status within the Pharmacare Programs is indicated and any existing criteria will apply.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Sandoz-Levetiracetam	1000mg Tab	02462028	DNP	SF	SDZ

Legend

PRESCRIBER CODES	BENEFIT STATUS	MANUFACTURER CODES
D - Physician / Dentist	S - Seniors' Pharmacare	AZE - AstraZeneca Canada Inc.
N - Nurse Practitioner	F - Community Services Pharmacare	BAY - Bayer Inc.
P - Pharmacist	- Family Pharmacare	HLR - Hoffmann-LaRoche Limited
M - Midwife	C - Drug Assistance for Cancer Patients	NV - Novartis Pharmaceuticals Canada Inc.
O - Optometrist	D - Diabetes Assistance Program	PDP - PendoPharm, Division of Pharmascience Inc.
	E - Exception status applies	SDZ - Sandoz Canada Incorporated

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New Exception Status Benefits

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

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Trelegy Ellipta (fluticasone furoate/ umeclidinium /vilanterol)	100mcg/ 62.5mcg/ 25mcg	02474522	DNP	E (SF)	GSK

Criteria

- For the treatment of chronic obstructive pulmonary disease (COPD), as defined by spirometry, in patients who experience inadequate control while being treated with a long-acting beta-2 agonist/long-acting muscarinic antagonist (LABA/LAMA).

Clinical Notes:

- COPD is defined by spirometry as a post-bronchodilator FEV_1/FVC ratio of less than 0.70. Spirometry reports from any point in time will be accepted. If spirometry cannot be obtained, reasons must be clearly explained and other evidence of COPD severity provided (i.e. MRC Dyspnea Scale Score grade).
- Inadequate control while being treated with a LABA/LAMA for at least two months is defined as persistent symptoms or experiencing two or more exacerbations of COPD in the previous year requiring treatment with antibiotics and/or systemic corticosteroids or at least one exacerbation of COPD requiring hospitalization.
- Patients should not be started on a LABA, LAMA and an inhaled corticosteroid (triple inhaled therapy) as initial therapy.

New Exception Status Benefits Continued…

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

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

Criteria Updates

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

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

Criteria Updates Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Actemra (tocilizumab)	162mg/ 0.9mL Autoinjector	02483327	DNP	E (SF)	HLR
Criteria	• If patient factors (e.g. intolerance) prevent the use of triple DMARD therapy, these must be described and dual therapy with DMARDs must be tried. • Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above. • Intolerant is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs. The nature of intolerance(s) must be clearly documented. **Claim Notes:** • Must be prescribed by a rheumatologist. • Combined use of more than one biologic DMARD will not be reimbursed. • Initial Approval: 6 months. • Renewal Approval: 1 year. Confirmation of continued response is required. • **Maximum Dosage Approved:** o Tocilizumab: 4mg/kg/dose once every 4 weeks followed by an increase to 8 mg/kg/dose based on clinical response				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Erelzi (etanercept)	25mg/0.5mL Prefilled Syringe	02462877	DNP	E (SF)	SDZ
	50mg/mL Prefilled Syringe	02462869	DNP	E (SF)	SDZ
	50mg/mL Prefilled Autoinjector	02462850	DNP	E (SF)	SDZ
Criteria	• For the treatment of patients with predominantly axial psoriatic arthritis who are refractory, intolerant or have contraindications to the sequential use of at least two NSAIDs at maximal tolerated dose for a minimum of two weeks each. • For the treatment of patients with predominantly peripheral psoriatic arthritis who are refractory, intolerant or have contraindications to: o The sequential use of at least two NSAIDs at maximal tolerated dose for a minimum of two weeks each; AND o Methotrexate (oral or parenteral) at a dose of ≥ 20mg weekly (≥15mg if patient is ≥65 years of age) for a minimum of 8 weeks; AND o Leflunomide for a minimum of 10 weeks or sulfasalazine for a minimum of 3 months.				

Criteria Updates Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Erelzi	25mg/0.5mL Prefilled Syringe	02462877	DNP	E (SF)	SDZ
(etanercept)	50mg/mL Prefilled Syringe	02462869	DNP	E (SF)	SDZ
	50mg/mL Prefilled Autoinjector	02462850	DNP	E (SF)	SDZ
Criteria	**Clinical Notes:** • For patients who do not demonstrate a clinical response to oral methotrexate, or who experience gastrointestinal intolerance, a trial of parenteral methotrexate must be considered. • Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above. • Intolerant is defined as demonstrating serious adverse effects to treatments. The nature of intolerance(s) must be clearly documented. **Claim Notes:** • Must be prescribed by a rheumatologist. • Combined use of more than one biologic DMARD will not be reimbursed. • Renewal approval: 1 year. Confirmation of continued response required. **For etanercept-naïve patients whose etanercept therapy is initiated after January 1, 2020 a biosimilar will be the product that is approved.**				

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

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

WHAT REMAINS THE SAME?

- Spirometry is required to confirm a COPD diagnosis, as recommended by respiratory specialists and COPD clinical practice guidelines. A COPD diagnosis, as defined by spirometry, is a post bronchodilator $FEV_1/FVC < 0.7$. Bourbeau 2017, GOLD 2017
- Progression to long-acting $beta_2$ agonists/long-acting muscarinic antagonists (LAMA/LABA) dual long acting bronchodilator therapy requires prior use of long acting bronchodilator monotherapy, although the minimum time frame is reduced to one month – see key changes below re: dual bronchodilator therapy.

KEY CHANGES TO CRITERIA

Long Acting Bronchodilator Therapy (LABA or LAMA)

LABA: Foradil, Onbrez, Serevent
LAMA: Spiriva Respimat and Handihaler, Incruse Ellipta, Seebri Breezhaler, Tudorza Genuair

- There is no longer a requirement for specific doses of short-acting bronchodilators prior to approval of a long acting bronchodilator.
- LAMA inhalers are funded in combination with a long-acting beta$_2$ agonist/inhaled corticosteroid (LABA/ICS), when patients experience inadequate control while being treated with a LABA/ICS **or** a LABA/LAMA for at least 2 months.
    - Inadequate control is defined as per persistent symptoms or experiencing two or more exacerbations of COPD in the previous year requiring treatment with antibiotics and/or system corticosteroids or at least one exacerbation of COPD requiring hospitalization.
- Criteria for approval of either a LABA or LAMA inhaler include COPD patients experiencing persistent symptoms or moderate to severe exacerbations.
    - Persistent symptoms are defined by a Medical Research Council (MRC) score of at least 3 or a COPD Assessment Test (CAT) score ≥ 10 and a post- bronchodilator FEV_1 < 80% predicted.
        - The CAT score is an addition which coincides with recommendations in clinical practice guidelines.
        - The FEV_1 cut off has been increased to 80% to coincide with the definition of moderate COPD.
    - Exacerbations are defined as experiencing 2 or more moderate exacerbations of COPD in the previous year requiring treatment with antibiotics and/or systemic corticosteroids OR at least 1 acute severe exacerbation of COPD (AECOPD) requiring hospital admission.
    - Clinical Note: LAMA monotherapy is recommended over LABA for prevention of exacerbations. Bourbeau 2017, GOLD 2017

Dual Bronchodilator Therapy (LABA/LAMA in one inhaler)

Anoro Ellipta, Duaklir Genuair, Inspiolto Respimat, Ultibro Breezhaler

- A LABA/LAMA inhaler may be approved after at least one month of monotherapy with either a LAMA or LABA who experience inadequate control.
    - Inadequate control is defined as persistent symptoms (e.g. MRC Dyspnea Scale of at least grade 3 or COPD Assessment test (CAT) score of at least 10).
- The timeframe is reduced to 1 month to allow faster access to patients with persistent symptoms despite a trial of monotherapy with either a LAMA or LABA.

LABA/ICS Therapy

Advair, Symbicort, Breo Ellipta

- LABA/ICS inhalers are funded only as a component of triple therapy (LABA/ICS + LAMA) in patients who experience inadequate control with the use of a LABA/LAMA for at least 2 months; OR for patients with characteristics of both COPD and asthma (i.e., asthma/COPD overlap - ACO).
    - Inadequate control is defined as per persistent symptoms or experiencing two or more exacerbations of COPD in the previous year requiring treatment with antibiotics and/or system corticosteroids or at least one exacerbation of COPD requiring hospitalization.
    - LABA/ LAMA are generally preferred over a LABA/ICS unless there are features of ACO.

LABA/ICS Therapy Continued…

- It is acknowledged that there is a lack of consensus on the definition for ACO, or the appropriate pharmacotherapy. The criteria for approval of a LABA/ICS inhaler in ACO will be based on patient history and lung function studies. Bourbeau 2017
- **Note:** Since the ACDR recommendations, updated Canadian Thoracic Society COPD guidelines were published in October 2019 which identify a role for LABA/ICS, primarily in patients with an eosinophil count ≥ 300 /µL and at high risk for exacerbations. Bourbeau 2019 However, eosinophil counts are not a consideration in the latest criteria update.

Triple Inhaler Therapy

LABA/ICS and LAMA or combined in one inhaler

- Approval for triple therapy (LABA/ICS plus LAMA) requires the patient to have inadequate control while being treated for at least 2 months with a LAMA/LABA inhaler; OR, in patients with asthma/COPD overlap after treatment with a LABA/ICS inhaler.
  - Inadequate control while being treated with a LABA/LAMA for at least two months is defined as persistent symptoms or experiencing two or more exacerbations of COPD in the previous year requiring treatment with antibiotics and/or systemic corticosteroids or at least one exacerbation of COPD requiring hospitalization.
- **Note:** Triple therapy is not recommended as initial therapy for COPD

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

Inhaler abbreviations: LABA= Long acting $beta_2$- agonist; LAMA= Long acting muscarinic antagonist; ICS = Inhaled corticosteroid

References

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

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

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

The full updated criteria for each product can found in the January update of the Nova Scotia formulary:

https://novascotia.ca/dhw/pharmacare/documents/formulary.pdf

The new request form for COPD medications can be found at the following link:
https://novascotia.ca/dhw/pharmacare/exception-status-drugs.asp

New Products

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

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

Criteria Code for Hepatitis C Medications

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

A written request must be provided to the Pharmacare office to allow coverage for the remaining duration of therapy. Treatment must be prescribed by a hepatologist, gastroenterologist, or infectious disease specialist (or other physician experienced in treating a patient with hepatitis C infection).

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

The new request form for hepatitis C medications can be found at the following link:
https://novascotia.ca/dhw/pharmacare/exception-status-drugs.asp

Legend

PRESCRIBER CODES	BENEFIT STATUS	MANUFACTURER CODES
D - Physician / Dentist	S - Seniors' Pharmacare	ATL - Labratoire Atlas Inc.
N - Nurse Practitioner	F - Community Services Pharmacare	GSK - GlaxoSmithKline Inc.
P - Pharmacist	- Family Pharmacare	HLR - Hoffmann-LaRoche Limited
M - Midwife	C - Drug Assistance for Cancer Patients	PFI - Pfizer Canada Inc.
O - Optometrist	D - Diabetes Assistance Program	PMS - Pharmacience Inc.
	E - Exception status applies	SAV - Sanofi-Aventis Canada Inc.
		SDZ - Sandoz Canada Incorporated
		TLG - Teligent Canada