Health and Community Services

The Newfoundland and Labrador Prescription Drug Program

CRITERIA FOR THE COVERAGE OF SPECIAL AUTHORIZATION DRUGS

Subject to revision

Coverage of special authorization drugs will be approved according to the following criteria upon receipt of the required clinical information from a health care professional involved in the patient's care, and subject to a medication review by staff of the Pharmaceutical Services Division. A special authorization request form has been prepared at the request of pharmacists and physicians which may be used to facilitate the approval process. Requests can be faxed or mailed and are assessed in the order received. The use of the form, while not mandatory, is encouraged to expedite the approval process.

Newfoundland Labrador

Health and Community Services

FESOTERODINE FUMARATE (TOVIAZ 4 MG, 8MG TABLET)

For the treatment of overactive bladder (not stress incontinence) after a reasonable trial, titrated, and of appropriate length* of oxybutynin IR, tolterodine OR solifenacin are not tolerated.

*an appropriate trial is considered to be of 12 weeks duration.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated October 2018

Health and Community Services

ABATACEPT (ORENCIA 250 MG VIAL, ORENCIA 125 MG/ML SYRINGE)

Rheumatoid Arthritis (RA):
250mg/15mL vial DIN 02282097
125mg/mL pre-filled syringe DIN 02402475

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) for a minimum of 12 weeks, followed by methotrexate in combination with at least two other DMARDs, such as hydroxychloroquine and sulfasalazine, for a minimum of 12 weeks;

OR

- Initial use of triple DMARD therapy with methotrexate in combination with at least two other DMARDs, such as hydroxychloroquine and sulfasalazine, for a minimum of 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 may take up to 24 weeks, however if no improvement is seen after 12 weeks of triple DMARD use, therapy should be changed.
- If the patient is intolerant to triple DMARD therapy, then dual therapy with DMARDs (methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) must be considered.
- Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above.
- Intolerant is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs. The nature of intolerance(s) must be clearly documented.

Claim Notes:

- Must be prescribed by a rheumatologist.
- Combined use of more than one biologic DMARD will not be reimbursed.
- **Intravenous infusion**: 500mg for patients <60 kg, 750mg for patients 60-100 kg and 1000mg for patients >100 kg, given at 0, 2, and 4 weeks then every 4 weeks thereafter.
- **Subcutaneous injection**: a single IV loading dose of up to 1,000mg may be given, followed by 125mg subcutaneous injection within a day, then once-weekly 125mg subcutaneous injections.
- Initial Approval: 6 months.

- Renewal Approval: 1 year. Confirmation of continued response is required

Juvenile Idiopathic Arthritis (pJIA)
250mg/15mL vial DIN 02282097

For children (6 years of age and older) with a diagnosis of juvenile idiopathic arthritis / who are intolerant to, or have not had an adequate response from etanercept.

Claim Notes:
- Must be prescribed by, or in consultation with, a rheumatologist who is familiar with the use of biologic DMARDs in children.
- Abatacept will not be reimbursed in combination with anti-TNF agents.
- Intravenous infusion: initial IV infusion dose is administered at 0, 2, and 4 weeks then every 4 weeks thereafter.
- Initial treatment is limited to a maximum of 16 weeks. Retreatment is permitted for children who demonstrated an adequate initial treatment response and who are experiencing a disease flare.

To facilitate this process, specific **RA Medication Special Authorization Forms** have been developed and can be found at:
http://www.health.gov.nl.ca/health/prescription/ra_meds_initiation.pdf
http://www.health.gov.nl.ca/health/prescription/ra_meds_continuation_request.pdf

Updated November 2016

Health and Community Services

ABIRATERONE (ZYTIGA 250 MG and 500MG)

In combination with prednisone for the treatment of metastatic castration-resistant prostate cancer in patients who:

- Are asymptomatic or mildly symptomatic after the failure of androgen deprivation therapy and who have not received prior chemotherapy

OR

- Have received prior chemotherapy containing docetaxel after the failure of androgen deprivation therapy. Patients are eligible to receive abiraterone OR enzalutamide but not sequential use of these agents. Patients who received abiraterone pre-docetaxel are not eligible for abiraterone after chemotherapy with docetaxel.

Approval period: 6 months
Dosing: 1000 mg daily

Renewals will be considered for patients who do not have evidence of disease progression AND who have not developed unacceptable toxicities that require discontinuation of abiraterone.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated August 2017

Health and Community Services

APIXABAN (ELIQUIS 2.5mg, 5mg TABLET)

For prevention of venous thromboembolic events (VTE) in patients who have undergone elective knee replacement surgery for treatment duration of 10 to 14 days.

For prevention of venous thromboembolic events (VTE) in patients who have undergone elective hip replacement surgery for treatment duration 32 to 38 days.

Please visit the link below if you require our special authorization form:
http://www.health.gov.nl.ca/health/forms/pdf/Thromboembolism_Prevention_Following_Surgery.pdf

For atrial fibrillation (AF):

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

Exclusion:
1. Patients with impaired renal function (creatinine clearance or estimated glomerular filtration rate < 25 mL/min) **OR**
2. Patients who are ≥ 75 years of age and who **do not** have documented stable renal function **OR**
3. Patients who have hemodynamically significant rheumatic valvular heart disease (especially mitral stenosis); **OR**
4. Patients who have prosthetic heart valves.

Notes:
(a) At-risk patients with atrial fibrillation are defined as those with a $CHADS_2$ score of ≥ 1. Prescribers may consider an antiplatelet regimen or oral anticoagulation for patients with a $CHADS_2$ score of 1.
(b) 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).
(c) Documented stable renal function is defined as creatinine clearance or estimated glomerular filtration rate maintained for at least 3 months.

(d) Dosing: the usual recommended dose is 5 mg twice daily; a reduced dose of apixaban 2.5 mg twice daily is recommended for patients with at least two [2] of the following: age ≥ 80 years, body weight ≤ 60 kg, or serum creatinine ≥ 133 micromole/litre.
(e) 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 apixaban product monograph).
(f) Patients starting apixaban should have ready access to appropriate medical services to manage a major bleeding event.

There is currently no data to support that apixaban provides adequate anticoagulation in patients with rheumatic valvular disease or those with prosthetic heart valves. As a result, apixaban is not recommended for these patient populations.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/atrial_fibrillation_medication_request.pdf

For the treatment of deep vein thrombosis (DVT) or pulmonary embolism (PE)

Approval Period: Up to six (6) months

Notes:

- The recommended dose of apixaban for patients initiating treatment is 10 mg twice daily for 7 days, followed by 5 mg taken orally twice daily (for treatment up to 6 months).
- Drug plan coverage for apixaban is an alternative to heparin/warfarin for up to 6 months. When used for greater than 6 months, apixaban is more costly than heparin/warfarin. As such, patients with an intended duration of therapy greater than 6 months should be considered for initiation on heparin/warfarin.
- Since renal impairment can increase bleeding risk, it is important to monitor renal function regularly. Other factors that increase bleeding risks should also be assessed and monitored (see product monograph).

Updated September 2015

Health and Community Services

Acamprosate (Campral 333mg tablet)

For the maintenance of abstinence from alcohol in patients with a diagnosis of alcohol dependence who:

- have been abstinent from alcohol for at least 4 days.
- the maximum treatment duration is 1 year.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2010

Health and Community Services

ACLIDINIUM / FORMOTEROL (DUAKLIR GENUAIR 400-12 MCG INH)

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:

- 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 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 LABA or LAAC.

Please visit the link below if you require our Chronic Obstructive Pulmonary Disease special authorization form:
http://www.health.gov.nl.ca/health/prescription/Chronic_Obstructive_Pulmonary_Disease_Form_2017.pdf

Updated May 2016

Health and Community Services

ACLIDINIUM BROMIDE (TUDORZA GENUAIR 400MCG INHALER)

Chronic Obstructive Pulmonary Disease (COPD):

- 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 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 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.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated December 2016

Health and Community Services

Adalimumab (Humira 40 mg/0.8 mL)

Rheumatoid Arthritis (RA)

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) for a minimum of 12 weeks, followed by methotrexate in combination with at least two other DMARDs, such as hydroxychloroquine and sulfasalazine, for a minimum of 12 weeks;

or

- Initial use of triple DMARD therapy with methotrexate in combination with at least two other DMARDs, such as hydroxychloroquine and sulfasalazine, for a minimum of 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 may take up to 24 weeks, however if no improvement is seen after 12 weeks of triple DMARD use, therapy should be changed.
- If the patient is intolerant to triple DMARD therapy, then dual therapy with DMARDs (methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) must be considered.
- Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above.
- Intolerant is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs. The nature of intolerance(s) must be clearly documented.

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:
  - Adalimumab: 40mg every two weeks with no dose escalation permitted

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 NSAID's at the optimum dose for a minimum period of 3 months observation or in whom NSAID's are contraindicated,

OR

- have peripheral symptoms and who have failed to respond to, or have contraindications to the sequential use of at least 2 NSAID's 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.

Requests for renewal must include information showing the beneficial effects of the treatment, specifically:

- a decrease of at least 2 points on the BASDAI scale, compared with the pre-treatment score;

OR

- patient and expert opinion of an adequate clinical response as indicated by a significant functional improvement (measured by outcomes such as HAQ or "ability to return to work").

Clinical Notes:

- 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.
- Combined use of more than one biologic DMARD will not be reimbursed.

Claim notes:

- Must be prescribed by a rheumatologist or internist
- Approvals will be for a maximum of 40mg every two weeks
- Initial Approval: 6 months.
- Renewal Approval: 1 year.

Psoriatic Arthritis:

For patients with active psoriatic arthritis who meet **all** of the following criteria:

- Have at least three active and tender joints, and
- Have not responded to an adequate trial of two DMARDs or have an intolerance or contraindication to DMARDs.

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 40mg every two weeks.
- Initial Approval: 12 weeks.
- Renewal Approval: 1 year. Requests for renewal can be reassessed for yearly coverage dependent on achieving improvement in symptoms of at least 20% (20% improvement in the American College of Rheumatology response criteria (ACR 20) or response using the Psoriatic Arthritis Response Criteria).

To facilitate this process specific **RA Medication Special Authorization Forms** have been developed and can be found at:
http://www.health.gov.nl.ca/health/prescription/ra_meds_initiation.pdf
http://www.health.gov.nl.ca/health/prescription/ra_meds_continuation_request.pdf

Polyarticular juvenile idiopathic arthritis (pJIA)

For patients aged 4-17 years with moderately or severe pJIA who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs (DMARDs).

Claim Notes:

- Must be prescribed by, or in consultation with, a rheumatologist who is familiar with the use of biologic DMARDs in children.
- Approvals will be for a maximum of 40mg every two weeks.
- Initial approval period: 16 weeks
- Renewal Approval: 1 year. Confirmation of continued response is required.

Crohn's Disease*:*

For the treatment of adult patients with moderately to severely active Crohn's disease who have contraindications, or are refractory, to therapy with corticosteroids and other immunosuppressants.

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 request must include current Crohn's Disease Activity Index (CDAI) or the Harvey-Bradshaw Index Assessment (HBI) score.
- Approvals will be for a maximum of 160mg followed by 80 mg two weeks later, then 40mg every two weeks.
- Initial Approval: 12 weeks.
- Renewal Approval: 1 year. Confirmation of continued response is required.
- It is recommended that clinical response to adalimumab be assessed four weeks after the first induction dose, using criteria such as a 100 point reduction in Crohn's Disease Activity Index (CDAI) or the Harvey-Bradshaw Index Assessment (HBI) with a score of 5 or less, or a decrease in score of 4 or more.

To facilitate this process a specific **Anti-TNF agents for Crohn's disease Special Authorization Form** has been developed and can be found at:
http://www.health.gov.nl.ca/health/forms/pdf/IBD.pdf

Chronic Plaque Psoriasis*:*

For patients with severe, debilitating 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 to, or unable to access phototherapy.

Requests for renewal must include information demonstrating an adequate response, defined as:

- ≥75% reduction in the Psoriasis Area and Severity Index (PASI) score from when treatment started (PASI 75), or

- ≥50% reduction in the PASI score (PASI 50) with a ≥5 point improvement in the Dermatology Life Quality Index (DLQI) from when treatment started, or
- A quantitative reduction in BSA affected with qualitative consideration of specific regions such as face, hands, feet, or genital region.

Claim Notes:
- Must be prescribed by a dermatologist.
- Combined use of more than one biologic DMARD will not be reimbursed.
- Approvals will be for a maximum of 80mg followed by 40mg in one week, then 40mg every two weeks thereafter.
- Initial Approval: 16 weeks.
- Renewal Approval: 1 year.
- Ongoing coverage for adalimumab maintenance therapy should only be provided for responders, as noted above.

To facilitate this process, a specific **Chronic Plaque Psoriasis Special Authorization Form** has been developed and can be found at:
http://www.health.gov.nl.ca/health/prescription/chronic_plaque_psoriasis_meds_coverage_request.pdf

Ulcerative colitis

For the treatment of adult patients with moderately to severely active ulcerative colitis who have a partial Mayo score > 4, and a rectal bleeding subscore ≥ 2 and are:
- refractory or intolerant to conventional therapy (i.e. 5-ASA for a minimum of 4 weeks, and prednisone ≥ 40mg daily for two weeks or IV equivalent for one week); or
- corticosteroid dependent (i.e. cannot be tapered from corticosteroids without disease recurrence; or have relapsed within three months of stopping corticosteroids; or require two or more courses of corticosteroids within one year.)

Renewal requests must include information demonstrating the beneficial effects of the treatment, specifically:
- a decrease in the partial Mayo score ≥ 2 from baseline, and
- a decrease in the rectal bleeding subscore ≥1.

Clinical Notes:
- Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above.
- Intolerant is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs. The nature of intolerance(s) must be clearly documented.
- Consideration will be given for patients who have not received a four week trial of aminosalicylates if disease is severe (partial Mayo score > 6).

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 dose: 160 mg at Week 0 (administered as four subcutaneous injections in one day or as two subcutaneous injections per day for two consecutive days), followed by

80 mg at Week 2. Beginning at Week 4, continue with a dose of 40 mg every other week.

- Adalimumab should only be continued in patients who have responded during the first 8 weeks of therapy.
- Initial Approval: 8 weeks.
- Renewal Approval: 1 year.

To facilitate this process, a specific Inflammatory Bowel Disease Special Authorization Form has been developed and can be found at:
http://www.health.gov.nl.ca/health/forms/pdf/IBD.pdf

Updated August 2017

Newfoundland Labrador

Health and Community Services

Adefovir Dipivixil (Hepsera 10mg tablets & generics)

In combination with lamivudine in patients who:

- developed failure to lamivudine, as defined by an increase in HBV DNA of ≥ 1 $\log_{10}$ IU/ml above the nadir, measured on two separate occasions within an interval of at least one month, after the first three months of lamivudine therapy, AND
- when failure to lamivudine is not due to poor adherence to therapy.

Coverage is approved for one year.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated February 2015

Health and Community Services

Afatinib (Giotrif 20mg, 30mg and 40mg)

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

Approval period: 12 months

Dosing: 40mg daily

Renewals will be considered for patients who do not have evidence of disease progression AND who have not developed unacceptable toxicities that require discontinuation of afatinib.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated June 2015

Newfoundland Labrador

Health and Community Services

AFLIBERCEPT (EYLEA 2 MG/0.05 ML VIAL)

Neovascular (wet) age-related macular degeneration (AMD):
A diagnosis of neovascular (wet) age-related macular degeneration (AMD);
  - Ocular Coherence Tomography (OCT) is recognized by the NLPDP as a relevant diagnostic test for wet AMD;
- Evidence of recent (< 3months) disease progression (e.g. blood vessel growth, as indicated by either fluorescein angiography, OCT or recent visual acuity changes);
- A corrected Visual acuity between 6/12 and 6/96;
  - Patients falling outside of the proposed VA criterion can be considered by the NLPDP on a case-by-case basis.
- A lesion whose size is less than or equal to 12 disc areas in its greatest linear dimension;
- When there is no permanent structural damage to the central fovea.

Any NLPDP beneficiary, who meets the above criteria, will have their drug plan coverage limited to a maximum of 15 vials used to treat the better seeing affected eye.

<u>Criteria for Exclusion</u>:

- Patients who have "permanent retinal damage", as defined by the Royal College of Ophthalmology guidelines, including any future amendments.

Diabetic Macular edema:
For the treatment of visual impairment due to diabetic macular edema meeting all of the following criteria:
- clinically significant diabetic macular edema for whom laser photocoagulation is also indicated, **and**
- a hemoglobin A1c of less than 11%, **and**
- drug plan coverage limited to **nine vials per patient**

Macular edema secondary to retinal vein occlusion:
For the treatment of visual impairment due to macular edema secondary to retinal vein occlusion in patients meeting both of the following criteria:
- clinically significant macular edema secondary to branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO), not previously treated with a vascular endothelial growth factor (VEG-F) inhibitor
- drug plan coverage will be limited to **24 months duration** AND not to exceed **10 vials** for branch retinal vein occlusion (BRVO) or **12 vials** for patients with central retinal vein occlusion (CRVO).

Exclusion: Coverage is not considered for clients who have reached NLPDP coverage limits on another ophthalmic antineovascularization agent.

Note: Coverage can be considered for switching between ophthalmic antineovascularization agents if coverage limit has not been reached. Coverage will be for the number of vials remaining within the coverage limit.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/lucentis_sa_form.pdf

Updated May 2017

Health and Community Services

Alendronate & Cholecalciferol (Fosavance 70/5600)

- For the treatment of osteoporosis associated with documented fracture.
- For the treatment of osteoporosis without documented fracture when a patient has a high 10 year fracture risk (based on age, sex and T-score, see Appendix 1 below for fracture risk table).
- As prophylaxis of corticosteroid induced osteoporosis in patient who will be or have been on systemic corticosteroid therapy for > 3 months.

Please note:
Alendronate & Cholecalciferol (Fosavance 70/5600) is open benefit for beneficiaries 65 years of age and older regardless of plan.

Appendix 1

10 Year Absolute Fracture Risk based on BMD

	WOMEN		
Age (years)	Low Risk < 10%	Moderate Risk 10% - 20%	High Risk > 20%
50	> - 2.3	- 2.3 to - 3.9	<- 3.9
55	> - 1.9	- 1.9 to - 3.4	< - 3.4
60	> - 1.4	- 1.4 to - 3.0	< - 3.0
65	> - 1.0	- 1.0 to – 2.6	< - 2.6
70	> - 0.8	- 0.8 to – 2.2	< - 2.2
75	> - 0.7	- 0.7 to – 2.1	< - 2.1
80	> - 0.6	- 0.6 to – 2.0	< - 2.0
85	> - 0.7	- 0.7 to – 2.2	< - 2.2

	MEN		
Age (years)	Low Risk < 10%	Moderate Risk 10% - 20%	High Risk > 20%
50	>-3.4	≤-3.4	---
55	>-3.1	≤-3.1	---
60	>-3.0	≤-3.0	---
65	>-2.7	≤-2.7	---
70	>-2.1	-2.1 to -3.9	<-3.9
75	>-1.5	-1.5 to -3.2	<-3.2
80	>-1.2	-1.2 to -3.0	<-3.0
85	>-1.3	-1.3 to -3.3	<-3.3

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2010

Health and Community Services

Alendronate (Generic 40mg, Fosamax 40mg tablet)

- For the treatment of Paget's Disease

Coverage will be limited to a 6 month approval.

Alendronate (Generic 10mg, 70mg tablet/Fosamax 10mg, 70mg tablet)

- For the treatment of osteoporosis associated with documented fracture.
- For the treatment of osteoporosis without documented fracture when a patient has a high 10 year fracture risk (based on age, sex and T-score, see Appendix 1 below for fracture risk table).
- As prophylaxis of corticosteroid induced osteoporosis in patient who will be or have been on systemic corticosteroid therapy for > 3 months.

Please note:
Alendronate 10mg & 70mg is open benefit for beneficiaries 65 years of age and older regardless of plan.

Appendix 1

10 Year Absolute Fracture Risk based on BMD

	WOMEN		
Age (years)	Low Risk < 10%	Moderate Risk 10% - 20%	High Risk > 20%
50	> - 2.3	- 2.3 to - 3.9	<- 3.9
55	> - 1.9	- 1.9 to - 3.4	< - 3.4
60	> - 1.4	- 1.4 to - 3.0	< - 3.0
65	> - 1.0	- 1.0 to – 2.6	< - 2.6
70	> - 0.8	- 0.8 to – 2.2	< - 2.2
75	> - 0.7	- 0.7 to – 2.1	< - 2.1
80	> - 0.6	- 0.6 to – 2.0	< - 2.0
85	> - 0.7	- 0.7 to – 2.2	< - 2.2

	MEN		
Age (years)	Low Risk < 10%	Moderate Risk 10% - 20%	High Risk > 20%
50	>-3.4	≤-3.4	---
55	>-3.1	≤-3.1	---
60	>-3.0	≤-3.0	---
65	>-2.7	≤-2.7	---
70	>-2.1	-2.1 to -3.9	<-3.9
75	>-1.5	-1.5 to -3.2	<-3.2
80	>-1.2	-1.2 to -3.0	<-3.0
85	>-1.3	-1.3 to -3.3	<-3.3

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated January 2016

Health and Community Services

Almotriptan malate (Axert 12.5mg & generics)

Coverage is provided as an open benefit up to 6 doses / 30 days[1]

Consideration is given for > 6 doses / 30 days for patients with >3 migraines/month despite prophylactic therapy.

- Coverage will be limited to a maximum of 12 doses / 30 days.

[1]Reimbursement will be available for a maximum quantity of 6 triptan doses per 30 days regardless of the agent(s) used within the 30 day period.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated May 2018

Health and Community Services

Ambrisentan (Volibris 5mg, 10mg tablet)

For the treatment of idiopathic pulmonary arterial hypertension (PAH) or pulmonary hypertension associated with connective tissue disease in patients with:

- with at least WHO functional class III pulmonary arterial hypertension (either idiopathic or associated with connective tissue disease)
- confirmed by right heart catheterization
- for doses up to 10mg daily

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2010

Health and Community Services

Anastrozole (Arimidex 1mg tablet & generics)

- First-line therapy in postmenopausal women with advanced breast cancer. (Indefinite coverage)
- For the adjuvant treatment of postmenopausal women with hormone receptor-positive invasive early breast cancer. (5 years)
- The extended adjuvant treatment of hormone receptor-positive invasive early breast cancer in postmenopausal women who have received approximately 5 years of prior standard adjuvant tamoxifen therapy. (5 years)

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated April 2014

Health and Community Services

APIXABAN (ELIQUIS 2.5mg, 5mg TABLET)

For prevention of venous thromboembolic events (VTE) in patients who have undergone elective knee replacement surgery for treatment duration of 10 to 14 days.

For prevention of venous thromboembolic events (VTE) in patients who have undergone elective hip replacement surgery for treatment duration 32 to 38 days.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/forms/pdf/request_rivaroxaban_xarelto.pdf

For atrial fibrillation (AF):

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

Exclusion:
1. Patients with impaired renal function (creatinine clearance or estimated glomerular filtration rate < 25 mL/min) **OR**
2. Patients who are ≥ 75 years of age and who **do not** have documented stable renal function **OR**
3. Patients who have hemodynamically significant rheumatic valvular heart disease (especially mitral stenosis); **OR**
4. Patients who have prosthetic heart valves.

Notes:
(a) At-risk patients with atrial fibrillation are defined as those with a $CHADS_2$ score of ≥ 1. Prescribers may consider an antiplatelet regimen or oral anticoagulation for patients with a $CHADS_2$ score of 1.
(b) 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).
(c) Documented stable renal function is defined as creatinine clearance or estimated glomerular filtration rate maintained for at least 3 months.

(d) Dosing: the usual recommended dose is 5 mg twice daily; a reduced dose of apixaban 2.5 mg twice daily is recommended for patients with at least two [2] of the following: age ≥ 80 years, body weight ≤ 60 kg, or serum creatinine ≥ 133 micromole/litre.
(e) 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 apixaban product monograph).
(f) Patients starting apixaban should have ready access to appropriate medical services to manage a major bleeding event.

There is currently no data to support that apixaban provides adequate anticoagulation in patients with rheumatic valvular disease or those with prosthetic heart valves. As a result, apixaban is not recommended for these patient populations.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/atrial_fibrillation_medication_request.pdf

For the treatment of deep vein thrombosis (DVT) or pulmonary embolism (PE)

Approval Period: Up to six (6) months

Notes:

- The recommended dose of apixaban for patients initiating treatment is 10 mg twice daily for 7 days, followed by 5 mg taken orally twice daily (for treatment up to 6 months).
- Drug plan coverage for apixaban is an alternative to heparin/warfarin for up to 6 months. When used for greater than 6 months, apixaban is more costly than heparin/warfarin. As such, patients with an intended duration of therapy greater than 6 months should be considered for initiation on heparin/warfarin.
- Since renal impairment can increase bleeding risk, it is important to monitor renal function regularly. Other factors that increase bleeding risks should also be assessed and monitored (see product monograph).

Updated September 2015

Health and Community Services

Aprepitant (Emend 80mg and 125mg tablets)

In combination with a 5-HT_3 antagonist class of anti-emetics and dexamethasone for the prevention of acute and delayed nausea and vomiting due to highly emetogenic cancer chemotherapy (eg cisplatin ≥70mg/$m^{2)}$ in patients who have experienced emesis despite treatment with a combination of a 5-HT_3 antagonist and dexamethasone in a previous cycle of highly emetogenic chemotherapy.

Please Note: The $5HT_3$ antagonist should only be used on the first day of chemotherapy (eg cisplatin ≥70mg/$m^{2)}$ with Aprepitant continuing on
Day 2 & 3).

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2010

Health and Community Services

ARIPIPRAZOLE (ABILIFY MAINTENA 300mg, 400mg prolonged release injectable suspension)

For the treatment of schizophrenia and related psychotic disorders (not dementia related) in patients:

- who are non-adherent to an oral antipsychotic.

OR

- who are currently receiving a long-acting injectable antipsychotic and require a switch to another injectable.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated December 2016

Health and Community Services

ABILIFY (ARIPIPRAZOLE 2mg, 5mg, 10mg, 15mg, 20mg & 30mg)

For the treatment of schizophrenia and related psychotic disorders (not dementia related) in patients:

- with a history of inadequate response or intolerance to at least one less expensive antipsychotic agent

OR

- who have a contraindication to less expensive options.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated December 2016

Health and Community Services

ASENAPINE MALEATE (SAPHRIS 5 MG TAB, 10MG TAB SUBLINGUAL)

For the acute treatment of bipolar disorder as either:

- Monotherapy, after inadequate response to a trial of lithium or divalproex sodium, and there is a history of inadequate response, or intolerance to at least one less expensive antipsychotic agent.
- Co-therapy with lithium or divalproex sodium, and there is a history of inadequate response or intolerance to at least one less expensive antipsychotic agent.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated December 2016

Health and Community Services

ATOMOXETINE (STRATTERA 10mg, 18mg, 25mg, 40mg, 60mg, 80mg, 100mg capsules & generics)

For treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients for whom stimulant medications are ineffective, not tolerated or not appropriate due to contraindication or concern of substance abuse.

Please note:
Reimbursement will not be considered for Biphentin, Concerta, Vyvanse, Adderall XR, and/or Strattera concurrently with methylphenidate (immediate release or sustained release formulation) or dexamphetamine.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated November 2018

Health and Community Services

AXITINIB (INLYTA) 1mg, 5mg

As a second-line therapy for patients with metastatic renal cell carcinoma of clear cell histology after failure of prior systemic therapy with either a cytokine or vascular endothelial growth factor receptor tyrosine kinase inhibitor (VEGFR TKI) treatment.

Approval period: 6 months

Dosing: 5-10 mg bid
(usual dose = 5 mg bid)

Renewals will be considered for patients who do not have evidence of disease progression AND who have not developed unacceptable toxicities that require discontinuation of axitinib..

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated June 2017

Health and Community Services

AZITHROMYCIN (ZITHROMAX 600 MG TABLET & generics)

For the prevention of disseminated *Mycobacterium avium* complex (MAC) disease in persons with advanced HIV infections.

Please note: Special Authorization is not required when the prescription is filled through the Regional Health Authority.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated May 2012

Newfoundland Labrador

Health and Community Services

CAYSTON 75MG INHALTION SOLUTION (AZTREONAM)

For the treatment of chronic pulmonary *Pseudomonas aeruginosa* infections when used as cyclic treatment (28-day cycles) in patients with moderate to severe cystic fibrosis (CF) **and** deteriorating clinical condition despite treatment with inhaled tobramycin.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated April 2012

Health and Community Services

Betamethasone/Calcipotriol (Dovobet gel)

For the topical treatment of scalp psoriasis in patients unresponsive to high-potency corticosteroid scalp solutions.

Coverage will be provided for up to 4 weeks. If recurrence takes place after discontinuation, treatment may be reinstituted.

The maximum daily dose including other calcipotriol-containing products on the body should not exceed 15 g and the maximum weekly dose should not exceed 100 g.

Dovobet Ointment is NOT considered for coverage.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated January 2018

Newfoundland Labrador

Health and Community Services

Blood Glucose Test Strips (for a complete list please see https://nlpdp.bell.ca/GeneralBulletins.aspx)

Diabetic Test strips are a regular benefit of the NLPDP and would only require special authorization in the following circumstances outlined below:

Beneficiaries receiving short acting insulin (with or without non-insulin diabetes medications) can access an annual maximum of 2500 test strips with no prior approval unless the beneficiary is using an insulin which is NOT funded through the NLPDP or require test strips in excess of 2500 per year.

No prior approval will be needed to access:

- an annual maximum of 700 test strips for patients receiving long acting insulin (with or without non-insulin diabetes medications and **not** using short acting insulin),
- an annual maximum of 100 test strips for patients receiving **only** non-insulin diabetes medications, and
- an annual maximum of 50 test strips for patients receiving **no** diabetes medications or insulin.
- an initial 50 test strips for patients receiving insulin therapy or non-insulin diabetes medications **NOT** funded through NLPDP to allow time for special authorization request processing.

The following Patient Categories will require prior approval:

1. An additional 100 test strips may be considered annually under exceptional circumstances for beneficiaries receiving long acting insulin (with or without non-insulin diabetes medications and **not** using short acting insulin) requiring in excess of the 700 test strips maximum.

2. An additional 50 test strips may be considered annually under exceptional circumstances for beneficiaries receiving **only** non-insulin diabetes medications requiring in excess of the 100 test strips maximum.

3. An additional 50 test strips may be considered annually under exceptional circumstances for beneficiaries **not** receiving diabetes medications or insulin requiring in excess of the 50 test strips maximum. Fill dates must be 6 months apart.

4. Beneficiaries being treated with insulin therapy or non-insulin diabetes medications **NOT** funded through NLPDP will be able to access 50 test strips without prior approval **BUT** will be required to seek prior approval to access the annual maximum for that individual.

5. Beneficiaries with Gestational Diabetes or Type 2 Diabetes and pregnant required to test more frequently will be required to seek prior approval to access test strips. Authorization will be set up for an amount determined by the requesting Health Care Professional.

PLEASE NOTE: In extenuating circumstances, aside from the above, a request for additional strips may be made in writing if there is a specific medical need.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/pdf/glucose/authorization_request.pdf

Updated July 2016

Health and Community Services

Bosentan (Tracleer 62.5mg, 125mg tablets & generics)

Idiopathic Pulmonary Arterial Hypertension (IPAH) functional class III and IV

- For the treatment of World Health Organization (WHO) functional class III and IV idiopathic pulmonary arterial hypertension (IPAH) who do not demonstrate vasoreactivity on testing or who do demonstrate vasoreactivity on testing but fail a trial of calcium channel blockers (CCB) or are intolerant to CCB.

Pulmonary Arterial Hypertension (PAH) secondary to scleroderma, congenital heart disease or HIV (functional class III and IV)

- For the treatment of World Health Organization (WHO) functional class III and IV pulmonary arterial hypertension (PAH) associated with scleroderma, congenital heart disease or HIV who do not respond to conventional therapy.

- Written initial request by a pulmonary arterial hypertension (PAH) specialist only.
- Diagnosis of PAH should be confirmed by right heart catheterization.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2010

Health and Community Services

BOSUTINIB (BOSULIF 100 MG, 500MG TABLET)

For the treatment of patients with chronic, accelerated or blast phase Philadelphia chromosome positive (Ph+) chronic myelogenous leukemia (CML) who have resistance/disease progression or intolerance to prior tyrosine kinase inhibitor (TKI) therapy, and for whom subsequent treatment with imatinib, nilotinib and dasatinib is not clinically appropriate

Approval Period: 12 months

Recommended Dose: 500mg once daily

Renewals will be considered for patients who are responding to treatment AND who have not developed unacceptable toxicities that require discontinuation of bosutinib.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated March 2016

Health and Community Services

BRIVARACETAM (BRIVLERA 10mg, 25mg, 50mg, 75mg, 100mg)

For adjunctive therapy in patients with refractory partial-onset seizures who meet all of the following criteria:

- Are under the care of a neurologist or a physician experienced in the treatment of epilepsy, AND
- Are currently receiving two or more antiepileptic drugs,
- Are not receiving concurrent therapy with Levetiracetam AND
- In whom all other less costly antiepileptic drugs are ineffective or not appropriate

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated December 2018

Newfoundland Labrador

Health and Community Services

BUDESONIDE/FORMOTEROL (SYMBICORT 100ug, 200ug)

Reversible Obstructive Airway Disease:

For treatment of asthma in patients in whom a combination of an inhaled steroid and long-acting beta agonist is desirable due to the failure of optimal doses of inhaled steroids *(failure defined as the need for frequent use of inhaled short-acting bronchodilators).

*Optimal defined as: >400mcg/day budesonide
>250mcg/day HFA- beclomethasone
>250mcg/day fluticasone
>200mcg/day mometasone
>400mcg/day ciclesonide

Chronic Obstructive Pulmonary Disease (COPD):

- 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 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 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.

Please visit the link below if you require our Chronic Obstructive Pulmonary Disease special authorization form:
http://www.health.gov.nl.ca/health/prescription/Chronic_Obstructive_Pulmonary_Disease_Form_2017.pdf

Updated November 2015

Health and Community Services

Bupropion HCL (Wellbutrin SR 100mg and 150mg, Wellbutrin XL 150mg, 300mg & generics)

- For the treatment of depression in patients for whom other treatments have failed or resulted in intolerance.

Please Note: not insured for smoking cessation.

Please note that coverage may be considered WITHOUT a Special Authorization request long as the beneficiary's medication history in the NLPDP database has had a paid (non-reversed) claim for an anti-depressant or bupropion within the past year.

The claimed dosage must not exceed the dose limitation (see our Benefit Listing at: www.health.gov.nl.ca/health/prescription/covered_openbenefitdrugs.html for details).

If there is no history of a previous benefit anti-depressant or bupropion claim, the normal Special Authorization Process will be required.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated September 2017

Health and Community Services

Cabergoline (Dostinex 0.5mg tablet & generics)

For the treatment of hyperprolactinemic disorders in patients who have failed to respond or are intolerant to treatment with bromocriptine.

Please note that coverage may be considered WITHOUT a Special Authorization request as long as the beneficiary's medication history in the NLPDP database shows the prior use of bromocriptine, Dostinex, Norprolac within the past year.

If there is no history of a previous claim for bromocriptine, Dostinex, Norprolac, the normal Special Authorization Process will be required.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated January 2012

Newfoundland Labrador

Health and Community Services

CANAGLIFLOZIN (INVOKANA 100mg, 300mg TABLET)

For the treatment of type 2 diabetes as a third drug added to metformin and a sulfonylurea for patients with inadequate glycemic control on metformin and a sulfonylurea AND in whom insulin is not an option.

To facilitate this process a specific **Oral Diabetes Medications Special Authorization Form** has been developed and can be found at:
http://www.health.gov.nl.ca/health/forms/pdf/oral_diabetes.pdf

Updated August 2015

Health and Community Services

Capecitabine (Xeloda 150mg, 500mg & generics)

Breast Cancer:

- For treatment of metastatic breast cancer where patients have progressed after prior chemotherapy.

Requests must be made from an oncologist and approval will be granted for six months, to be renewed as required.

Colorectal Cancer:

- As monotherapy in patients with advanced or metastatic colorectal cancer (MRCRC), with an ECOG performance status of 0-2 as an alternative to treatment with combination therapy (5-FU/LV/irinotecan) and/or are unable to tolerate first line therapy.

  Requests must be made from an oncologist and approval will be granted for six months, to be renewed upon request.

- As part of the CAPOX regimen for the first-line and second-line treatment of metastatic colorectal cancer (mCRC).

  Requests must be made from an oncologist and approval will be granted for six months, to be renewed upon request.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2010

Health and Community Services

Carbamazepine (Tegretol 20mg/ml suspension & generics)

For patients who are fed via gastric tube.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2010

Newfoundland Labrador

Health and Community Services

Carvedilol (Coreg and Generic 3.125mg, 6.25mg, 12.5mg, 25mg tablet)

- For the treatment of stable symptomatic congestive heart failure (CHF) in patients receiving combination therapy with an ace inhibitor and a diuretic, with or without digoxin.

- For the treatment of stable symptomatic heart failure with left ventricular ejection fraction (LVEF) less than or equal to 40%.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2010

Health and Community Services

CERTOLIZUMAB (CIMZIA 200 MG/ML PREFILLED SYRINGE, PREFILLED AUTOINJECTOR)

Rheumatoid arthritis (RA):

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) for a minimum of 12 weeks, followed by methotrexate in combination with at least two other DMARDs, such as hydroxychloroquine and sulfasalazine, for a minimum of 12 weeks;

OR

- Initial use of triple DMARD therapy with methotrexate in combination with at least two other DMARDs, such as hydroxychloroquine and sulfasalazine, for a minimum of 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 may take up to 24 weeks, however if no improvement is seen after 12 weeks of triple DMARD use, therapy should be changed.
- If the patient is intolerant to triple DMARD therapy, then dual therapy with DMARDs (methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) must be considered.
- Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above.
- Intolerant is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs. The nature of intolerance(s) must be clearly documented.

Claim Notes:

- Must be prescribed by a rheumatologist.
- Combined use of more than one biologic DMARD will not be reimbursed.
- Response to be assessed after 16 weeks of treatment and therapy continued only if there is clinical response.
- Initial Approval: 6 months.
- Renewal Approval: 1 year.
    - Requests for renewal can be reassessed for yearly coverage dependent on

patient achieving an improvement in symptoms (ACR) of at least 20%.

- Dosage Approved:
    - Loading dose of 400mg at Weeks 0, 2 and 4. Maximum maintenance dose of 200mg every 2 weeks or alternatively, 400mg every 4 weeks.

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 ar least 2 NSAIDs at the optimum dose for a minimum 3 month observation period or in whom, NSAIDs are contraindicated

OR

- Have peripheral symptoms and who have failed to respond to , or have contraindications to, the sequentials use of at least 2 NSAIDs at the optimum dose for a minimum 3 month observation period and have had an inadequate response to an optimal dose or maximal tolerated dose of DMARD

- Requests for renewal must include information showing the beneficial effects of the treatment, specifically:
    - A decrease of at least 2 points on the BASDAI scale, compared with the pre-treatment score;

    OR

    - Patient and expert opinion of an adequate clinical response as indicated by a significant functional improvement (measured by outcomes such as HAQ or "ability to return to work").

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 internist.
- Combined use of more than one biologic DMARD will not be reimbursed.
- Approvals will be for a maximum of 400mg at weeks 0, 2, and 4, then 200mg every two weeks (or 400mg every four weeks).
- Initial Approval: 6 months.
- Renewal Approval: 1 year.

Psoriatic Arthritis

For patients with active psoriatic arthritis who meet **all** of the following of the following criteria:

- Have at least three active and tender joints.
- Have not responded to an adequate trial of two DMARDs or have an intolerance or contraindication to DMARDs.

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 400mg at weeks 0, 2, and 4, then 200mg every two weeks (or 400mg every four weeks).
- Initial Approval: 24 weeks.
- Renewal Approval: 1 year. Requests for renewal can be reassessed for yearly coverage dependent on achieving improvement in symptoms of at least 20% (20% improvement in the American College of Rheumatology response criteria (ACR 20) or response using the Psoriatic Arthritis Response criteria).

To facilitate this process, specific **RA Medication Special Authorization Forms** have been developed and can be found at:
http://www.health.gov.nl.ca/health/prescription/ra_meds_initiation.pdf
http://www.health.gov.nl.ca/health/prescription/ra_meds_continuation_request.pdf

Updated December 2017

Health and Community Services

Chlorhexidine Gluconate 0.12% Mouthwash (Gum Paroex)

For the treatment of oral mucositis in patients receiving chemotherapy or radiotherapy related to cancer treatment.

Please visit the following link if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated January 2017

Newfoundland Labrador

Health and Community Services

Ciprofloxacin/Dexamethasone Otic Solution (Ciprodex otic solution)

- In patients with acute otitis media with otorrhea through tympanostomy tubes who require treatment.
- In patients with acute otitis externa in the presence of a tympanostomy tube or known perforation of the tympanic membrane.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2010

Health and Community Services

Clozapine (Clozaril, Gen 25mg, 50mg, 100mg, 200mg, Apo 25mg, 100mg)

For patients diagnosed with treatment resistant schizophrenia who have not obtained a satisfactory clinical response, despite treatment with appropriate courses of maximum tolerated***** therapeutic doses, of at least **two chemically unrelated** anti-psychotic medications.

*****intolerance is defined as the inability to achieve adequate benefit due to dose-limiting intolerable adverse effects such as parkinsonism, dystonia, akathesia and tardive dyskinesia.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated February 2015

Health and Community Services

COBIMETINIB (COTELLIC) 20MG TABLETS

In combination with vemurafenib, for the treatment of patients with previously untreated BRAF V600 mutation-positive unresectable stage III or stage IV melanoma who have a good performance status. Treatment should continue until unacceptable toxicity or disease progression. If brain metastases are present, patients should be asymptomatic or have stable symptoms.

Approval Period: 6 months

Dosing: 60mg once daily for 21 days every 28 days

Renewals will be considered for patients who do not have evidence of disease progression. AND who have not developed unacceptable toxicities that require discontinuation of cobimetinib.

NOTE: Cobimetinib, or the combination of Cobimetinib and Vemurafenib, is not approved in patients who have progressed on prior BRAF targeted therapy.
Patients who received combination of Cobimetinib and Vemurafenib are not eligible for coverage of any other BRAF targeted therapy as a subsequent line of therapy following disease progression (e.g., monotherapy with Dabrafenib, Trametinib or Vemurafenib).
Patients who experience toxicity to combination therapy but without disease progression, will be eligible for coverage of either Vemurafenib as monotherapy if clinically appropriate or Dabrafenib and/or Trametinib as combination therapy or as monotherapy.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated June 2017

Health and Community Services

Codeine (Codeine Contin 50mg, 100mg, 150mg , 200mg tablets)

For patients with persistent pain***** who have been stabilized on a titrated dose of an oral short-acting codeine product.

*** Please note**: in order to assess requests for coverage in the treatment of non-malignant pain, the Department will require the following information:

- Results of any xrays/CT scans/MRIs.
- Information relating to any consultations completed and their recommendations (ie surgical, orthopedic and/or physiotherapy consultations).
- Surgical history.
- Current analgesic uses, current dosage, and assessment of current level of pain control.
- Use of antidepressants and/or anticonvulsants if pain is neuropathic.
- Any other information you feel is pertinent to the request.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2010

Health and Community Services

CRIZOTINIB (XALKORI 200 MG, 250MG TABLET)

Second-line therapy for patients with ALK-positive advanced non-small cell lung cancer (NSCLC) with an ECOG performance status ≤ 2

OR

First-line therapy for patients with an ALK-positive NSCLC with an ECOG performance status of 0-2.

Approval Period: 6 months

Recommended Dose: 250mg twice daily

Renewals will be considered for patients who do not have evidence of disease progression AND who have not developed unacceptable toxicities that require discontinuation of crizotinib.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated March 2016

Newfoundland Labrador

Health and Community Services

Cyproterone Acetate/ Ethinyl Estradiol (Diane-35, Cyestra-35)

For the treatment of acne in patients who have not responded to conventional therapy, including a trial of Norgestimate / Ethinyl Estradiol.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2010

Health and Community Services

DABIGATRAN ETEXILATE MESYLATE (PRADAXA 110 MG, 150MG CAPSULE)

For the prevention of stroke and systemic embolism in at-risk patients with non-valvular atrial fibrillation (AF) for whom:

- Anticoagulation is inadequate following at least a two month trial of warfarin; **OR**
- Warfarin is contraindicated or not possible due to inability to regularly monitor through International Normalized Ratio (INR) testing (i.e. no access to INR testing services at a laboratory, clinic, pharmacy and at home).

The following patient groups are excluded from coverage for dabigatran for atrial fibrillation:

- Patients with impaired renal function (creatinine clearance or estimated glomerular filtration rate < 30 mL/min) **OR**
- Patients 75 years of age or older without documented stable renal function **OR**
- Patients with hemodynamically significant rheumatic valvular heart disease, especially mitral stenosis **OR**
- Patients with prosthetic heart valves

Notes:

1. At-risk patients with atrial fibrillation are defined as those with a $CHADS_2$ score of ≥ 1.
2. 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).
3. 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 dabigatran Product Monograph).
4. Documented stable renal function is defined as creatinine clearance or estimated glomerular filtration rate that maintained for at least three months (i.e. 30-49 mL/min for 110 mg twice daily dosing or ≥ 50 mL/min for 150 mg twice daily dosing).
5. There is currently no data to support that dabigatran provides adequate anticoagulation in patients with rheumatic valvular disease or those with prosthetic heart valves, so dabigatran is not recommended in these populations.
6. Patients starting dabigatran should have ready access to appropriate medical services to manage a major bleeding event.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/atrial_fibrillation_medication_request.pdf

Updated June 2016

Health and Community Services

DABRAFENIB (TAFINLAR) 50mg, 75mg capsules

First-line BRAF-mutation targeted treatment (i.e. patients may be treatment naïve or previously treated with checkpoint inhibitor immunotherapy and/or chemotherapy) with Tafinlar Mekinist (Dabrafenib Trametinib) combination therapy for patients with BRAF V600 mutation positive, unresectable or metastatic melanoma and who have an ECOG performance status of 0 or 1. If brain metastases are present, patients should be asymptomatic or have stable symptoms. Treatment should continue until disease progression.

OR

First-line BRAF-mutation targeted treatment (i.e. patients may be treatment naïve or previously treated with checkpoint inhibitor immunotherapy and/or chemotherapy) with Tafinlar monotherapy for patients with BRAF V600 mutation positive, unresectable or metastatic melanoma and who have an ECOG performance status of 0 or 1. If brain metastases are present, patients should be asymptomatic or have stable symptoms. Treatment should continue until disease progression.

Approval period: 6 months

Dosing: 150mg twice daily

Renewals will be considered for patients who do not have evidence of disease progression. AND who have not developed unacceptable toxicities that require discontinuation of dabrafenib.

NOTE: Dabrafenib, or the combination of Dabrafenib and Trametinib, is not approved in patients who have progressed on prior BRAF targeted therapy.
Patients who received combination of Dabrafenib and Trametinib are not eligible for coverage of any other BRAF targeted therapy as a subsequent line of therapy following disease progression (e.g., monotherapy with Dabrafenib, Trametinib or Vemurafenib).
Patients who experience toxicity to combination therapy, but without disease progression, will be eligible for coverage of either Dabrafenib or Trametinib as monotherapy if clinically appropriate or Vemurafenib.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated February 2017

Health and Community Services

DACLATASVIR (DAKLINZA 30mg, 60mg TABLET)

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

	Approval Period and Regimen
Genotype 1b • Without cirrhosis or with compensated cirrhosis	24 weeks in combination with asunaprevir
Genotype 3 • Without cirrhosis	12 weeks in combination with sofosbuvir
Genotype 3 • With compensated or decompensated cirrhosis • Post-liver transplant with no cirrhosis or with compensated cirrhosis	12 weeks in combination with sofosbuvir and ribavirin

Patients must also meet all of the following criteria:

- Prescribed by a hepatologist, gastroenterologist, or infectious disease specialist (or other prescribers with expertise in the treatment of hepatitis C infection)
- Lab-confirmed hepatitis C genotype 1b and 3
- Quantitative HCV RNA value within the last 6 months.
- Fibrosis stage F2 or greater (Metavir scale or equivalent) or Fibrosis stage less than F2 and at least one of the following poor prognostic factors:
  - Co-infected with HIV or hepatitis B virus
  - Post-organ transplant (liver and/or non-liver transplant)
  - Extra-hepatic manifestations
  - Chronic kidney disease stage 3, 4 or 5 as defined by the National Kidney Foundation Kidney Disease Outcomes Quality Initiative
  - Co-existent liver disease with diagnostic evidence of fatty liver disease (e.g., non-alcoholic steatohepatitis)
  - Patients with diabetes being treated with antihyperglycemic medications
  - Woman of childbearing age who is planning a pregnancy within the next 12 months

Clinical Notes:

1. Treatment-experienced is defined as patients who have been previously treated with a peginterferon/ribavirin regimen including regimens containing HCV protease inhibitors; and who have not experienced an adequate response.
2. 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.
3. Extra-hepatic manifestations include but are not limited to: symptomatic vasculitis associated with HCV-related mixed cryoglobulinaemia, HCV immune complex-related nephropathy and non-Hodgkin B cell lymphoma, porphyria cutanea tarda, lichen planus, and glomerulonephritis.
4. Chronic kidney disease stage 3, 4 or 5 includes patients with glomerular filtration rate (GFR) <60 mL/min/1.73m2 for ≥ 3 months.
5. Special Authority requests for patients with fibrosis stage less than F2 and fatty liver disease must include a confirmation that ultrasound imaging has been done with diagnosis of fatty liver disease.
6. Compensated cirrhosis is defined as a Child-Turcotte-Pugh (CTP) score of 5 to 6 (Class A).
7. Decompensated cirrhosis is defined as a CTP score of 7 or above (Class B or C). Special Authority requests for patients with decompensated cirrhosis must include a clinical history or ultrasound imaging diagnosis, laboratory test reports and fibrosis score test performed in the last 12 months. Acceptable methods include liver biopsy, transient elastography (FibroScan) and serum biomarker panels (such as AST-to-Platelet Ratio Index (APRI) or Fibrosis-4 (FIB-4) score) either alone or in combination. Supporting documentation must be submitted.
8. Re-treatment for direct-acting antiviral failures will be considered on a case-by-case basis under the formulary exception process.

Claim Note:

Claims that exceed the maximum claim amount of $9,999.99 must be divided and submitted as separate transactions on different days.

Please note: A single professional fee will be paid per 30 day supply.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/forms/pdf/hepatitis_C_treatment_request.pdf

Updated September 2017

Newfoundland Labrador

Health and Community Services

Dalteparin sodium (Fragmin 2500U, 3500U, 7500U, 10000U, 12500U, 15000U, 18000U, 25000U vials & syringe),

- For the prevention of VTE following:
    - total hip replacement (THR) surgery or hip fracture surgery (maximum coverage up to 35 days)
    - total knee replacement (TKR) surgery (maximum coverage up to 10 days)

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/forms/pdf/Thromboembolism_Prevention_Following_Surgery.pdf

- For treatment of acute Venous Thromboembolism (VTE)
    - coverage is limited to 7 to 10 days while establishing a therapeutic INR
    - extended treatment of recurrent VTE may be considered in patients with treatment failure on therapeutic doses of warfarin. Coverage will be limited to a 3 month period.

- For prophylaxis of VTE, coverage is limited to patients with concomitant anticoagulation syndromes, or in patients who have failed to reach therapeutic INR while on oral anticoagulant therapy.
    - Coverage will be limited to a 3 month period.

Anticoagulation in patients with cancer:

- For the treatment of VTE in cancer patients:
    - acute treatment limited to 10 days (while warfarinizing)
    - extended treatment in symptomatic VTE in cancer patients who have had a recurrent VTE on warfarin therapy. Coverage will be limited to a 3 month period.

- For the secondary prevention of symptomatic VTE:
    - For cancer patients who are on active chemotherapy with agents which interact with warfarin OR in patients who have failed oral anticoagulants as evidenced by an extension or recurrence of DVT.
    - **Maximum treatment duration 6 months.**

Please note that the routine use of LMWH in cancer patients to improve survival was reviewed and NOT recommended as there was no consistent evidence to support use.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated March 2016

Newfoundland Labrador

Health and Community Services

DAPAGLIFLOZIN (FORXIGA 5mg, 10mg tablet)

For the treatment of type 2 diabetes as a third drug added to metformin and a sulfonylurea for patients with inadequate glycemic control on metformin and a sulfonylurea AND in whom insulin is not an option.

To facilitate this process a specific **Oral Diabetes Medications Special Authorization Form** has been developed and can be found at:
http://www.health.gov.nl.ca/health/forms/pdf/oral_diabetes.pdf

Updated February 2017

Health and Community Services

DAPAGLIFLOZIN/METFORMIN HCL (XIGDUO 5 MG-850 MG, 5 MG-1000 MG TABLET)

For the treatment of type 2 diabetes in patients who are already stabilized on therapy with metformin, a sulfonylurea and dapaglifozin to replace the individual components of dapagliflozin and metformin **and** for whom insulin is not an option.

To facilitate this process a specific **Oral Diabetes Medications Special Authorization Form** has been developed and can be found at:
http://www.health.gov.nl.ca/health/forms/pdf/oral_diabetes.pdf

Updated September 2017

Health and Community Services

Darbepoetin (Aranesp 10ug, 20ug, 30ug, 40ug, 50ug, 60ug, 80ug, 100ug, 130ug, 150ug, 300ug, and 500ug)

Chronic Renal Failure:

- For anemia of chronic renal failure* (chronic kidney disease) for patients who:
    - Have a serum creatinine level > 176umol/L (2mg/dL) OR GFR < 1ml/sec/1.73m2 (60 mL/min/1.73m2) for three or more months AND who have an anemia work-up showing hemoglobin < 100g/L (10g/dL) or hematocrit < 30% and normochromic normocytic anemia.

Written request from a medical specialist required.

Anemia in hematologic malignancy:

- For the treatment of anemia in hematologic malignancy* in transfusion dependent patients:
    - With a baseline Hgb ≤ 90g/L whose transfusion requirements are ≥ 2 units of packed red blood cells (PRBC/month) over a 3 month period.

An initial trial of 12 weeks (2.25ug/kg/week) will be approved with documentation of dose, Hgb and therapeutic outcome (#of transfusions).

Further 12 week cycle can be approved dependent on evidence of clinical response or reduced treatment requirements to < 2 units of PRBC/month. If transfusion requirements increase to ≥ 2 units/month (over a 3 month period), one dose increase may be attempted (maximum dose 4.5ug/kg/week).

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2010

Newfoundland Labrador

Health and Community Services

DARIFENACIN (ENABLEX 7.5mg & 15mg tablet)

For the treatment of overactive bladder (not stress incontinence) after a reasonable trial, titrated, and of appropriate length* of oxybutynin IR, tolterodine OR solifenacin are not tolerated.

*an appropriate trial is considered to be of 12 weeks duration.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated October 2018

Health and Community Services

DARUNAVIR/COBICISTAT (PREZCOBIX 800 MG-150 MG TABLET)

For treatment of human immunodeficiency virus (HIV) infection in treatment-naïve and treatment-experienced patients without darunavir (DRV) resistance-associated mutation (RAMS).

This drug, as with other antivirals in the treatment of HIV, should be used under the direction of an infectious disease specialist.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated November 2016

Newfoundland Labrador

Health and Community Services

Darunavir (Prezista 75mg, 150mg, 300mg, 400mg & 600mg tablet)

- For use in treatment-experienced pediatric HIV-1 patients.
- For the treatment of HIV-1 in patients who are treatment naïve for whom a protease inhibitor (PI) therapy is indicated.
- As an alternate protease inhibitor (PI) as part of a HIV treatment regimen for the treatment-experienced adult patients who have demonstrated failure to multiple PI's and in whom less expensive PI's are not a treatment option.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated April 2013

Newfoundland Labrador
Health and Community Services

Dasatinib monohydrate (Sprycel 20mg, 50mg, 70mg, 80mg, 100mg, 140mg tablet)

Chronic Myelogenous Leukemia (CML):

- For adult patients with chronic phase CML with primary or acquired resistance to imatinib (600mg/day) at doses of 100mg per day or 70mg two times daily.
- For adult patients with chronic phase CML who progress to accelerated phase on imatinib 600mg per day. Dosing recommendation: 140mg per day.
- For adult patients with chronic phase CML who has blast crisis while on imatinib 600mg per day. Dosing recommendation: 140mg per day.
- For adult patients with CML who have intolerance to imatinib or have experienced grade 3 or higher toxicities to imatinib.
- Renewal criteria: Request for renewal must specify how the patient has benefited from therapy and is expected to continue to do so.

Duration of initial approval: 1 year
Duration of renewal: 1 year

Philadelphia chromosome positive acute lymphoblastic leukemia:

- For adult patients whose disease is resistant to imatinib-containing chemotherapy (patient must have tried 600mg/day),
- **OR** have experienced grade 3 non-hematologic toxicity,
- **OR** grade 4 hematologic toxicity to imatinib persisting for more than 7 days.

Request for renewal must specify that the patient has benefited from therapy and is expected to continue to do so.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2012

Newfoundland Labrador

Health and Community Services

Deferasirox (Exjade 125mg, 250mg and 500mg tablets & generics):
For patients who require iron chelation but in whom desferoxamine is contraindicated.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated September 2017

Health and Community Services

DEFERIPRONE (FERRIPROX 1000MG TABLET, 100 mg/mL oral solution

For the treatment of patients with transfusional iron overload due to thalassemia syndromes when current chelation therapy is inadequate.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated May 2017

Health and Community Services

DENOSUMAB (PROLIA 60 MG/ML SYRINGE)

For the treatment of osteoporosis in post-menopausal women and male patients 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 Criteria:

- High fracture risk defined as either: a moderate 10-year fracture risk (10% to 20%) with a prior fragility fracture; or a high 10-year fracture risk (≥ 20%) as defined by either the Canadian Association of Radiologists and Osteoporosis Canada (CAROC) tool or the World Health Organization's Fracture Risk Assessment (FRAX) tool.
- Refractory is defined as an unsatisfactory response to bisphosphonates is typically defined as a fragility fracture and/or evidence of a decline in BMD below pre-treatment baseline levels, despite adherence for one year.

Updated March 2018

Health and Community Services

DENOSUMAB (XGEVA 120 MG/1.7 ML VIAL)

For the prevention of skeletal related events (SREs) in patients with castrate-resistant prostate cancer (CRPC) with one or more documented bony metastases and good performance status (Eastern Cooperative Oncology Group [ECOG] performance status score of 0, 1, or 2).

Approval Period: Indefinite

Recommended Dose: 1.7 ml every four weeks

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated April 2014

Health and Community Services

Diazepam Rectal Gel (Diazepam 5mg/ml rectal gel)

For the management of patients with epilepsy who have failed to respond to benefit lorazepam formulations (either sublingual tablets or injection administered rectally).

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2010

Health and Community Services

DIENOGEST (VISANNE 2 MG TABLET)

For the management of pelvic pain associated with endometriosis in patients for whom one or more less costly hormonal options are either ineffective or cannot be used.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2012

Health and Community Services

DIMETHYL FUMARATE (TECFIDERA 120mg, 240mg CAPSULE)

For the treatment of patients with Multiple Sclerosis (MS) who meet the following criteria:

- Written request from a neurologist.
- Subjects over 18 years.
- Confident diagnosis of relapsing-remitting MS.
- Two relapses in the previous 24 months (Relapse defined as the appearance of symptoms and signs compatible with MS, lasting greater than 24 hours and not due to a rise in temperature.)
- Kurtzke EDSS score of 6.5 or less (assistance needed to walk about 20m without resting).

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated June 2015

Newfoundland Labrador

Health and Community Services

DOLUTEGRAVIR (TIVICAY 50 MG TABLET)

For the treatment of HIV in both treatment-naive and treatment-experienced adults andchildren 12 years of age and older weighing at least 40kg, in combination with other antiretrovirals.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2015

Newfoundland Labrador

Health and Community Services

Donepezil (Aricept 5mg, 10mg tablets & generics)

For the treatment of patients with mild to moderate dementia who meet the following criteria:

- A Mini-Mental State Examination (MMSE) score of 10 to 30 AND;
- A Functional Assessment Staging Test (FAST) score of 4 to 5; and

Initial requests for reimbursement will be considered for a 6 month approval; subsequent requests may be considered for a maximum 12 months approval.

FAST		STAGE FUNCTIONAL IMPAIRMENT DUE TO COGNITIVE DEFICIT (NOT PHYSICAL)
4	Mild	IADLs: needs assistance (Instrumental Activities of Daily Living include complex tasks such as managing money and medications, shopping, cooking, driving, housekeeping, using telephone)
5	Moderate	Re-wearing clothes; requires assistance in such basic tasks of daily life as choosing proper clothing. Patient can no longer function independently
6	Moderately Severe	ADLs: needs assistance, especially with dressing and bathing (i.e. unable to bathe properly; inability to handle the mechanics of toileting); eventually experiences urinary and fecal incontinence (Activities of Daily Living include dressing, washing, toileting, feeding, mobility)
7	Severe	Non-verbal, non-ambulatory

Adapted from: Reisberg, B. Functional Assessment Staging (FAST). Psychopharmacology Bulletin 1988;24(4):653-9

To facilitate this process specific **Cholinesterase Inhibitor Special Authorization Forms** have been developed and can be found at:
http://www.health.gov.nl.ca/health/forms/pdf/Donepezil_Galantamine_Rivastigmine.pdf

Updated February 2017

Health and Community Services

DORNASE ALFA (PULMOZYME 1 MG/ML AMPOULE)

Coverage is considered when prescribed by CF physicians in recognized CF clinics for patients with a FEV_1<70% predicted with clinically significant decline in FEV_1 not responsive to usual treatment.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated January 2013

Newfoundland Labrador

Health and Community Services

Duloxetine (Cymbalta 30mg & 60mg & generics)

For treatment of neuropathic pain in diabetic patients who:

- are unresponsive to **TWO** adequate courses of less costly alternative agents such as a tricyclic antidepressant agent or an anticonvulsant agent.

Dose to be limited to a maximum of 60mg daily.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2016

Health and Community Services

Efavirenez/emtricitabine/tenofovir (Atripla 600mg/200mg/300mg & generics)
For the treatment of HIV-1 infection where the virus is susceptible to each of tenofovir, emtricitabine and efavirenz **AND**:

- **Efavirenez/emtricitabine/tenofovir** is used to replace existing therapy with its component drugs, **OR**
- The patient is treatment naïve, **OR**
- The patient has established viral suppression but requires antiretroviral therapy modification due to intolerance or adverse effects.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated September 2017

Health and Community Services

ELBASVIR/GRAZOPREVIR (ZEPATIER 50mg/100mg tablet)

For treatment-naïve or treatment-experienced adult patients with chronic hepatitis C without cirrhosis or with compensated cirrhosis who meet the following criteria:

- Must be prescribed by a hepatologist, gastroenterologist, or infectious disease specialist (or other physician experienced in treating a patient with hepatitis C infection).
- Laboratory-confirmed hepatitis C genotype 1 or 4.
- Quantitative hepatitis C virus (HCV) RNA value within the last 6 months.
- Fibrosis stage of F0 or greater (Metavir scale or equivalent).

	Aproval Period and Regimen
Genotype 1 • Treatment-naïve • Treatment-experienced prior relapsers	12 weeks *(8 weeks may be considered in treatment-naïve genotype 1b patients without significant fibrosis or cirrhosis)*
Genotype 1b • Treatment-experienced on-treatment virologic failures	12 weeks
Genotype 1a • Treatment-experienced on-treatment virologic failures	16 weeks in combination with ribavirin
Genotype 4 • Treatment-naïve • Treatment-experienced prior relapsers	12 weeks
Genotype 4 • Treatment-experienced on-treatment virologic failures	16 weeks in combination with ribavirin

Exclusion criteria:

- Patients currently being treated with another HCV antiviral agent.
- Retreatment for failure or re-infection in patients who have received an adequate prior course of an HCV direct-acting antiviral drug regimen may be considered on an exceptional case-by-case basis.

Clinical Notes:

1. Treatment-experienced is defined as a patient who has been previously treated with PegIFN/RBV regimens, including regimens containing HCV protease inhibitors (for genotype 1), and who has **not** experienced an adequate response.
2. "Treatment-experienced prior relapser" is defined as a patient who has undetectable HCV RNA at the end of previous PegIFN/RBV therapy, including regimens containing NS3/4A protease inhibitors (for genotype 1), but with a subsequent detectable HCV RNA during follow-up.
3. "Treatment-experienced on-treatment virologic failure" is defined as a patient who has been previously treated with PegIFN/RBV regimens, including regimens containing HCV protease inhibitors (for genotype 1), and who has **not** experienced adequate response, including a null response, partial response or virologic breakthrough or rebound.
4. 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.
5. Compensated cirrhosis is defined as a Child-Turcotte-Pugh (CTP) score of 5 to 6 (Class A).

NOTES:

- Special Authorization requests must include the genotype report from the latest post-treatment course.
- Special Authorization requests must include the most recent HCV RNA test performed in the last 6 months.
- Special Authorization requests must include a fibrosis score test performed in the last 12 months. Acceptable methods include liver biopsy, transient elastography (FibroScan) and serum biomarker panels (AST-to-Platelet Ratio Index (APRI)) either alone or in combination.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/forms/pdf/hepatitis_C_treatment_request.pdf

Updated August 2018

Health and Community Services

ELBASVIR/GRAZOPREVIR (ZEPATIER 50mg/100mg tablet)

For treatment-naïve or treatment-experienced adult patients with chronic hepatitis C with no cirrhosis or with compensated cirrhosis who meet the following criteria:

	Aproval Period and Regimen
Genotype 1 • Treatment-naïve • Treatment-experienced prior relapsers	12 weeks *(8 weeks may be considered in treatment-naïve genotype 1b patients without significant fibrosis or cirrhosis)*
Genotype 1b • Treatment-experienced on-treatment virologic failures	12 weeks
Genotype 1a • Treatment-experienced on-treatment virologic failures	16 weeks in combination with ribavirin
Genotype 4 • Treatment-naïve • Treatment-experienced prior relapsers	12 weeks
Genotype 4 • Treatment-experienced on-treatment virologic failures	16 weeks in combination with ribavirin

Patients must also meet all of the following criteria:

- Prescribed by a hepatologist, gastroenterologist, or infectious disease specialist (or other prescribers with expertise in the treatment of hepatitis C infection).
- Lab-confirmed hepatitis C genotype 1 or 4.
- Quantitative hepatitis C virus (HCV) RNA value within the last 6 months.
- Fibrosis stage F2 or greater (Metavir scale or equivalent) or Fibrosis stage less than F2 (Metavir scale or equivalent) and at least one of the following:
  - Co-infected with HIV or hepatitis B virus
  - Post-organ transplant (liver and/or non-liver transplant)
  - Extra-hepatic manifestations
  - Chronic kidney disease stage 3, 4 or 5 as defined by the National Kidney Foundation Kidney Disease Outcomes Quality Initiative

- Co-existent liver disease with diagnostic evidence of fatty liver disease (e.g., non-alcoholic steatohepatitis)
- Patients with diabetes being treated with antihyperglycemic medications.
- Woman of childbearing age who is planning a pregnancy within the next 12 months

Clinical Notes:

1. Treatment-experienced is defined as a patient who has been previously treated with PegIFN/RBV regimens, including regimens containing HCV protease inhibitors (for genotype 1), and who has **not** experienced an adequate response.
2. "Treatment-experienced prior relapser" is defined as a patient who has undetectable HCV RNA at the end of previous PegIFN/RBV therapy, including regimens containing NS3/4A protease inhibitors (for genotype 1), but with a subsequent detectable HCV RNA during follow-up.
3. "Treatment-experienced on-treatment virologic failure" is defined as a patient who has been previously treated with PegIFN/RBV regimens, including regimens containing HCV protease inhibitors (for genotype 1), and who has **not** experienced adequate response, including a null response, partial response or virologic breakthrough or rebound.
4. 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.
5. Extra-hepatic manifestations include but are not limited to: symptomatic vasculitis associated with HCV-related mixed cryoglobulinaemia, HCV immune complex-related nephropathy and non-Hodgkin B cell lymphoma, porphyria cutanea tarda, lichen planus, and glomerulonephritis.
6. Chronic kidney disease stage 3, 4 or 5 includes patients with glomerular filtration rate (GFR) <60 mL/min/1.73m^2 for ≥ 3 months.
7. Compensated cirrhosis is defined as a Child-Turcotte-Pugh (CTP) score of 5 to 6 (Class A).

Claim Note:

Claims that exceed the maximum claim amount of $9,999.99 must be divided and submitted as separate transactions on different days. Please note: A single professional fee will be paid per 30 day supply.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/forms/pdf/hepatitis_C_treatment_request.pdf

Updated August 2017

Health and Community Services

EPLERENONE (INSPRA 25mg, 50 MG TABLET)

For the treatment of patients who have New York Heart Association (NYHA) class II chronic heart failure with left ventricular systolic dysfunction (with ejection fraction ≤ 35%), as a complement to standard therapy.

Clinical Note:
Patients must be on optimal therapy with an angiotensin-converting enzyme (ACE) inhibitor OR an angiotensin-receptor blocker (ARB), AND a beta-blocker (unless contraindicated) at the recommended dose or maximal tolerated dose.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2018

Health and Community Services

Elvitegravir/Cobicistat/Emtricitabine/Tenofovir alafenamide (GENVOYA 150mg/150mg/200mg/10mg tablet (EVG/COBI/FTC/TAF))

As a complete regimen for the treatment of HIV-1 infection in adult and pediatric patients 12 years of age and older (and weighing ≥ 35kg) and with no known mutations associated with resistance to the individual components of GENVOYA

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated August 2017

Health and Community Services

ELVITEGRAVIR/COBICISTAT/EMTRICITABINE/TENOFOVIR (STRIBILD 150-150-200-300MG tablet)

As a complete regimen for antiretroviral treatment-naive HIV-1 infected patients in whom efavirenz is not indicated.

Please visit the following link if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated June 2015

Health and Community Services

EMPAGLIFLOZIN (JARDIANCE 10mg, 25mg,)

For the treatment of type 2 diabetes as a third drug **added** to metformin **and** a sulfonylurea for patients with inadequate glycemic control on metformin and a sulfonylurea **AND** in whom insulin is not an option.

To facilitate this process a specific **Oral Diabetes Medications Special Authorization Form** has been developed and can be found at:
http://www.health.gov.nl.ca/health/forms/pdf/oral_diabetes.pdf

Updated June 2016

Health and Community Services

EMTRICITAB/RILPIVIRINE/TENOFOVIR (COMPLERA 200 MG-25MG-300MG TAB)

For the treatment of human immunodeficiency virus type 1 (HIV-1):

- in antiretroviral treatment-naïve patients, or
- to replace the three components given as dual or triple therapy for patients stabilized on appropriate doses.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated May 2012

Newfoundland Labrador

Health and Community Services

EMTRICITABINE/RILPIVIRINE/TENOFOVIR (ODEFSEY 200 MG-25 MG-25 MG TABLET)

As a complete regimen for the treatment of adults infected with HIV-1 with no known mutations associated with resistance to the non-nucleoside reverse-transcriptase inhibitor (NNRTI) class, tenofovir or FTC, and with a viral load ≤ 100,000 copies/mL

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated December 2018

Newfoundland Labrador
Health and Community Services

EMTRICITABINE/TENOFOVIR (TRUVADA 200mg/300mg tablets & generics)

HIV-1 treatment
As a dual nucleoside/nucleotide option for the treatment of HIV patients where the virus is susceptible to both agents and efavirenez is not indicated due to adverse effects or antiretroviral resistance.

Pre-Exposure Prophylaxis (PrEP)

Men Who Have Sex With Men (MSM) and Transgender Women (TGW):
For pre-exposure prophylaxis (PrEP), in combination with safer sex practices, to reduce the risk of sexually acquired HIV-1 infection in adults at high risk who report condomless anal sex within the last six months and any of the following:

- Infectious syphilis or rectal bacterial sexually transmitted infection (STI), particularly if diagnosed in the preceding 12 months;
- Recurrent use of nonoccupational postexposure prophylaxis (nPEP) (more than once);
- Ongoing sexual relationship with an HIV-positive partner who is not receiving stable ART and/or does not have an HIV viral load <200 copies/ mL. (i.e. not on ART or >200 copies/mL); or
- High-incidence risk index (HIRI)-MSM risk score ≥ 11.
  Please refer to the BC-CfE PrEP guidelines or the Canadian PrEP Guidelines which include details about how to calculate the HIRI-MSM risk score.

Heterosexual exposure:
For pre-exposure prophylaxis (PrEP), in combination with safer sex practices, to reduce the risk of sexually acquired HIV-1 infection in heterosexual men and women at high risk of acquiring HIV infection who meet both of the following:

- Condomless vaginal or anal sex; and
- Ongoing sexual relationship with an HIV-positive partner who is not receiving stable ART and/or does not have an HIV viral load <200 copies/ mL. (i.e. not on ART or >200 copies/mL).

People who inject drugs (PWID):
For pre-exposure prophylaxis (PrEP) for PWID who are at high risk of acquiring HIV infection and meet both of the following:

- Report sharing of injection equipment; and
- Have an HIV-positive injecting partner who is not receiving stable ART and/or does not have an HIV viral load < 200 copies/mL.

Clinical notes:

- PrEP should be part of a combination prevention strategy that includes behavioural interventions such as condoms and risk reduction counseling.

- PrEP is not recommended in the context of a stable closed relationship with a single partner with no or negligible risk of having transmissible HIV.

Claim Notes:

- Coverage is limited to 30 days on the initial fill and 90 days on subsequent fills.
- Confirmation of a negative HIV test is required on the initial request and every 3 months thereafter.

Please NOTE:
An initial consultation with the Provincial Immunodeficiency Nurse Practitioner will be required prior to initiating any patients on Pre-Exposure Prophylaxis (PrEP).
Kimberley Burt
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LeMarchant Rd.,St.John's,NL.
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Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/forms/pdf/Pre-Exposure_Prophylaxis.pdf

Updated October 2018

Health and Community Services

Enoxaparin sodium (LOVENOX prefilled syringes 30mg/0.3ml, 40mg/0.4ml, 60mg/0.6ml, 80mg/0.8ml, 100mg/ml, Multiple dose vial 300mg/3ml, HP 120mg/0.8ml, 150mg/ml)

For **treatment** of acute Venous Thromboembolism (VTE)

- coverage is limited to 7 to 10 days while establishing a therapeutic INR
- extended treatment of recurrent VTE may be considered in patients with treatment failure on therapeutic doses of warfarin. Coverage will be limited to a 3 month period.

For the **prophylaxis** of thromboembolism (VTE) following:

- total hip replacement (THR) surgery or hip fracture surgery (maximum coverage up to 35 days)
- total knee replacement (TKR) surgery (maximum coverage up to 10 days)

- For the prophylaxis of venous thromboembolism (VTE) post abdominal or pelvic surgery for management of a malignant tumor.
    - Approval up to 10 days

OR

    - Approval up to 28 days for high risk patients e.g. those with a history of VTE and/or anesthesia lasting > 2 hours and/or bed rest lasting > 4 days following surgery.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/forms/pdf/Thromboembolism_Prevention_Following_Surgery.pdf

- For prophylaxis of venous thromboembolism (VTE), coverage is limited to patients with concomitant anticoagulation syndromes, or in patients who have failed to reach therapeutic INR while on oral anticoagulant therapy.
    - Coverage will be limited to a 3 month period.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated March 2016

Health and Community Services

Entecavir (Baraclude 0.5mg tablets & generics)

For the treatment of chronic hepatitis B infection in patients with:

- documented cirrhosis on radiographic or histologic grounds AND
- a HBV DNA concentration above 2000 IU/ml.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated February 2015

Health and Community Services

ENZALUTAMIDE (XTANDI 40 MG CAPSULE)

For treatment of patients with metastatic castration resistant prostate cancer (mCRPC), who have progressed on docetaxel-based chemotherapy with an ECOG performance status ≤2 and no risk factors for seizures and would be an alternative to abiraterone for patients in the post-docetaxel setting but would not be an add-on therapy to abiraterone treatment;

OR

For the treatment of patients with asymptomatic or mildly symptomatic metastatic castration-resistant prostate cancer (mCRPC) who have evidence of disease progression following androgen deprivation therapy (ADT), who have not received prior chemotherapy for mCRPC and who have an ECOG performance status of 0 or 1, and no risk factor for seizures.

Approval Period: 6 months

Recommended Dose: 160mg once daily

Renewals will be considered for patients who do not have evidence of disease progression AND who have not developed unacceptable toxicities that require discontinuation of enzalutamide.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated October 2015

Health and Community Services

Epinephrine (Ana-kit, Epipen, Epipen Jr, Allerject 0.15, 0.3mg Voice Assisted Auto Injector)

For the emergency treatment of anaphylactic reactions, when out of reach of immediate medical attention.

Approval will be provided to replace used or expired units as needed.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2018

Health and Community Services

Epoprostenol sodium (CARIPUL & FLOLAN 0.5mg, 1.5mg vials for injection)

- For the treatment of patients with pulmonary arterial hypertension (primary (idiopathic) or scleroderma-associated) with NYHA functional class III or IV unresponsive to therapy with vasodilators and bosentan.

- For the treatment of severe/advanced (NYHA functional class IV) pulmonary arterial hypertension.

Written request from a medical specialist required.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated May 2014

Health and Community Services

EPROSARTAN/HYDROCHLOROTHIAZIDE (TEVETEN Plus 600 mg-12.5 mg TABLET)

For use in patients who have failed or had intolerable side effects to treatment with candesartan/ hydrochlorothiazide, irbesartan/hydrochlorothiazide, losartan/hydrochlorothiazide, telmisartan/ hydrochlorothiazide AND valsartan/hydrochlorothiazide.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated April 2014

Newfoundland Labrador

Health and Community Services

EPROSARTAN MESYLATE (TEVETEN 400mg, 600mg TABLET)

For use in patients who have failed or had intolerable side effects to treatment with candesartan, irbesartan, losartan, telmisartan AND valsartan.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated April 2014

Health and Community Services

Erythropoietin Alpha (Eprex 1000 U, 2000 U, 3000 U, 4000 U, 5000U, 6000 U, 8000 U, 10,000U, 20,000 U, 30,000 U, 40,000 U)

Chronic Renal Failure:

- For anemia of chronic renal failure* (chronic kidney disease) for patients who:
    - Have a serum creatinine level > 176umol/L (2mg/dL) OR GFR < 1ml/sec/1.73m2 (60 mL/min/1.73m2) for three or more months AND who have an anemia work-up showing hemoglobin < 100g/L (10g/dL) or hematocrit < 30% and normochromic normocytic anemia.

Written request from a medical specialist required.

Anemia in hematologic malignancy:

- For the treatment of anemia in hematological malignancy* for those patients who:
    - are transfusion dependent with a baseline Hgb ≤ 90g/L and whose transfusion requirements are ≥ 2 units of packed red blood cells per month (PRBC/month) over a 3 month period.

Initial approval will be for a 12 week period only. Further consideration beyond this period (for 12 week approvals) can be considered dependent on evidence of satisfactory clinical response or reduced treatment requirements to < 2 units of PRBC/month. If transfusion requirements increase to ≥ 2 units/month (over a 3 month period), one dose increase may be attempted (maximum dose 60,000 iu per week).

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2010

Health and Community Services

ESLICARBAZEPINE (APTIOM 200mg, 400mg, 600mg, 800mg tablet)

For the treatment of patients with refractory partial-onset seizures as adjunctive therapy who meet **all** of the following criteria:

- Are under the care of a neurologist or physician experienced in the treatment of epilepsy **AND**
- Are currently receiving two or more antiepileptic drugs **AND**
- In whom all other antiepileptic drugs are ineffective or not appropriate.

Please visit the following link if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated December 2015

Health and Community Services

ETANERCEPT (ENBREL 25 MG VIAL KIT, ENBREL 50 MG/ML SYRINGE, BRENZYS 50 MG/ML (BRENZYS 50 MG/ML (0.98 ML) SYRINGE, BRENZYS 50 MG/ML (0.98 ML) PEN, ERELZI 25 MG/0.5 ML SYRINGE, 50 MG/ML SYRINGE, 50 MG/ML PEN)

Rheumatoid Arthritis (RA): *(Brenzys, Erelzi)*
NOTE: All new requests for coverage of etanercept received after March 1, 2018 will be approved for the **biosimilar version only**.

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) for a minimum of 12 weeks, followed by methotrexate in combination with at least two other DMARDs, such as hydroxychloroquine and sulfasalazine, for a minimum of 12 weeks;

or

- Initial use of triple DMARD therapy with methotrexate in combination with at least two other DMARDs, such as hydroxychloroquine and sulfasalazine, for a minimum of 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 may take up to 24 weeks, however if no improvement is seen after 12 weeks of triple DMARD use, therapy should be changed.
- If the patient is intolerant to triple DMARD therapy, then dual therapy with DMARDs (methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) must be considered.
- Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above.
- Intolerant is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs. The nature of intolerance(s) must be clearly documented.

Claim Notes:
- Must be prescribed by a rheumatologist.
- Combined use of more than one biologic DMARD will not be reimbursed.
- All new requests for coverage of etanercept received after March 1, 2018 will be approved for the biosimilar version only.
- Initial Approval: 6 months
- Renewal Approval: 1 year. Confirmation of continued response is required.
- Maximum Dosage Approved:

- Etanercept: 25mg twice a week or 50mg once a week with no dose escalation permitted

Ankylosing Spondylitis: (Brenzys, Erelzi)

NOTE: All new requests for coverage of etanercept received after March 1, 2018 will be approved for the **biosimilar version** only.

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 observation or in whom NSAIDs are contraindicated,

OR

- have peripheral symptoms and who have failed to respond to, or have contraindications to, the sequential use of at least 2 NSAIDs at the optimum dose for a minimum period of 3 months observation and have had an inadequate response to an optimal dose or maximal tolerated dose of a DMARD.

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 internist.
- Combined use of more than one biologic DMARD will not be reimbursed.
- All new requests for coverage of etanercept received after March 1, 2018 will be approved for the biosimilar version only.
- Approvals will be for a maximum of 50mg per week.
- Initial Approval: 6 months.
- Renewal Approval: 1 year

Polyarticular Juvenile Idiopathic Arthritis (pJIA): (Erelzi)

NOTE: All new requests for coverage of etanercept received after April 1, 2018 will be approved for the biosimilar version only.

- For the treatment of moderate to severely active, polyarticular juvenile rheumatoid arthritis in children (age 4-17) who have not responded to adequate treatment with one or more DMARDs for at least 3 months or who have intolerance to DMARDs, and do not have a contraindication to etanercept.

Claim Notes:

- Must be prescribed by, or in consultation with, a rheumatologist, who is familiar with the use of biologic DMARDs in children.
- All new requests for coverage of etanercept will be approved for the biosimilar version only.
- Approvals will be for a maximum of 0.8mg/kg, up to 50mg per week.

Psoriatic Arthritis:

- For the treatment of psoriatic arthritis in patients who have not responded to an adequate trial of two DMARDs or have had intolerance or contraindication to DMARDs.

  Traditional agents include methotrexate, IM gold, sulfasalazine, hydroxychloroquine, azathioprine, chloroquine, D-penicillamine and cyclosporine.

Chronic Plaque Psoriasis:

For patients with severe debilitating psoriasis who meet all of the following criteria:

- Body surface involvement of greater than 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 to or unable to access phototherapy.

Coverage will be approved initially for 3 months.

Can be reassessed for yearly coverage dependent on the patient achieving a response of greater than or equal to 75% reduction in PASI (Psoriasis Area Severity Index) score or greater than 50% reduction in PASI with a greater than or equal to 5 point improvement in DLOI (Dermatology Life Quality Index) or a quantitative reduction in BSA (Body Surface Area) affecting the face, hands, feet or genital region.

Written request from a dermatologist.

Dosage restricted to 50mg twice weekly for 3 months followed by a reduction to a maintenance dose of 50mg weekly.

Coverage will not be provided for two biologicals concurrently.

To facilitate this process, a specific **Chronic Plaque Psoriasis Special Authorization Form** has been developed and can be found at:
http://www.health.gov.nl.ca/health/prescription/chronic_plaque_psoriasis_meds_coverage_request.pdf

Updated April 2018

Health and Community Services

EVEROLIMUS (Afinitor) 2.5mg, 5mg, 10mg

Metastatic Renal Cell Carcinoma (MRCC)
For the second-line treatment of metastatic renal cell carcinoma with clear cell morphology, in
patients previously treated with a funded tyrosine kinase inhibitor.

Approval Period: 6 months

Recommended Dose: 10mg daily until disease progression or development of unacceptable toxicity requiring discontinuation of everolimus

Renewals will be considered for patients who do not have evidence of disease progression AND who have not developed unacceptable toxicities that require discontinuation of everolimus.

Advanced Breast Cancer
For the treatment of hormone-receptor positive, HER2 negative advanced breast cancer, in postmenopausal women with ECOG performance status ≤ 2 after recurrence or progression following a non-steroidal aromatase inhibitor (NSAI), if the treating oncologist would consider using exemestane.

Approval Period: 9 months

Recommended Dose: 10mg daily until disease progression or development of unacceptable toxicity requiring discontinuation of everolimus

Renewals will be considered for patients who do not have evidence of disease progression AND who have not developed unacceptable toxicities that require discontinuation of everolimus.

Pancreatic Neuroendocrine Tumor (pNET)
For the treatment of patients with progressive, unresectable, well or moderately differentiated, locally advanced or metastatic pancreatic neuroendocrine tumors (pNET) with good performance status (ECOG 0-2), until disease progression.

Note: Patients whose disease progresses on sunitinib are not eligible for funded treatment with everolimus for pNET

Approval Period: 12 months

Recommended Dose: 10mg daily until disease progression or development of unacceptable toxicity requiring discontinuation of everolimus

Renewals will be considered for patients who do not have evidence of disease progression AND who have not developed unacceptable toxicities that require discontinuation of everolimus.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated June 2017

Health and Community Services

Exemestane (Aromasin 25mg & generics)

- First-line therapy in postmenopausal women with advanced breast cancer. (Indefinite coverage).
- For the adjuvant treatment of postmenopausal women with hormone receptor-positive invasive early breast cancer. (5 years)
- The extended adjuvant treatment of hormone receptor-positive invasive early breast cancer in postmenopausal women who have received approximately 5 years of prior standard adjuvant tamoxifen therapy. (5 years)
- In combination with everolimus for the treatment of hormone-receptor positive, HER2 negative advanced breast cancer, in postmenopausal women with ECOG performance status ≤ 2 after recurrence or progression following a non-steroidal aromatase inhibitor (letrozole or anastrozole).

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated September 2014

Health and Community Services

Ezetimibe (Ezetrol 10mg tablet & generics)

- Co-administration with statins for patients not reaching treatment goals on maximum tolerated doses of statins alone.

- For the treatment of hypercholesterolemia, as monotherapy, in patients who are intolerant to fibrates (where appropriate) and statins.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated December 2014

Health and Community Services

Febuxostat (Uloric 80mg tablet)

For the treatment of patients with symptomatic gout who have documented Drug-induced Hypersensitivity Syndrome* to allopurinol.

*is characterized by a major skin manifestation, fever, multi-organ involvement, lymphadenopathy, and hematological abnormalities (eosinophilia, atypical lymphocytes). The onset of symptoms usually occurs two to eight weeks after therapy initiation of the causative drug. At least three of the above listed characteristics should be present including the involvement of at least one extracutaneous organ system.

Please visit the following link if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated August 2011

Health and Community Services

Fentanyl (Duragesic 12.5ug, 25mcg/hr, 50mcg/hr, 75mcg/hr, 100mcg/hr transdermal system and generics)

For the treatment of malignant or chronic non-malignant pain* in **adult patients** who were previously receiving **continuous opioid administration (long-acting opioids)** or who are unable to take oral therapy.

*** Please note**: in order to assess requests for coverage in the treatment of non-malignant pain, the Department will require the following information:

- Results of any xrays/CT scans/MRIs.
- Information relating to any consultations completed and their recommendations (ie., surgical, orthopedic and/or physiotherapy consultations).
- Surgical history.
- Current analgesic uses, current dosage, and assessment of current level of pain control.
- Use of antidepressants and/or anticonvulsants if pain is neuropathic.
- Any other information you feel is pertinent to the request.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2010

Health and Community Services

Feroterol/ipratropium nebules (Duovent nebules)

Failure or intolerance to ipratropium/salbutamol nebules (Combivent).

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2010

Newfoundland Labrador

Health and Community Services

FESOTERODINE FUMARATE (TOVIAZ 4 MG, 8MG TABLET)

For the treatment of overactive bladder (not stress incontinence) after a reasonable trial, titrated, and of appropriate length* of oxybutynin IR, tolterodine OR solifenacin are not tolerated.

*an appropriate trial is considered to be of 12 weeks duration.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated October 2018

Newfoundland Labrador

Health and Community Services

FIDAXOMICIN (DIFICID 200mg TABLET)

For the treatment of patients with Clostridium Difficile Infection (CDI), where the patient has:

- a second or subsequent recurrence following treatment with oral vancomycin; or
- treatment failure with oral vancomycin for the current CDI episode; or
- an intolerance or contraindication to oral vancomycin.

Re-treatment criteria:

- Re-treatment with fidaxomicin will only be considered for an early relapse occurring within 8 weeks of the start of the most recent fidaxomicin course.

Clinical Notes:

1. Treatment failure is defined as 14 days of vancomycin therapy without acceptable clinical improvement.
2. Intolerant is defined as demonstrating serious adverse effects to treatments. The nature of intolerance(s) must be clearly documented.

Claim Notes:

- Should be prescribed by, or in consultation with, an infectious disease specialist or gastroenterologist.
- Requests will be approved for 200mg twice a day for 10 days.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated January 2019

Health and Community Services

FILGRASTIM (GRASTOFIL 300MCG/0.5ML, 480MCG/0.8ML SYRINGE)

Coverage is considered for patients receiving moderate to severely myelosuppressive chemotherapy for:

Primary prophylaxis:

- When given as an integral part of an aggressive chemotherapy regimen with curative intent in order to maintain dose intensity in compressed interval or dose dense treatment, as specified in a chemotherapy protocol.
    - Chemotherapy protocol must be supplied with request

- For use in patients ≥65 years who are receiving CHOP.

Secondary prophylaxis:
Coverage is considered for patients receiving moderate to severely myelosuppressive chemotherapy with curative intent who:

- have experienced an episode of febrile neutropenia, neutropenic sepsis or profound neutropenia in a previous cycle of chemotherapy; **OR**
- For use in patients who have experienced a dose reduction or treatment delay longer than one week due to neutropenia.

Dosing for chemotherapy support:

- The manufacturer recommends an initial dose of 5ug/kg/day.
- Patients ≤ 70kg use 1ml vial (300ug).
- Patients > 70kg use 1.6ml vial (480ug).

Clinical Notes:

- Patients with non-curative cancer receiving chemotherapy with palliative intent are not eligible for either primary or secondary G-CSF prophylaxis.
- Profound neutropenia is defined as an ANC ≤ 0.1 x 10^9 per litre.

Claim Notes:

- All requests for coverage of filgrastim will be approved for Grastofil brand only.
- Patients who have existing coverage the Neupogen brand will continue to have this brand covered until the current special authorization approval expires.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated April 2018

Health and Community Services

FINGOLIMOD (GILENYA 0.5 MG CAPSULE)

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

- Failure to respond to full and adequate courses[1] of at least one at least one disease modifying therapy publicly listed on the NLPDP Formulary ; **OR** documented intolerance[2] to at least 2 therapies
- Have experienced one or more clinically disabling relapses in the previous year
- Demonstrate a significant increase in T2 lesion load compared with that from a previous MRI scan **OR** have at least one gadolinium enhancing lesion
- Request is being made by and followed by a neurologist experienced in the management of RRMS
- Patient has a recent Expanded Disability Status Scale (EDSS) score less than or equal to 5.5 (i.e. patients must be able to ambulate at least 100 meters without assistance)

[1] Failure to respond to full and adequate courses is defined as a trial of at least 6 months of one disease modifying therapy publicly listed on the NLPDP Formulary **AND** experienced at least one disabling relapse (attack) while on therapy.
(MRI report does NOT need to be submitted with the request)

[2] Intolerance is defined as documented serious adverse effects or contraindications that are incompatible with further use of that class of drug. (Note that skin reactions at the site of the injection do NOT qualify as a contraindication to interferon or glatiramer therapy.)

<u>Requirements for Initial Requests:</u>
• The patient's physician must provide 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.

<u>Renewal requests will be considered:</u>
• Date and details of the most recent neurological examination and EDSS scores must be provided (exam must have occurred within that last 90 days);

AND

• Patient must be stable or have experienced no more than 1 disabling attack/relapse in the past year;

AND

• The recent Expanded Disability Status Scale (EDSS) score must be less than or equal to 5.5 (i.e. patients must be able to ambulate at least 100 meters without assistance)

Dosage: 0.5 mg once daily

Approval period: 1 year

Exclusion Criteria:

- Combination therapy of Fingolimod with other disease modifying therapies (e.g. *Avonex, Betaseron, Copaxone, Rebif, Extavia, Tysabri, Aubagio, Tecfidera*) will not be funded.
- Combination therapy of fingolimid with Fampyra will not be funded.
- Patients with EDSS > 5.5 will not be funded
- Patients who have experienced a heart attack or stroke within the 6 months prior to the funding request will not be considered.
- Patients with a history of sick sinus syndrome, atrioventricular block, significant QT prolongation, bradycardia, ischemic heart disease, or congestive heart failure will not be considered.
- Patients younger than 18 years of age will not be considered.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated November 2016

Health and Community Services

FLUDARABINE (FLUDARA 10 MG TABLET)

For the treatment of patients with previously untreated chronic lymphocytic leukemia (CLL) when used in combination with rituximab.

Usual Dose: 40mg/m^2 po daily Days 1 to 5 every 28 days for a total of six cycles unless disease progression or unacceptable toxicity occurs

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated April 2012

Health and Community Services

Fluoxetine 20mg/5ml liquid

For use in patients who are unable to swallow the oral capsule formulation.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated September 2010

Health and Community Services

FLUTICASONE/SALMETEROL (ADVAIR DISKUS 100ug, 250ug, 500ug, ADVAIR MDI 125ug, 250ug)

Reversible Obstructive Airway Disease:

For treatment of asthma in patients in whom a combination of an inhaled steroid and long-acting beta agonist is desirable due to the failure of optimal doses of inhaled steroids *(failure defined as the need for frequent use of inhaled short-acting bronchodilators).

*Optimal defined as: >400mcg/day budesonide
>250mcg/day HFA- beclomethasone
>250mcg/day fluticasone
>200mcg/day mometasone
>400mcg/day ciclesonide

Chronic Obstructive Pulmonary Disease (COPD):

- 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 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 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.

Please visit the link below if you require our Chronic Obstructive Pulmonary Disease special authorization form:
http://www.health.gov.nl.ca/health/prescription/Chronic_Obstructive_Pulmonary_Disease_Form_2017.pdf

Updated November 2015

Health and Community Services

FLUTICASONE FUROATE/VILANTEROL (BREO ELLIPTA *100mcg/25mcg and 200mcg/25mcg dry powder for inhalation*)

Reversible Obstructive Airway Disease (Asthma)

For treatment of moderate to severe asthma in patients in whom:

- are compliant with inhaled corticosteroids at optimal doses; and
- require additional symptom control, (e.g., cough, awakening at night, missing activities such as school, work or social activities because of asthma symptoms); and
- require increasing amounts of short-acting beta$_2$-agonists, indicative of poor control

Chronic Obstructive Pulmonary Disease (COPD):

- 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 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 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.

Please visit the link below if you require our Chronic Obstructive Pulmonary Disease special authorization form:
http://www.health.gov.nl.ca/health/prescription/Chronic_Obstructive_Pulmonary_Disease_Form_2017.pdf

Updated November 2016

Health and Community Services

FORMOTEROL (FORADIL 12mcg CAPSULE FOR INHALATION, OXEZE 6mg, 12mcg/dose TURBUHALER)

Reversible Obstructive Airway Disease:

For the treatment of asthma where optimal doses of inhaled steroids* are being used and breakthrough symptoms require frequent use of inhaled short-acting bronchodilators.

*Optimal defined as: >400mcg/day budesonide
>250mcg/day HFA- beclomethasone
>250mcg/day fluticasone
>200mcg/day mometasone
>400mcg/day ciclesonide

Chronic Obstructive Pulmonary Disease (COPD):

- 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 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 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.

Please visit the link below if you require our Chronic Obstructive Pulmonary Disease special authorization form:
http://www.health.gov.nl.ca/health/prescription/Chronic_Obstructive_Pulmonary_Disease_Form_2017.pdf

Updated November 2015

Health and Community Services

Fosfomycin tromethamine (MONUROL 3 GRAM PACKET)

For the treatment of uncomplicated urinary tract infections in adult female patients where:

- The infecting organism is resistant to other oral agents **OR**
- Other less costly treatments are not tolerated.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated May 2014

Health and Community Services

Gabapentin (Neurontin 100mg, 300mg, 400mg, 600mg capsules and generics)

- For adjunctive management of epilepsy not satisfactorily controlled by conventional therapy.
- For the treatment of neuropathic pain associated with diabetic peripheral neuropathy (DPN), post herpetic neuralgia (PHN) and spinal cord injury in patients who have failed an adequate trial with a tricyclic antidepressant (e.g., nortriptyline, imipramine, desipramine, amitriptyline)

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated October 2013

Health and Community Services

Galantamine (Reminyl ER 8mg, ER 16mg, ER 24mg & generics)

For the treatment of patients with mild to moderate dementia who meet the following criteria:

- A Mini-Mental State Examination (MMSE) score of 10 to 30 AND;
- A Functional Assessment Staging Test (FAST) score of 4 to 5; and

Initial requests for reimbursement will be considered for a 6 month approval; subsequent requests may be considered for a maximum 12 months approval.

FAST		STAGE FUNCTIONAL IMPAIRMENT DUE TO COGNITIVE DEFICIT (NOT PHYSICAL)
4	Mild	IADLs: needs assistance (Instrumental Activities of Daily Living include complex tasks such as managing money and medications, shopping, cooking, driving, housekeeping, using telephone)
5	Moderate	Re-wearing clothes; requires assistance in such basic tasks of daily life as choosing proper clothing. Patient can no longer function independently
6	Moderately Severe	ADLs: needs assistance, especially with dressing and bathing (i.e. unable to bathe properly; inability to handle the mechanics of toileting); eventually experiences urinary and fecal incontinence (Activities of Daily Living include dressing, washing, toileting, feeding, mobility)
7	Severe	Non-verbal, non-ambulatory

Adapted from: Reisberg, B. Functional Assessment Staging (FAST). Psychopharmacology Bulletin 1988;24(4):653-9

To facilitate this process specific **Cholinesterase Inhibitor Special Authorization Forms** have been developed and can be found at:
http://www.health.gov.nl.ca/health/forms/pdf/Donepezil_Galantamine_Rivastigmine.pdf

Updated February 2017

Newfoundland Labrador

Health and Community Services

GLATIRAMER ACETATE (GLATECT 20 MG/ML SYRINGE, COPAXONE 20 MG/ML SYRINGE[1])

For the treatment of Multiple Sclerosis (MS) in patients who meet the following criteria:

- Written request from a neurologist.
- Subjects over 18 years.
- Confident diagnosis of relapsing-remitting, relapsing-progressive, or secondary progressive MS.
- Two relapses in the previous 24 months (Relapse defined as the appearance of symptoms and signs compatable with MS, lasting greater than 24 hours and not due to a rise in temperature.)
- Kurtzke EDSS score of 6.5 or less (assistance needed to walk about 20m without resting).

Claim Notes:

- New requests for coverage of Copaxone will not be considered.
- Glatect brand of glatiramer is the preferred glatiramer therapy who are treatment naïve.
- **coverage will only be considered for the Copaxone 20MG/ML[1] brand in patients stabilized prior to August 21, 2018)**

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated August 2018

Health and Community Services

GLYCOPYRRONIUM BROMIDE (SEEBRI BREEZHALER 50 MCG CAP)

Chronic Obstructive Pulmonary Disease (COPD):

- 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 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 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.

Please visit the link below if you require our Chronic Obstructive Pulmonary Disease special authorization form:
http://www.health.gov.nl.ca/health/prescription/Chronic_Obstructive_Pulmonary_Disease_Form_2017.pdf

Updated November 2015

Health and Community Services

Golimumab (SIMPONI 50mg/0.5ml Prefilled syringe, 50mg/0.5ml Autoinjector, ±100mg/1.0mL Prefilled syringe, ±100mg/1.0mL Autoinjector)

Rheumatoid Arthritis (RA): 50mg/0.5ml Prefilled syringe, 50mg/0.5ml Autoinjector

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) for a minimum of 12 weeks, followed by methotrexate in combination with at least two other DMARDs, such as hydroxychloroquine and sulfasalazine, for a minimum of 12 weeks;

or

- Initial use of triple DMARD therapy with methotrexate in combination with at least two other DMARDs, such as hydroxychloroquine and sulfasalazine, for a minimum of 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 may take up to 24 weeks, however if no improvement is seen after 12 weeks of triple DMARD use, therapy should be changed.
- If the patient is intolerant to triple DMARD therapy, then dual therapy with DMARDs (methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) must be considered.
- Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above.
- Intolerant is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs. The nature of intolerance(s) must be clearly documented.

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:
  - Golimumab: 50mg once a month with no dose escalation permitted

Ankylosing Spondylitis: 50mg/0.5ml Prefilled syringe, 50mg/0.5ml Autoinjector

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 NSAID's at the optimum dose for a minimum period of 3 months observation or in whom NSAID's are contraindicated,

OR

- have peripheral symptoms and who have failed to respond to, or have contraindications to the sequential use of at least 2 NSAID's 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.

Requests for renewal must include information showing the beneficial effects of the treatment, specifically:

- a decrease of at least 2 points on the BASDAI scale, compared with the pre-treatment score;

OR

- patient and expert opinion of an adequate clinical response as indicated by a significant functional improvement (measured by outcomes such as HAQ or "ability to return to work").

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 internist.
- Combined use of more than one biologic DMARD will not be reimbursed.
- Approvals will be for a maximum of 50mg per month.
- Initial Approval: 4 months.
- Renewal Approval: 1 year.
- Maximum Dosage Approved:
- Maximum Dosage Approved:
    - Golimumab: 50mg once a month with no dose escalation permitted

Psoriatic Arthritis: 50mg/0.5ml Prefilled syringe, 50mg/0.5ml Autoinjector

For patients with active psoriatic arthritis who meet **all** of the following criteria:

- Have at least three active and tender joints.
- Have not responded to an adequate trial of two DMARDs or have an intolerance or contraindication to DMARDs.

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 50mg per month.
- Initial Approval: 4 months.
- Renewal Approval: 1 year.
    - Requests for renewal can be reassessed for yearly coverage dependent on achieving improvement in symptoms of at least 20% (*20% improvement in the American College of Rheumatology response criteria (ACR 20) or response using the Psoriatic Arthritis Response Criteria).*
- Maximum Dosage Approved:
    - Golimumab: 50mg once a month with no dose escalation permitted

Ulcerative Colitis: 50mg/0.5ml Prefilled syringe, 50mg/0.5ml Autoinjector, 100mg/1.0mL Prefilled syringe, 100mg/1.0mL Autoinjector

For the treatment of adult patients with moderately to severely active ulcerative colitis who have a partial Mayo score > 4, and a rectal bleeding subscore ≥ 2 and are:

- refractory or intolerant to conventional therapy (i.e. 5-ASA for a minimum of 4 weeks, and prednisone ≥ 40mg daily for two weeks or IV equivalent for one week); or
- corticosteroid dependent (i.e. cannot be tapered from corticosteroids without disease recurrence; or have relapsed within three months of stopping corticosteroids; or require two or more courses of corticosteroids within one year.)

Renewal requests must include information demonstrating the beneficial effects of the treatment, specifically:
- a decrease in the partial Mayo score ≥ 2 from baseline, and
- a decrease in the rectal bleeding subscore ≥1.

Clinical Notes:
- Consideration will be given for patients who have not received a four week trial of aminosalicylates if disease is severe (partial Mayo score > 6).
- 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 gastroenterologist or physician with a specialty in gastroenterology.
- Combined use of more than one biologic DMARD will not be reimbursed.
- Initial dose: 200 mg initially administered by subcutaneous injection at Week 0, followed by 100 mg at Week 2 and then 50 mg every 4 weeks, thereafter.
- Initial Approval: 16 weeks.
- Renewal Approval: 1 year.

[±] **Please note:** The 100mg/1mL dosage forms are indicated for the treatment of ulcerative colitis only.

To facilitate this process, a specific Anti-TNF agents for Ulcerative Colitis Special Authorization Form has been developed and can be found at: http://www.health.gov.nl.ca/health/forms/pdf/IBD.pdf

Updated April 2017

Health and Community Services

Granisetron HCL (Kytril 1mg tablet & generics)

The following Anti-emetics are covered by the Program as open benefits, with limitations, for chemo induced nausea and vomiting only:
***Ondansetron 4mg and 8mg tab**: up to 3 tablets in a 24 hour period **Granisetron 1mg tab:** up to 2 tablets in a 24 hour period*
***Dolasetron 100mg tab:** 1 tablet in a 24 hour period*

The quantity limits above may only be filled as an open benefit for the first fill of any chemo anti-emetic drug. A special authorization is required for a higher quantity dispensed than noted above for a first fill or for any subsequent fills of any chemo anti-emetic drug.

Special Authorization criteria:

Coverage is considered for the treatment of emesis in patients who:

- are receiving **moderate to highly** emetogenic chemotherapy **OR**
- are receiving **mildly** emetogenic chemotherapy and have experienced episodes of nausea and vomiting related to such treatment, not responding to therapeutic doses of benefit antiemetics (metoclopramide, dexamethasone and prochlorperazine), or where these agents are not tolerated or contraindicated **OR**
- Post **radiation** therapy

Duration of therapy:

- Coverage will be provided to a maximum of **48 hours post chemo** for all patients (i.e. to a maximum of 9 tablets of ondansetron for a 1 day iv chemo regimen).
- Coverage will be limited to **one dose post-radiation** therapy.

In order to accurately assess requests for coverage, we require the following information:

For Chemotherapy:
-chemotherapy agents (including dose)
-number of days per cycle for each agent
-cycle frequency
-expected treatment duration (total number of cycles)
-previous antiemetic trials and the outcome

For Radiotherapy:
-targeted area
-number of days per cycle
-cycle frequency
-expected treatment duration (total number of cycles)

-previous antiemetic trials and the outcome

Duration of approval will be for the full course of the chemotherapy regimen.

Other drug and non-drug causes or pre-existing nausea and vomiting should be identified and eliminated.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated August 2011

Health and Community Services

Hydromorphone (Hydromorph Contin 3mg, 4.5mg, 6mg, 9mg, 12mg, 18mg, 24mg, 30mg)

For patients with persistent pain* who have been stabilized on a titrated dose of an oral short-acting hydromorphone product OR whose pain is not adequately controlled or who are intolerant to oral sustained-release morphine or oxycodone products despite dose titration and adjuvant antiemetics and laxatives.

*** Please note**: In order to assess requests for coverage in the treatment of non-malignant pain the Department will require the following information:

- Results of any xrays/CT scans/MRIs.
- Information relating to any consultations completed and their recommendations (ie surgical, orthopedic and/or physiotherapy consultations).
- Surgical history.
- Current analgesic uses, current dosage, and assessment of current level of pain control.
- Use of antidepressants and/or anticonvulsants if pain is neuropathic.
- Any other information you feel is pertinent to the request.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated April 2012

Health and Community Services

IBRUTINIB (IMBRUVICA 140 MG CAPSULE)

1. For patients with previously untreated chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) for whom fludarabine-based treatment is considered inappropriate, such as patients with high risk disease (example: chromosome 17p deletion).

2. For patients with chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) who have received at least one prior therapy and are considered inappropriate for treatment or retreatment with a fludarabine-based regimen.

3. For the treatment of patients with relapsed / refractory mantle cell lymphoma (MCL)

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.

Claim Notes:

Sequential use of ibrutinib and Zydelig (idelalisib) will not be reimbursed. Exceptions may be considered in the case of intolerance or contraindication without disease progression, or when required as a bridge to allogeneic stem cell transplant.
Initial approval: 1 year
Renewal approval: 1 year

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated August 2018

Health and Community Services

ICATIBANT (FIRAZYR 30MG/ML pre-filled syringes)

For the treatment of acute attacks of hereditary angioedema (HAE) in adults with lab confirmed c1-esterase inhibitor deficiency (type I or type II) under the following conditions:

- Treatment of non-laryngeal attacks of at least moderate severity, **or**
- Treatment of acute laryngeal attacks

Clinical Notes:

- Coverage is limited to a single dose for self-administration per attack
- Must be prescribed by physicians with experience in the treatment of HAE

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated October 2018

Health and Community Services

IDELALISIB (ZYDELIG) 100mg, 150mg tablets

Idelalisib (Zydelig) in combination with rituximab for the treatment of patients with relapsed chronic lymphocytic leukemia (CLL). Treatment should continue until unacceptable toxicity or disease progression.

Approval period: 12 months

Dosing: 150mg twice daily

Renewals will be considered for patients who do not have evidence of disease progression AND who have not developed unacceptable toxicities that require discontinuation of idelalisib.

Patients previously approved for Imbruvica (Ibrutinib) coverage and whose disease has progressed are not eligible for coverage of Zydelig (idelalisib).

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated January 2017

Health and Community Services

Imiquimod (Aldara 5% cream & generics)

- For the treatment of external genital and perianal warts and condyloma acuminata in adults.

- For the treatment of actinic keratosis on the head and neck in patients who have failed treatment with 5FU and cryotherapy.

- For treatment of biopsy-confirmed primary superficial basal cell carcinoma:

    - with a tumor diameter of ≤ 2 cm **AND**
    - located on the trunk, neck or extremities (excluding hands and feet) **AND**
    - where surgery or irradiation therapy is not medically indicated
        - Recurrent lesions in previously irradiated area OR
        - Multiple lesions, too numerous to irradiate or remove surgically.

    Approval Period: 6 weeks (renewals for the same tumor will not be considered).
    Note: Surgical management should be considered first-line for superficial basal cell carcinoma in most patients, especially for isolated lesions.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated May 2014

Health and Community Services

INDACATEROL/GLYCOPYRRONIUM (ULTIBRO BREEZHALER 110-50 MCG)

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 bronchodilator (long-acting beta-$_2$ agonist [LABA] or long-acting anticholinergic [LAAC])

Clinical Notes:

- Moderate to severe COPD is defined by spirometry (post-bronchodilator) FEV_1 < 60% predicted and FEV_1/FVC ratio of < 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$_2$ agonist (LABA) or long-acting anticholinergic therapy (LAAC).

Please visit the link below if you require our Chronic Obstructive Pulmonary Disease special authorization form:
http://www.health.gov.nl.ca/health/prescription/Chronic_Obstructive_Pulmonary_Disease_Form_2017.pdf

Updated July 2015

Health and Community Services

INDACATEROL (ONBREZ BREEZHALER 75ug CAPSULE)

Chronic Obstructive Pulmonary Disease (COPD):

- 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 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 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.

Please visit the link below if you require our Chronic Obstructive Pulmonary Disease special authorization form:
http://www.health.gov.nl.ca/health/prescription/Chronic_Obstructive_Pulmonary_Disease_Form_2017.pdf

Updated November 2015

Health and Community Services

INFLIXIMAB (INFLECTRA 100MG Vial, RENFLEXIS 100MG/Vial, Remicade 100MG VIAL)

Rheumatoid arthritis (RA): (Inflectra, Renflexis & Remicade)

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) for a minimum of 12 weeks, followed by methotrexate in combination with at least two other DMARDs, such as hydroxychloroquine and sulfasalazine, for a minimum of 12 weeks;

OR

- Initial use of triple DMARD therapy with methotrexate in combination with at least two other DMARDs, such as hydroxychloroquine and sulfasalazine, for a minimum of 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 may take up to 24 weeks, however if no improvement is seen after 12 weeks of triple DMARD use, therapy should be changed.
- If the patient is intolerant to triple DMARD therapy, then dual therapy with DMARDs (methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) must be considered.
- Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above.
- Intolerant is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs. The nature of intolerance(s) must be clearly documented.

Claim Notes:

- Must be prescribed by a rheumatologist.
- Combined use of more than one biologic DMARD will not be reimbursed.
- Patients will not be permitted to switch from Inflectra or Renflexis to another infliximab product or vice versa, if previously trialed and deemed unresponsive to therapy.
- 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 followed by maintenance therapy of 3mg/kg/dose every 8 weeks.

Please note: Inflectra or Renflexis are the preferred infliximab therapy for treatment naïve patients (coverage will only be considered for Remicade in patients stabilized prior to June 1, 2016)

To facilitate this process specific RA Medications Special Authorization Forms have been developed and can be found at:
http://www.health.gov.nl.ca/health/prescription/ra_meds_initiation.pdf
http://www.health.gov.nl.ca/health/prescription/ra_meds_continuation_request.pdf

Ankylosing Spondylitis: (Inflectra, Renflexis & Remicade)
For the treatment of patients with moderate to severe ankylosing spondylitis (e.g. Bath AS Disease Activity Index (BASDAI) score $\geq$ 4 on 10 point scale) who:

- have axial symptoms* and who have failed to respond to the sequential use of at least 2 NSAIDs at the optimum dose for a minimum period of 3 months observation or in whom NSAIDs are contraindicated

OR

- have peripheral symptoms and who have failed to respond to, or have contraindications to, the sequential use of at least 2 NSAIDs at the optimum dose for a minimum period of 3 months observation and have had an inadequate response to an optimal dose or maximal tolerated dose of a DMARD.

Renewal Requests:

- Requests for renewal must include information showing the beneficial effects of the treatment, specifically:
  - a decrease of at least 2 points on the BASDAI scale, compared with the pre-treatment score;

  OR

  - patient and expert opinion of an adequate clinical response as indicated by a significant functional improvement (measured by outcomes such as HAQ or “ability to return to work”).

Clinical Notes:

- 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
- Patients will not be permitted to switch from Inflectra or Renflexis to another infliximab product or vice versa, if previously trialed and deemed unresponsive to therapy.

Claim Notes:

- Must be prescribed by a rheumatologist or internist
- Combined use of more than one biologic DMARD will not be reimbursed.
- Initial Approval: 6 months.
- Renewal Approval: 1 year.
- Approvals will be for a maximum of 5mg/kg at weeks 0, 2 and 6, then every 6 to 8 weeks thereafter.

Please note: Inflectra or Renflexis are the preferred infliximab therapy for treatment naïve patients (coverage will only be considered for Remicade in patients stabilized prior to June 1, 2016)

To facilitate this process specific **RA Medications Special Authorization Forms** have been developed and can be found at:
http://www.health.gov.nl.ca/health/prescription/ra_meds_initiation.pdf
http://www.health.gov.nl.ca/health/prescription/ra_meds_continuation_request.pdf

Chronic Plaque Psoriasis (PsO): (Inflectra, Renflexis & Remicade)
For patients with severe, debilitating PsO who meet all of the following criteria:

- Body Surface Area (BSA) involvement of > 10% and/or significant involvement of the face, hands, feet or genital region.
- Failure to respond to, contraindications to or intolerant of methotrexate and cyclosporine.
- Failure to respond to, intolerant of or unable to access phototherapy.

Clinical Notes:

- Continuation of therapy beyond 12 weeks will be based on response. Patients not responding adequately at these time points should have treatment discontinued with no further treatment with the same agent recommended.
- An adequate response is defined as either:
    - ≥75% reduction in the Psoriasis Area and Severity Index (PASI) score from when treatment started (PASI 75),

    OR
    - ≥50% reduction in the PASI score (PASI 50) with a ≥5 point improvement in the Dermatology Life Quality Index (DLQI) from when treatment started,

    OR
    - A quantitative reduction in BSA affected with qualitative consideration of specific regions such as face, hands, feet, or genital region. 3. Concurrent use of >1 biologic will not be approved
- Combined use of more than one biologic DMARD will not be reimbursed.
- Patients will not be permitted to switch from Inflectra or Renflexis to another infliximab product or vice versa, if previously trialed and deemed unresponsive to therapy.

Claim Notes:

- Must be prescribed by a dermatologist.
- Combined use of more than one biologic DMARD will not be reimbursed.
- Initial Approval: 12 weeks.
- Renewal Approval: 1 year.
- Approval limited to a dose of 5 mg/kg administered at 0, 2, and 6 weeks, then every 8 weeks up to a year (if response criteria met at 12 weeks)

Please note: Inflectra or Renflexis are the preferred infliximab therapy for treatment naïve patients (coverage will only be considered for Remicade in patients stabilized prior to June 1, 2016)

To facilitate this process a specific **Chronic Plaque Psoriasis Special Authorization Form** has been developed and can be found at:
http://www.health.gov.nl.ca/health/prescription/chronic_plaque_psoriasis_meds_coverage_request.pdf

Psoriatic Arthritis: (Inflectra, Renflexis only)

For patients with active psoriatic arthritis who meet **all** of the following criteria:

- Have at least three active and tender joints.
- Have not responded to an adequate trial of two DMARDs or have an intolerance or contraindication to DMARDs.

Claim Notes:

- Must be prescribed by a rheumatologist.
- All requests for coverage of infliximab for infliximab-naïve patients (including those on induction therapy) will be approved for Inflectra or Renflexis brand only.
- Combined use of more than one biologic DMARD will not be reimbursed.
- Initial Approval: 24 weeks.
- Renewal Approval: 1 year. Requests for renewal can be reassessed for yearly coverage dependent on achieving improvement in symptoms of at least 20% (20% improvement in the American College of Rheumatology response criteria (ACR 20) or response using the Psoriatic Arthritis Response Criteria).
- Approvals will be for a maximum of 5mg/kg at weeks 0, 2 and 6, then every 6 to 8 weeks thereafter.

Please note: Inflectra or Renflexis is the preferred infliximab therapy for treatment naïve patients (coverage will only be considered for Remicade in patients stabilized prior to June 1, 2016)

To facilitate this process specific **RA Medication Special Authorization Forms** have been developed and can be found at:
http://www.health.gov.nl.ca/health/prescription/ra_meds_initiation.pdf
http://www.health.gov.nl.ca/health/prescription/ra_meds_continuation_request.pdf

Crohn's disease: (Inflectra, Renflexis & Remicade)

For the treatment of pediatric[1] and adult patients with moderately to severely active Crohn's disease who have contraindications, or are refractory, to therapy with corticosteroids and other immunosuppressants.

Claim Notes:

- Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology.
- Concurrent use of other biologic DMARDS not approved.
- Initial request must include current Crohn's Disease Activity Index (CDAI) or the Harvey Bradshaw Index Assessment (HBI) score.
- All requests for coverage for infliximab-naïve patients (including those on induction therapy) will be approved for Inflectra or Renflexis only.
- Initial Approval: 3 infusions of infliximab 5mg/kg at week 0, 2 & 6.

- Renewal Approval: Continued coverage dependent on evidence of response using criteria such the 100 point reduction in Crohn's Disease Activity Index (CDAI) or the Harvey-Bradshaw Index Assessment (HBI) with a score of 5 or less or a decrease in score of 4 or more.
- Renflexis is indicated for use in pediatric[1] patients 9 years of age and older. The safety and efficacy of RENFLEXIS is not established in patients less than 9 years of age.

The maximum approved dose is 5mg/kg every 8 weeks.
Please note: Inflectra or Renflexis are the preferred infliximab therapy for treatment naïve patients (coverage will only be considered for Remicade in patients stabilized prior to December 5, 2016)

To facilitate this process, a specific **Anti-TNF agents for Crohn's disease Special Authorization Form** has been developed and can be found at:
http://www.health.gov.nl.ca/health/forms/pdf/IBD.pdf

Ulcerative colitis (UC) (Inflectra or Renflexis only)

For the treatment of pediatric[2] adult patients with moderately to severely active ulcerative colitis who have a partial Mayo score > 4, and a rectal bleeding subscore ≥ 2 and are:

- refractory or intolerant to conventional therapy (i.e. 5-ASA for a minimum of 4 weeks, and prednisone ≥ 40mg daily for two weeks or IV equivalent for one week); or
- corticosteroid dependent (i.e. cannot be tapered from corticosteroids without disease recurrence; or have relapsed within three months of stopping corticosteroids; or require two or more courses of corticosteroids within one year.)

Renewal requests must include information demonstrating the beneficial effects of the treatment, specifically:
- a decrease in the partial Mayo score ≥ 2 from baseline, and
- a decrease in the rectal bleeding subscore ≥1.

Clinical Notes:
- Consideration will be given for patients who have not received a four week trial of aminosalicylates if disease is severe (partial Mayo score > 6).
- 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 gastroenterologist or physician with a specialty in gastroenterology.

- Combined use of more than one biologic DMARD will not be reimbursed.
- All requests will be approved for Inflectra or Renflexis only; requests for Remicade will not be considered.
- Renflexis is indicated for use in pediatric[2] patients 6 years of age and older. The safety and efficacy of RENFLEXIS have not been established in patients less than 6 years of age.
- Initial Approval: 12 weeks.
- Renewal Approval: 1 year.
- **Maximum Quantity Reimbursed:**
  Infliximab: 5 mg/kg at weeks 0, 2 and 6, then every 8 weeks thereafter.

To facilitate this process, a specific Anti-TNF agents for Ulcerative Colitis Special Authorization Form has been developed and can be found at:
http://www.health.gov.nl.ca/health/forms/pdf/IBD.pdf

Updated December 2018

Health and Community Services

INSULIN DETEMIR (LEVEMIR 100 UNIT/ML PENFILL, LEVEMIR FLEXTOUCH 100 unit/ml)

For patients who have been diagnosed with Type 1 or Type 2 diabetes AND

- who have experienced unexplained nocturnal hypoglycemia at least once a month despite optimal management with insulin glargine OR
- have documented severe or continuing systemic or local allergic reactions to both NPH insulin and insulin glargine OR
- who have experienced unexplained nocturnal hypoglycemia at least once a month despite optimal management with NPH insulin and who have documented severe or continuing systemic or local allergic reactions to insulin glargine

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/Levemir.pdf

Updated February 2018

Health and Community Services

INSULIN LISPRO (HUMALOG KWIKPEN 100 UNIT/ML, HUMALOG KWIKPEN 200 UNIT/ML, HUMALOG 100 UNIT/ML VIAL, PEN)

- For patients with insulin-dependant diabetes on multiple insulin dosing (greater or equal to 3 injections of regular insulin per day) and who are experiencing frequent hypoglycemia or poor glycemic control on their current regimen.

- For patients with insulin-dependant diabetes who are using an insulin pump[1].

- For patients with insulin-dependant diabetes who, for convenience purposes, wish to use this insulin and are willing to pay the difference in price from traditional regular insulin (i.e. NLPDP will pay the cost normally reimbursed for regular insulin (Humulin R) and the patient would be responsible for the difference). (HUMALOG 100 UNIT/ML VIAL, PEN only**)**

Please Note:
[1]HUMALOG KWIKPEN 200 unit/ml should not be administered via a subcutaneous infusion pump, or mixed with any other insulin (including HUMALOG 100 units/mL).

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated February 2017

Newfoundland Labrador

Health and Community Services

Interferon alfa-2a (Roferon A 3M iu, 9M iu, or 18M iu injection)

- For chronic hepatitis B or C.
- For chronic myelogenous leukemia (CML).
- For hairy cell leukemia.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2010

Newfoundland Labrador

Health and Community Services

Interferon alfa-2b (Intron A 3M iu, 5M iu, or 10M iu injection)

- For chronic Hepatitis B or C.
- For malignant melanoma.
- For basal cell carcinoma.
- For chronic myelogenous leukemia (CML).
- For hairy cell leukemia.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2010

Health and Community Services

Interferon Beta-1A (Avonex, Avonex PS, Avonex Pen, Rebif, Rebif Initiation pack, Multi-dose cartridge, Plegridy Starter pack 63mcg/0.5mL, 94mcg/0.5mL prefilled pen and prefilled syringe, Admin pack 125mcg/0.5mL prefilled pen and prefilled syringe) and Interferon Beta-1B (Betaseron, Betaseron Initiation Pack, Extavia 0.3mg vial)

For the treatment of patients with Multiple Sclerosis (MS) who meet the following criteria:

- Written request from a neurologist.
- Subjects over 18 years.
- Confident diagnosis of relapsing-remitting MS.
- Two relapses in the previous 24 months (Relapse defined as the appearance of symptoms and signs compatible with MS, lasting greater than 24 hours and not due to a rise in temperature.)
- Kurtzke EDSS score of 6.5 or less (assistance needed to walk about 20m without resting).

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated May 2017

Health and Community Services

IRON DEXTRAN COMPLEX (INFUFER 50mg/ml VIAL, DEXIRON 50mg/ml AMPUL)

DIN 02221780, DIN 02205963

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.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated November 2015

Health and Community Services

ITRACONAZOLE (SPORANOX 100 MG CAPSULE)

- For the treatment of severe systemic fungal infections not responding to alternative therapy.
- For the treatment of severe or resistant fungal infections in immunocompromised patients not responding to alternative therapy.
- For the treatment of skin infections (excluding onychomycosis) caused by dermatophyte fungi not responding to alternative therapy.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated November 2015

Newfoundland Labrador

Health and Community Services

IVABRADINE (LANCORA 5mg, 7.5mg TABLET)

For the treatment of stable chronic heart failure with reduced left ventricular ejection fraction (LVEF) (<35%) in adult patients with New York Heart Association (NYHA) classes II or III who are in sinus rhythm with a resting heart rate >77 beats per minute (bpm), to reduce the incidence of cardiovascular mortality and hospitalizations for worsening heart failure, administered in combination with standard chronic heart failure therapies if the following are met:

- Patients with NYHA class II to III symptoms despite at least four weeks of treatment with a stable dose of an angiotensin converting enzyme inhibitor (ACEI) or an angiotensin II receptor blocker (ARB) in combination with a beta blocker and, if tolerated, a mineralocorticoid receptor antagonist (MRA) AND
- Patients with at least one hospitalization due to heart failure in the last year AND
- Resting heart rate must be documented as ≥ 77 bpm on average using either an ECG on at least three separate visits or by continuous monitoring AND
- Patients should be under the care of a specialist experienced in the treatment of heart failure for patient selection, titration, follow-up and monitoring.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated December 2018

Health and Community Services

IVACAFTOR (KALYDECO 150 MG TABLET)

For the treatment of cystic fibrosis in patients who meet the following criteria:

- Age 6 years and older; **AND**
- Patient has documented G551D mutation in the Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) gene.

Initial renewal criteria[1]:

Renewals will be considered in patients with documented response to treatment (after at least 6 months of therapy), as evidenced by the following:

In cases where the patient's sweat chloride levels prior to commencing therapy were above 60 mmol/litre:

i. the Patient's sweat chloride level fell below 60 mmol/litre; **OR**
ii. the Patient's sweat chloride level is 30% lower than the level reported in a previous test;

In cases where the patient's sweat chloride levels prior to commencing therapy were below 60 mmol/litre:

i. the patient's sweat chloride level is 30% lower than the level reported in a previous test; **OR**
ii. the patient demonstrates a sustained absolute improvement in FEV1 of at least 5% when compared to the FEV1 test conducted prior to the commencement of therapy.

Subsequent renewal criteria after the patient has met the initial renewal criteria:
The Patient is continuing to benefit from therapy with Kalydeco.

[1] It should be noted that, while baseline sweat chloride levels and FEV1 are not required to meet initial approval criteria for Kalydeco, these parameters may be used to evaluate the effect of Kalydeco upon renewal of the request. It is important that the physician measures baseline sweat chloride levels and FEV1 and provides this information upon renewal to avoid delays in the assessment of the renewal funding decision as these measurements may be required to evaluate renewal requests.

Dispensing Management Principles: 150 mg of Kalydeco every 12 hours may be approved. Patients will be limited to receiving a one-month supply per prescription from the dispensing pharmacy.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2015

Health and Community Services

IXEKIZUMAB (TALTZ 80 MG/ML SYRINGE, 80 MG/ML AUTOINJECTOR)

Psoriatic Arthritis:

For patients with active psoriatic arthritis who meet **all** of the following criteria:

- Have at least three active and tender joints, and
- Have not responded to an adequate trial of two DMARDs or have an intolerance or contraindication to DMARDs.

Claim Notes:

- Must be prescribed by a rheumatologist.
- Combined use of more than one biologic DMARD will not be reimbursed.
- Initial Approval: 6 months.
- The recommended dose is 160 mg by subcutaneous injection (two 80 mg injections) at Week 0, followed by 80 mg every 4 weeks.
- Renewal Approval: 1 year. Requests for renewal can be reassessed for yearly coverage dependent on achieving improvement in symptoms of at least 20% (20% improvement in the American College of Rheumatology response criteria (ACR 20) or response using the Psoriatic Arthritis Response Criteria).

Please visit the link below if you require our standard special authorization form:
https://www.health.gov.nl.ca/health/prescription/ra_meds_initiation.pdf
https://www.health.gov.nl.ca/health/prescription/ra_meds_continuation_request.pdf

Psoriasis

For patients with severe, debilitating 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 to, or unable to access phototherapy.

Requests for renewal must include information demonstrating an adequate response, defined as:

- Achievement of a ≥ 75% reduction in Psoriasis Area Severity Index (PASI) score, **or**
- A ≥ 50% reduction in PASI with a ≥ 5 point improvement in the Dermatology Life Quality Index (DLQI) **or**
- A significant reduction in BSA, involved with consideration of important regions such as the face, hands, or genital region.
- Ongoing coverage for ixekizumab maintenance therapy should only be provided for responders, as noted above.

Claim Notes:

- Must be prescribed by a dermatologist.
- Combined use of more than one biologic DMARD will not be reimbursed.
- Initial approval limited to 12 weeks.
- Approved for maintenance therapy not exceeding 80mg every four weeks.
- The recommended dose of ixekizumab is a 160 mg subcutaneous injection (SC) at week 0; followed by 80 mg SC at weeks 2, 4, 6, 8, 10, and 12; followed by 80 mg SC every 4 weeks.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/chronic_plaque_psoriasis_meds_coverage_request.pdf

Updated January 2019

Health and Community Services

Locosamide (Vimpat 50mg, 100mg, 150mg & 200mg tablets)

For the treatment of patients with refractory partial-onset seizures as adjunctive therapy who meet **all** of the following criteria:

- Are under the care of a neurologist or physician experienced in the treatment of epilepsy **AND**
- Are currently receiving two or more antiepileptic drugs **AND**
- In whom all other antiepileptic drugs are ineffective or not appropriate.

Please visit the following link if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated August 2011

Health and Community Services

Lactulose (generics)

- For the prophylaxis and treatment of portal-systemic encephatopathy (PSE).
- In combination with rifaximin, for patients unable to achieve adequate control of overt hepatic encephalopathy (HE) recurrence with maximal tolerated doses of lactulose alone.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated May 2016

Health and Community Services

Lansoprazole (Prevacid 15mg, 30mg capsule and generics, Prevacid FasTab 15mg, 30mg)

Requests for lansoprazole will be considered for patients in whom there has been therapeutic failure of 8 week trials of regular benefit PPIs (i.e. omeprazole 20mg, rabeprazole 20mg daily, pantoprazole sodium 40mg daily and pantoprazole magnesium 40mg daily.)

Requests for lansoprazole 30mg BID will only be considered if there has been inadequate response to an 8 week trial of lansoprazole 30mg OD dosing for the indications listed below:

Indication and Diagnostic Information	Maximum Approval Period	
Symptomatic GERD or other reflux-associated indication (i.e. non-cardiac chest pain).	Considered for short-term (8 weeks) approval	
Erosive/ulcerative esophagitis or Barrett's esophagus	Considered for long term approval	
Peptic Ulcer Disease (PUD): Confirmed Gastric/duodenal ulcers	Considered for up to 12 weeks	
Zollinger-Ellison Syndrome	Considered for long term approval	
Gastro-duodenal protection (ulcer prophylaxis) for high risk patients (e.g. high risk NSAID users).	Considered for one year with reassessment.	
H pylori eradication	Regimen	Drugs and dose
	Bismuth quadruple (PBMT)	PPI standard dose BID[a] Metronidazole 500 mg tid to qid Tetracycline 500 mg QID Bismuth subsalicylate[b]
	Non bismuth quadruple therapy	PPI standard dose BID[a] Metronidazole 500 mg

		tid to qid Amoxicillin 1000 mg bid Clarithromycin 500 mg bid
	PAC triple therapy (same as HP PAC)	PPI standard dose BID[a] Amoxicillin 1000 mg bid Clarithromycin 500 mg bid
	PMC triple therapy	PPI standard dose BID[a] Metronidazole 500 mg tid to qid Clarithromycin 500 mg bid
	PAM triple therapy	PPI standard dose BID[a] Amoxicillin 1000 mg bid Metronidazole 500 mg tid to qid
	A second treatment will be considered providing that at least a four-week period has elapsed since the end of the previous treatment and that retreatment within a three month period uses a different antibiotic regimen. Additional treatments within one year will require diagnostic confirmation of the continued presence of H. pylori. Additional treatments within one year will require diagnostic confirmation of the continued presence of H. pylori. *A PPI at BID dosing will be reimbursed with special authorization as part of an approved H. pylori eradication regimen for 14 days.	

a. Standard dose PPI: lansoprazole 30 mg, omeprazole 20 mg, pantoprazole 40 mg, and rabeprazole 20mg.
b. Bismuth subsalicylate (Pepto Bismol) 262 mg 2 tablets four times daily.

Prevacid 15mg, 30mg FasTabs are considered for patients who meet the indications above **and** who require delivery of medication through a feeding tube.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated March 2018

Health and Community Services

LEDIPASVIR/SOFOSBUVIR (HARVONI 90mg/400mg TABLET)

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

	Approval Period and Regimen
Genotype 1 • Treatment-naïve without cirrhosis, who have pre-treatment HCV RNA level < 6 million IU/mL and mono-HCV infected only	8 weeks
Genotype 1 • Treatment-naïve without cirrhosis, who have pre-treatment HCV RNA level ≥ 6 million IU/mL • Treatment-naïve with compensated cirrhosis • Treatment-naïve with advanced liver fibrosis (Fibrosis stage F3-F4) • Treatment-experienced without cirrhosis • HCV/HIV co-infected without cirrhosis or with compensated cirrhosis	12 weeks
Genotype 1 • Treatment-experienced with compensated cirrhosis	24 weeks
Genotype 1 • Decompensated cirrhosis • Liver transplant recipients without cirrhosis or with compensated cirrhosis	12 weeks in combination with ribavirin

Patients must also meet all of the following criteria:

- Prescribed by a hepatologist, gastroenterologist, or infectious disease specialist (or other prescribers with expertise in the treatment of hepatitis C infection)
- Lab-confirmed hepatitis C genotype 1
- Quantitative HCV RNA value within the last 6 months.
- Fibrosis stage

Clinical Notes:

1. Treatment-experienced is defined as a patient who has been previously treated with peginterferon/ribavirin regimen, including regimen containing HCV protease inhibitors, and who has not experienced an adequate response.
2. 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.
3. Compensated cirrhosis is defined as a Child-Turcotte-Pugh (CTP) score of 5 to 6 (Class A) and decompensated cirrhosis as a CTP score of 7 or above (Class B or C).
4. Re-treatment for direct-acting antiviral failures will be considered on a case-by-case basis under the formulary exception process.

Claim Note:
Claims that exceed the maximum claim amount of $9,999.99 must be divided and submitted as separate transactions on different days.
Please note: A single professional fee will be paid per 30 day supply.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/forms/pdf/hepatitis_C_treatment_request.pdf

Updated August 2017

Health and Community Services

Lenalidomide (Revlimid 5mg, 10mg, 15mg, 20mg & 25mg capsules)

Newly diagnosed Multiple Myeloma following autologous stem-cell transplantation (Post-ASCT) - NDMM

- For maintenance treatment
- 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 Approval Period: 3 months
Initial dose: 10mg daily AND dose adjustments (5-15mg) may be necessary based on individual patient characteristics/responses

Renewals will be considered for patients who do not have evidence of disease progression AND who have not developed unacceptable toxicities that require discontinuation of lenalidomide.
Renewal Approval Period: 12 months

Newly Diagnosed Multiple Myeloma Not Eligible for Stem Cell Transplant – TNE

For first line treatment of patients with multiple myeloma who are not eligible for autologous stem cell transplantation (TNE). Treatment should be in combination with dexamethasone for patients with an ECOG performance status less than or equal to 2 and until disease progression.

Approval Period: 12 months
Recommended Dose: 25mg daily for first 21 days of repeated 28 day cycles
Renewal requires physician reassessment and request.

Relapsed Refractory Multiple Myeloma – MM-AOPT

For the treatment of multiple myeloma when used in combination with dexamethasone, in patients who:

- Are not candidates for autologous stem cell transplant
  AND
- Where the patient is either:
  - Refractory to or has relapsed after the conclusion of initial or subsequent treatments and who is unsuitable for further chemotherapy;
    OR
  - Has completed at least one full treatment regimen as initial therapy and has experienced an intolerance to their current chemotherapy

Approval Period: 12 months
Recommended Dose: 25mg daily for first 21 days of repeated 28 day cycles
Renewal requires physician reassessment and request.

Myelodysplastic Syndrome (MDS) – MDS

For the treatment of Myelodysplastic Syndrome (MDS) in patients with:

- Demonstrated diagnosis of MDS on bone marrow aspiration
- Presence of 5-q deletion documented by appropriate generic testing
- International Prognostic Scoring System (IPSS) risk category low or intermediate-1*
- Presence of symptomatic anemia (defined as transfusion dependent)**

* Calculator available on www.uptodate.com
** Requests for patients who are not transfusion-dependent will be considered on a case-by-case basis. The physician should provide clinical evidence of symptomatic anemia affecting the patient's quality of life and the rationale for why transfusions are not being used.

Initial approval period: 6 months
Recommended starting dose: 10mg daily for first 21 days of repeated 28 day cycles

Renewal criteria:

- For patients who were transfusion-dependent and have demonstrated a reduction in transfusion requirements of at least a 50%.
- Renewal requests for all other patients will be considered on a case-by-case basis. Information describing the results of serial CBC (pre- and post-lenalidomide) and any other objective evidence of response should be included.

Renewal Approval Period: 12 months

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated December 2016

Health and Community Services

LENVATINIB (LENVIMA) 24MG, 20MG, 14MG AND 10MG CAPSULES

Treatment of patients with locally recurrent or metastatic, progressive, radioactive-iodine-refractory differentiated thyroid cancer (DTC). Treatment should be for patients with good performance status and who otherwise meet the eligibility criteria of the SELECT trial and should continue until treatment progression or unacceptable toxicity.

Approval Period: 12 months

Usual Dose: 24mg daily

Renewals will be considered for patients who do not have evidence of disease progression. AND who have not developed unacceptable toxicities that require discontinuation of lenvatinib.

SELECT Trial Eligibility Criteria:
Inclusion criteria:

- 18 Years and older
- Histologically or cytologically confirmed diagnosis of one of the following DTC subtypes: Papillary thyroid cancer (PTC) or follicular thyroid cancer (FTC).
- Measurable disease according to (RECIST 1.1) and confirmed by central radiographic review.
- 131 I-refractory/resistant disease.
- Evidence of disease progression within 12 months prior to signing informed consent (+1 month screening window).
- Prior treatment with 0 or 1 vascular endothelial growth-factor (VEGF) or vascular endothelial growth-factor receptors (VEGFR) targeted therapy.
- Adequate renal, liver, bone marrow, and blood coagulation function, as defined in the protocol.

Exclusion criteria:

- Anaplastic or medullary carcinoma of the thyroid
- 2 or more prior VEGF/ VEGFR-targeted therapies
- Received any anticancer treatment within 21 days or any investigational agent within 30 days prior to the first dose of study drug.

Updated May 2018

Health and Community Services

Letrozole (Femara 2.5mg & generics)

- First-line therapy in postmenopausal women with advanced breast cancer. (Indefinite coverage)
- For the adjuvant treatment of postmenopausal women with hormone receptor-positive invasive early breast cancer. (5 years)
- The extended adjuvant treatment of hormone receptor-positive invasive early breast cancer in postmenopausal women who have received approximately 5 years of prior standard adjuvant tamoxifen therapy. (5 years)

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated April 2014

Health and Community Services

LEVOCARNITINE (CARNITOR 100mg/ml solution, 330mg tablet)

- For the treatment of primary systemic carnitine deficiency.
- For the treatment of patients with an inborn error of metabolism that results in secondary carnitine deficiency.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated September 2014

Health and Community Services

LEVOFLOXACIN (LEVAQUIN 250mg, 500mg tablet & generics)

- For step-down therapy after hospital discharge for the treatment of nosocomial pneumonia, community acquired pneumonia (CAP) or acute exacerbation of chronic bronchitis (AECB).

- For the treatment of severe pneumonia in nursing home patients.

- For the treatment[1] of CAP in patients
    - with co-morbidity[2] upon radiographic confirmation of pneumonia, *or*
    - who have failed first line therapies (macrolide, doxycycline, amoxicillin-clavulanate).

- For the treatment[1] of AECB in complicated patients[3] who have failed treatment with one of the following (amoxicillin, doxycycline, TMP-SMX, cefuroxime, macrolide, ketolide or amoxicillin-clavulanate).

[1] If treated with an antibiotic within the past 3 months choose an antibiotic from a different class.

[2] Co-morbidity includes chronic lung disease, malignancy, diabetes, liver, renal or congestive heart failure, use of antibiotics or steroids in the past 3 months, suspected macroaspiration, hospitalization within last 3 months, HIV/AIDs, smoking, malnutrition or acute weight loss.

[3] Complicated AECB defined as increased cough and sputum, sputum purulence and increased dyspnea **AND**

- FEV_1 < 50% predicted
  OR
- FEV 50-65% and one of the following:
    - ≥ 4 exacerbations per year
    - Ischemic heart disease
    - Chronic oral steroid use
    - Antibiotic use in the past 3 months

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2010

Newfoundland Labrador

Health and Community Services

LINAGLIPTIN (TRAJENTA 5 MG TABLET)

For the treatment of type 2 diabetes as a third drug **added** to metformin **and** a sulfonylurea for patients with inadequate glycemic control on metformin and a sulfonylurea **AND** in whom insulin is not an option.

To facilitate this process a specific **Oral Diabetes Medications Special Authorization Form** has been developed and can be found at: http://www.health.gov.nl.ca/health/forms/pdf/oral_diabetes.pdf

Updated March 2012

Health and Community Services

LINAGLIPTIN/METFORMIN HCL (JENTADUETO 2.5mg-500mg, 2.5mg-850mg, 2.5mg-1000mg TABLET)

For the treatment of type 2 diabetes in patients with inadequate glycemic control on metformin and a sulfonylurea and in whom insulin is not an option AND who are already stabilized on therapy with metformin, a sulfonylurea and linagliptin, to replace the individual components of linagliptin and metformin in these patients.

To facilitate this process a specific **Oral Diabetes Medications Special Authorization Form** has been developed and can be found at:
http://www.health.gov.nl.ca/health/forms/pdf/oral_diabetes.pdf

Updated November 2014

Health and Community Services

Linezolid (Zyvoxam 600mg tablet & generics)

- For treatment of VRE (Vancomycin resistant enterococcus) proven infections.
- For the treatment of MRSA/MRSE (Methicillin resistant s.aureus/ methicillin resistant s.epidermidis) proven infections in those patients who are unresponsive to, or intolerant of vancomycin.

Upon the request of an infectious disease specialist only.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2010

Health and Community Services

LISDEXAMFETAMINE DIMESYLATE (VYVANSE 10mg, 20mg, 30mg, 40mg, 50mg, 60mg)

For treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients who:

- Have experienced unsatisfactory results due to poor symptom control, side effects, administrative barriers and/or societal barriers.

AND

- Have been tried on methylphenidate (immediate release or sustained release formulation) or dexamphetamine (immediate release or sustained release formulation) with unsatisfactory results.

Claim Notes:

- The maximum dose reimbursed is 60mg daily.

Please note: Reimbursement will not be considered for Biphentin, Concerta and/or Vyvanse concurrently with methylphenidate (immediate release or sustained release formulation) or dexamphetamine.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated November 2017

Health and Community Services

LURASIDONE (LATUDA 40mg, 80mg, 120mg TABLET)

For the treatment of schizophrenia and related psychotic disorders (not dementia related) in patients:

- with a history of inadequate response or intolerance to at least one less expensive antipsychotic agent

OR

- who have a contraindication to less expensive options.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated December 2016

Health and Community Services

Maracirov (Celsentri 150mg, 300mg tablets)

For the treatment of HIV-1 infection given in combination with other antiretroviral medications in patients:

- Who have CCR5 tropic viruses **and**
- Who have documented resistance to at least one agent from each of the three main classes of antiretroviral agents (nucleoside reverse transcriptase inhibitors, non- nucleoside reverse transcriptase inhibitors, protease inhibitors).

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2010

Newfoundland Labrador

Health and Community Services

MEPOLIZUMAB (NUCALA 100 MG VIAL)

For adjunctive treatment of adult patients with severe eosinophilic asthma who are inadequately controlled with high-dose inhaled corticosteroids (ICS) and one or more additional asthma controller(s) (e.g., a long-acting beta-agonist [LABA]), and have a blood eosinophil count of ≥ 150 cells/mcL at initiation of treatment with mepolizumab or ≥ 300 cells/mcL in the past 12 months, if one of the following clinical criteria are met:

Clinical Criteria:

- 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 pulmonary function tests (i.e., spirometry) OR
- Are treated with daily oral corticosteroids (OCS).

Stopping Criteria

- failure to achieve a decrease in any clinically significant exacerbations[1] at 12 months

OR

- failure to achieve a decrease in the maintenance OCS[2] dose at 12 months

Clinical Notes:

[1]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.

[2]A decrease in the maintenance OCS is defined as a decrease in OCS use 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.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated October 2018

Health and Community Services

Methadone For Addiction:

Methadone Maintenance (PIN 00967211): (Daily Witnessed Doses):

For patients diagnosed with opiate dependence and who are being treated for opiate withdrawal and/or opiate addiction. Before coverage is considered, the following information is required for assessment:

- A diagnosis of substance abuse or opiate withdrawal.
- History of drugs used, dose, route of administration and duration of dependence.
- Other treatment options tried (e.g. non-medical detox) and results.
- A Physician-Patient Treatment agreement must be signed.

Consideration for coverage of Methadone will only be given for patients who are undergoing random urine screening and participating in regular addictions counseling.

Concurrent usage of opiates will result in termination of coverage of Methadone by this Department.

To facilitate this process, a specific **Methadone Special Authorization Form** has been developed and can be found at:
http://www.health.gov.nl.ca/health/prescription/Methadone_Daily_Dispensing.pdf

Methadone Carry (Take-Home doses) (PIN 00907555):

The criteria for determining appropriateness for take-home doses are based on patient and community safety, and on clinical stability, where clinical stability can be defined by:

- Stable dose of methadone (with allowances for occasional dose increases or when tapering)
- Patient has been in Opioid Agonist Treatment Program for:
    - at least three months, or
    - for two months and either
        - Meets the conditions for accelerated schedule, or
        - Exceptional take-home doses on compassionate grounds.
    - for 4 weeks and lives in a community that does not have a pharmacy that is open on a weekend day, has no hospital available for weekend dispensing, does not have transportation to a pharmacy in a different community and the patient does not have any of the conditions where take-home doses shall not be prescribed, as listed in CPSNL MMT Standards and Guidelines.

- No recent drug or alcohol use with four consecutive weeks of documented negative random UDS tests before starting take-home doses
- Compliance with treatment directives
- Stable housing
- Emotional stability and good insight into take-home dose safety issues
- Capability to be reached in a timely fashion for notification of requirement for urine drug screens (typically being accessible by telephone)
- A written take-home dose agreement has been signed by the patient

Carry doses can be considered on a case by case basis for medical disability or compassionate basis with written request from the Methadone prescriber containing the appropriate documentation to support his/her request.

Concurrent usage of opiates will result in termination of coverage of Methadone by this Department.

To facilitate this process, a specific Methadone Carry Dose Special Authorization Form has been developed and can be found at:
http://www.health.gov.nl.ca/health/forms/pdf/Methadone_Take_Home_Doses.pdf

Updated January 2017

Health and Community Services

Methadone (Metadol 1mg, 5mg, 10mg, 25mg tablet)

Palliative analgesia:

For use as a replacement for other narcotic analgesics in palliative care patients who are requiring frequent and continuous dosing of short-acting opiates.

Chronic Non-Malignant Pain:

For use as a replacement for other narcotic analgesics in chronic non-malignant pain patients who have been thoroughly investigated and in whom alternate treatments (including treatment with lower potency opioids) have been unsuccessful, or are not feasible and are, therefore, requiring frequent and continuous dosing of higher potency narcotics.*

*** Please note: in order to assess requests for coverage in the treatment of non-malignant pain, the Department will require the following information**:

- Results of any xrays/CT scans/MRIs.
- Information relating to any consultations completed and their recommendations (i.e., surgical, orthopedic and/or physiotherapy consultations).
- Surgical history.
- Past analgesic use and response; current analgesic use, dosage, and assessment of current level of pain control.
- Any other information you feel is pertinent to the request.

Requests are only considered for those physicians holding a valid license to prescribe methadone.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2010

Newfoundland Labrador

Health and Community Services

METHADONE HCL (METHADOSE 10mg/ml ORAL CONCENTRATE - DYE FREE, SUGAR FREE, UNFLAVORED, METADOL-D 10mg/ml clear, unflavored, colorless CONCENTRATE)

DIN 02394618, DIN 02244290

Methadone Maintenance (Daily Witnessed Doses):

For patients diagnosed with opiate dependence and who are being treated for opiate withdrawal and/or opiate addiction. Before coverage is considered, the following information is required for assessment:

- A diagnosis of substance abuse or opiate withdrawal.
- History of drugs used, dose, route of administration and duration of dependence.
- Other treatment options tried (e.g. non-medical detox) and results.
- A Physician-Patient Treatment agreement must be signed.

Consideration for coverage of Methadone will only be given for patients who are undergoing random urine screening and participating in regular addictions counseling.

Concurrent usage of opiates will result in termination of coverage of Methadone by this Department.

To facilitate this process, a specific **Methadone Special Authorization Form** has been developed and can be found at:
http://www.health.gov.nl.ca/health/prescription/Methadone_Daily_Dispensing.pdf

Methadone Carry (Take-Home doses):

The criteria for determining appropriateness for take-home doses are based on patient and community safety, and on clinical stability, where clinical stability can be defined by:

- Stable dose of methadone (with allowances for occasional dose increases or when tapering)
- Patient has been in Opioid Agonist Treatment Program for:
    - at least three months, or
    - for two months and either
        - Meets the conditions for accelerated schedule, or
        - Exceptional take-home doses on compassionate grounds.

- for 4 weeks and lives in a community that does not have a pharmacy that is open on a weekend day, has no hospital available for weekend dispensing, does not have transportation to a pharmacy in a different community and the patient does not have any of the conditions where take-home doses shall not be prescribed, as listed in CPSNL MMT Standards and Guidelines.

- No recent drug or alcohol use with four consecutive weeks of documented negative random UDS tests before starting take-home doses
- Compliance with treatment directives
- Stable housing
- Emotional stability and good insight into take-home dose safety issues
- Capability to be reached in a timely fashion for notification of requirement for urine drug screens (typically being accessible by telephone)
- A written take-home dose agreement has been signed by the patient

Carry doses can be considered on a case by case basis for medical disability or compassionate basis with written request from the Methadone prescriber containing the appropriate documentation to support his/her request.

Concurrent usage of opiates will result in termination of coverage of Methadone by this Department.

To facilitate this process, a specific Methadone Carry Dose Special Authorization Form has been developed and can be found at:
http://www.health.gov.nl.ca/health/forms/pdf/Methadone_Take_Home_Doses.pdf

Updated January 2017

Health and Community Services

METHYLPHENIDATE ER-C (CONCERTA & generic METHYLPHENIDATE ER-C 18mg, 27mg, 36mg & 54mg tablet)

For treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients who:

- Have experienced unsatisfactory results due to poor symptom control, side effects, administrative barriers and/or societal barriers.

AND

- Have been tried on methylphenidate (immediate release or sustained release formulation) or dexamphetamine (immediate release or sustained release formulation) with unsatisfactory results.

Claim Notes:

- The maximum dose reimbursed is 72mg daily.
- Reimbursement will not be considered for Biphentin, Concerta and/or Vyvanse concurrently with methylphenidate (immediate release or sustained release formulation) or dexamphetamine.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated November 2018

Health and Community Services

Methylphenidate (Biphentin 10mg, 15mg, 20mg, 30mg, 40mg, 50mg 60mg, 80mg tablet)

For treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients who:

- Have experienced unsatisfactory results due to poor symptom control, side effects, administrative barriers and/or societal barriers.

AND

- Have been tried on methylphenidate (immediate release or sustained release formulation) or dexamphetamine (immediate release or sustained release formulation) with unsatisfactory results.

Claim Notes:

- The maximum dose reimbursed is 80mg daily.
- Reimbursement will not be considered for Biphentin, Concerta and/or Vyvanse concurrently with methylphenidate (immediate release or sustained release formulation) or dexamphetamine (immediate release or sustained release formulation).

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated November 2018

Health and Community Services

MIRABEGRON (MYRBETRIQ ER 25mg, 50mg TABLET)

For the treatment of overactive bladder (not stress incontinence) after a reasonable trial, titrated, and of appropriate length* of oxybutynin IR, tolterodine OR solifenacin are not tolerated.

*an appropriate trial is considered to be of 12 weeks duration.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated October 2018

Health and Community Services

MIXED SALTS AMPHETAMINE EXTENDED–RELEASE (ADDERALL XR 5mg, 10mg, 15mg, 20mg, 30mg CAPSULE)

For treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients age 6 to 25 years who:

- Have experienced unsatisfactory results due to poor symptom control, side effects, administrative barriers and/or societal barriers.

AND

- Have been tried on methylphenidate (immediate release or long-acting formulation) or dexamphetamine (immediate release or sustained release formulation) or with unsatisfactory results.

Claim Notes:

- The maximum dose reimbursed is 30mg daily.

Please note: Reimbursement will not be considered for Biphentin, Concerta, Vyvanse and/or Adderall XR concurrently with methylphenidate (immediate release or sustained release formulation) or dexamphetamine.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated November 2018

Newfoundland Labrador

Health and Community Services

Modafinil (Alertec 100mg tablet and generics)

For the treatment of narcolepsy confirmed by a sleep study.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated May 2014

Health and Community Services

MOMETASONE/FORMOTEROL (ZENHALE 50ug-5ug, 100ug-5ug, 200ug-5ug INHALER

Reversible Obstructive Airway Disease (Asthma):

For treatment of moderate to severe asthma in patients in whom:

- are compliant with inhaled corticosteroids at optimal doses; and
- require additional symptom control, (e.g., cough, awakening at night, missing activities such as school, work or social activities because of asthma symptoms); and
- require increasing amounts of short-acting beta$_2$-agonists, indicative of poor control

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated October 2016

Health and Community Services

Montelukast (Singulair 4mg oral granules, 4mg, 5mg chewable tablet and 10mg tablet & generics)

For the treatment of moderate to severe asthma in adults and children (2 – 14 years old) who:

- Despite compliance are not adequately controlled with a moderate or high dose inhaled corticosteroid and require additional symptom control (e.g. cough, awakening at night, missing activities such as school, work, social activities because of asthma symptoms,

AND

- Require increasing amounts of short-acting beta$_2$-agonists, indicative of poor control.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2010

Health and Community Services

Moxifloxacin (Avelox 400mg tablet & generics)

- For step-down therapy after hospital discharge for the treatment of nosocomial pneumonia, community acquired pneumonia (CAP) or acute exacerbation of chronic bronchitis (AECB).

- For the treatment of severe pneumonia in nursing home patients.

- For the treatment[1] of CAP in patients:

    - with co-morbidity[2] upon radiographic confirmation of pneumonia,

OR

    - who have failed first line therapies (macrolide, doxycycline, amoxicillin-clavulanate).

- For the treatment[1] of AECB in complicated patients[3] who have failed treatment with one of the following (amoxicillin, doxycycline, TMP-SMX, cefuroxime, macrolide, ketolide or amoxicillin-clavulanate).

[1] If treated with an antibiotic within the past 3 months choose an antibiotic from a different class.

[2] Co-morbidity includes chronic lung disease, malignancy, diabetes, liver, renal or congestive heart failure, use of antibiotics or steroids in the past 3 months, suspected macroaspiration, hospitalization within last 3 months, HIV/AIDs, smoking, malnutrition or acute weight loss.

[3] Complicated AECB defined as increased cough and sputum, sputum purulence and increased dyspnea, **AND**

- FEV_1 < 50% predicted

    OR

- FEV 50-65% and one of the following:
    - ≥ 4 exacerbations per year
    - Ischemic heart disease
    - Chronic oral steroid use
    - Antibiotic use in the past 3 months

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2010

Health and Community Services

Nadroparin calcium (Fraxiparine 9500U, 19,000U)

- For the prevention of VTE following:
  - total hip replacement (THR) surgery or hip fracture surgery (maximum coverage up to 35 days)
  - total knee replacement (TKR) surgery (maximum coverage up to 10 days)

  Please visit the link below if you require our standard special authorization form:
  http://www.health.gov.nl.ca/health/forms/pdf/Thromboembolism_Prevention_Following_Surgery.pdf

- For treatment of acute Venous Thromboembolism (VTE)
  - coverage is limited to 7 to 10 days while establishing a therapeutic INR
  - extended treatment of recurrent VTE may be considered in patients with treatment failure on therapeutic doses of warfarin. Coverage will be limited to a 3 month period.

- For prophylaxis of VTE, coverage is limited to patients with concomitant anticoagulation syndromes, or in patients who have failed to reach therapeutic INR while on oral anticoagulant therapy.
  - Coverage will be limited to a 3 month period.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated February 2011

Health and Community Services

Naratriptan (Amerge 1mg and 2.5mg tablet and generics)

For the treatment of patients with acute migraine attacks who have an intolerance or insufficient response to all triptans listed as regular benefits (e.g. almotriptan, rizatriptan, sumatriptan, zolmitriptan).

Coverage limited to 6 doses / 30 days[1]

- More than 6 doses / 30 days considered for patients with >3 migraines/month on average despite prophylactic therapy (up to a maximum of 12 doses / 30 days).

[1]Reimbursement will be available for a maximum quantity of 6 triptan doses per 30 days regardless of the agent(s) used within the 30 day period.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated May 2018

Health and Community Services

Nilotinib (Tasigna capsule)

Written request from an oncologist/hematologist required.

Initial approval period: one year

Request for renewal must specify that the patient has benefited from therapy and is expected to continue to do so. Renewal: one year

Tasigna 150mg

For the first-line treatment of adult patients with Philadelphia chromosome positive chronic myeloid leukemia in chronic phase.

Tasigna 200mg

For the treatment of adult patients with accelerated phase (AP) or chronic phase (CP) Philadelphia chromosome positive (Ph+) CML who are resistant to or intolerant of imatinib AND either have a mutational resistance to dasatinib predicted by mutational analysis OR uncontrolled pleural effusions on dasatinib.

Please visit the following link if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated March 2012

Health and Community Services

NINTEDANIB (OFEV 100mg, 150mg capsule)

Adult patients with a diagnosis of mild to moderate idiopathic pulmonary fibrosis (IPF):

- Diagnosis confirmed by a respirologist and a high-resolution CT scan within the previous 24 months.
- All other causes of restrictive lung disease (e.g. collagen vascular disorder or hypersensitivity pneumonitis) should be excluded.
- Mild to moderate IPF is defined as forced vital capacity (FVC) greater than or equal to 50% of predicted.
- Patient is under the care of a physician with experience in IPF

Initial approval period: 7 months (allow 4 weeks for repeat pulmonary function tests)

Initial renewal criteria (at 6 months):

Patients must NOT demonstrate progression of disease defined as an absolute decline in percent predicted FVC of ≥ 10% from initiation of therapy until renewal (initial 6 month treatment period). IF a patient has experienced progression as defined above, then the results should be validated with a confirmatory pulmonary function test conducted 4 weeks later.

Approval period: 6 months

Second and subsequent renewals (at 12 months and thereafter):

Patients must NOT demonstrate progression of disease defined as an absolute decline in percent predicted FVC of ≥ 10% within any 12 month period. If a patient has experienced progression as defined above, then the results should be validated with a confirmatory pulmonary function test conducted 4 weeks later.

Approval period: 12 months

Exclusion criteria:
Combination use of Ofev (nintedanib) and Esbriet (pirfenidone) will not be funded.

Notes:
Patients who have experienced intolerance or failure to Ofev (nintedanib) or Esbriet (pirfenidone) will be considered for the alternate agent provided that the patient continues to meet the above coverage criteria.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/forms/pdf/Pirfenidone_Nintedanib.pdf

Updated February 2017

Health and Community Services

OCRIPLASMIN (JETREA INTRAVIT INJ 2.5MG/ML)

For the treatment of **symptomatic** vitreomacular adhesion (VMA) if the following clinical criteria and conditions are met:

Clinical Criteria:

- 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).

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated January 2015

Health and Community Services

Olanzapine Orally Disintegrating tablets (Zyprexa Zydis 5mg, 10mg, 15mg, 20mg tablets & generics)

Schizophrenia and related psychotic disorders:

- For the treatment of schizophrenia and related psychotic disorders (not dementia related) in patients with a history of inadequate response or intolerance to at least one less expensive antipsychotic agent OR who have a contraindication to less expensive options.

Bipolar Disorder:

- **Acute**: For the treatment of an acute episode of bipolar disorder following inadequate response or intolerance to another atypical antipsychotic.
- **Maintenance**: For maintenance therapy in those patients who have responded to acute treatment with olanzapine following inadequate response or intolerance to another atypical antipsychotic.

Coverage will be considered to a MAXIMUM daily dose of 30mg.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated December 2016

Health and Community Services

Olanzapine (Zyprexa 2.5mg, 5mg, 7.5mg, 10mg, 15mg, and generics)

Schizophrenia and related psychotic disorders:

- For the treatment of schizophrenia and related psychotic disorders (not dementia related) in patients with a history of inadequate response or intolerance to at least one less expensive antipsychotic agent OR who have a contraindication to less expensive options.

Bipolar Disorder:

- **Acute**: For the treatment of an acute episode of bipolar disorder following inadequate response or intolerance to another atypical antipsychotic.
- **Maintenance**: For maintenance therapy in those patients who have responded to acute treatment with olanzapine following inadequate response or intolerance to another atypical antipsychotic.

Coverage will be considered to a MAXIMUM daily dose of 30mg.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated November 2016

Health and Community Services

OMALIZUMAB (XOLAIR 150 MG VIAL)

For the treatment of patients ≥ 12 years of age with moderate to severe chronic idiopathic urticaria (CIU) who remain symptomatic (presence of hives and/or associated itching) despite optimum management with H1 antihistamines.

Requirement for Initial Requests:

- Prescribed by a specialist (allergist, immunologist, dermatologist, etc.) or other authorized prescriber with knowledge of CIU treatment.
- Documentation of the most recent urticaria activity score over 7 days (UAS7) must be provided on the submitted request.

Renewal Criteria:

- Requests for renewal will be considered if the patient has achieved:
  - complete symptom control for less than 12 consecutive weeks; or
  - partial response to treatment, defined as at least a ≥ 9.5 point reduction in baseline urticaria activity score over 7 days (UAS7)

Clinical Notes:

1. Treatment cessation could be considered for patients who experience complete symptom control for at least 12 consecutive weeks at the end of a 24 week treatment period.
2. In patients who discontinue treatment due to temporary symptom control, re-initiation can be considered if CIU symptoms reappear.
3. Optimum management for H1 antihistamines is defined as at up to 4 times the standard daily dose.

Claim Notes:

• Approvals will be for a maximum dose of 300mg every four weeks.
• Initial approval: 24 weeks

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated January 2018

Health and Community Services

Omeprazole (Losec 10mg, 20mg tablets, delayed release capsule and generics)

Omeprazole doses ≤ 20mg daily (10mg and 20mg tablets, delayed release capsules) are listed as regular benefits.

Doses above 20mg daily require special authorization.

Requests for omeprazole 20mg BID will only be considered if there has been inadequate response to an 8 week trial of omeprazole 20mg OD dosing for the indications listed below:

Indication and Diagnostic Information	Maximum Approval Period	
Symptomatic GERD or other reflux-associated indication (i.e. non-cardiac chest pain).	Considered for short-term (8 weeks) approval	
Erosive/ulcerative esophagitis or Barrett's esophagus	Considered for long term approval	
Peptic Ulcer Disease (PUD): Confirmed Gastric/duodenal ulcers	Considered for up to 12 weeks	
Zollinger-Ellison Syndrome	Considered for long term approval	
Gastro-duodenal protection (ulcer prophylaxis) for high risk patients (e.g. high risk NSAID users).	Considered for one year with reassessment.	
H pylori eradication	Regimen	Drugs and dose
	Bismuth quadruple (PBMT)	PPI standard dose BID[a] Metronidazole 500 mg tid to qid Tetracycline 500 mg QID Bismuth subsalicylate[b]
	Non bismuth quadruple therapy	PPI standard dose BID[a] Metronidazole 500 mg tid to qid Amoxicillin 1000 mg bid Clarithromycin 500 mg bid
	PAC triple therapy (same as HP PAC)	PPI standard dose BID[a] Amoxicillin 1000 mg bid Clarithromycin 500 mg bid
	PMC triple therapy	PPI standard dose BID[a] Metronidazole 500 mg tid to qid

		Clarithromycin 500 mg bid
	PAM triple therapy	PPI standard dose BID[a] Amoxicillin 1000 mg bid Metronidazole 500 mg tid to qid
	A second treatment will be considered providing that at least a four-week period has elapsed since the end of the previous treatment and that retreatment within a three month period uses a different antibiotic regimen. Additional treatments within one year will require diagnostic confirmation of the continued presence of H. pylori. Additional treatments within one year will require diagnostic confirmation of the continued presence of H. pylori. *A PPI at BID dosing will be reimbursed with special authorization as part of an approved H. pylori eradication regimen for 14 days.	

a. Standard dose PPI: lansoprazole 30 mg, omeprazole 20 mg, pantoprazole 40 mg, and rabeprazole 20mg.
b. Bismuth subsalicylate (Pepto Bismol) 262 mg 2 tablets four times daily.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated March 2018

Health and Community Services

Ondansetron (Zofran 4mg, 8mg tablet and generics, 4mg ODT, 8mg ODT, 4mg/ml oral solution and generics)

The following Anti-emetics are covered by the Program as open benefits, with limitations, for chemo induced nausea and vomiting only:
***Ondansetron 4mg and 8mg tab**: up to 3 tablets in a 24 hour period **Granisetron 1mg tab:** up to 2 tablets in a 24 hour period*
***Dolasetron 100mg tab:** 1 tablet in a 24 hour period*

The quantity limits above may only be filled as an open benefit for the first fill of any chemo anti-emetic drug. A special authorization is required for a higher quantity dispensed than noted above for a first fill or for any subsequent fills of any chemo anti-emetic drug.

Special Authorization criteria:

Coverage is considered for the treatment of emesis in patients who:

- are receiving **moderate to highly** emetogenic chemotherapy **OR**
- are receiving **mildly** emetogenic chemotherapy and have experienced episodes of nausea and vomiting related to such treatment, not responding to therapeutic doses of benefit antiemetics (metoclopramide, dexamethasone and prochlorperazine), or where these agents are not tolerated or contraindicated **OR**
- Post **radiation** therapy

Duration of therapy:

- Coverage will be provided to a maximum of **48 hours post chemo** for all patients (i.e. to a maximum of 9 tablets of ondansetron for a 1 day iv chemo regimen).
- Coverage will be limited to **one dose post-radiation** therapy.

In order to accurately assess requests for coverage, we require the following information:

For Chemotherapy:
-chemotherapy agents (including dose)
-number of days per cycle for each agent
-cycle frequency
-expected treatment duration (total number of cycles)
-previous antiemetic trials and the outcome
For Radiotherapy:
-targeted area
-number of days per cycle
-cycle frequency
-expected treatment duration (total number of cycles)
-previous antiemetic trials and the outcome

Duration of approval will be for the full course of the chemotherapy regimen.

Other drug and non-drug causes or pre-existing nausea and vomiting should be identified and eliminated.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated August 2011

Health and Community Services

Oseltamivir (Tamiflu 30mg, 45mg, 75mg capsules)

For beneficiaries residing in long-term care facilities* during an influenza outbreak situation and further to the recommendation of a Medical Officer of Health:

- For treatment of long-term care facility residents with clinically suspected or lab confirmed influenza A or B. *A clinically suspected case is one in which the patient meets the criteria of influenza-like illness and there is confirmation of influenza A or B circulating within the facility or surrounding community.*

- For prophylaxis of long-term care* residents where the facility has an influenza A or B outbreak. Prophylaxis should be continued until the outbreak is over. An outbreak is declared over 7 days after the onset of the last case in the facility.

* *Long-term care facility* refers to a licensed nursing home.

Please visit the following link if you require our standard special authorization form:
https://www.health.gov.nl.ca/health/forms/pdf/tamiflu_for_long_term_care_residents.pdf

Updated January 2019

Health and Community Services

Oxcarbazepine (Trileptal 150mg, 300mg, 600mg tablets, liquid & generics)

For use in patients who have a diagnosis of epilepsy AND have had an inadequate response or are intolerant to at least 3 other formulary agents (prior or current use) including carbamazepine.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2010

Health and Community Services

Oxybutynin XL (Ditropan XL 5mg, 10mg, and Uromax CR 10mg, CR 15mg tablets)

For the treatment of overactive bladder (not stress incontinence) after a reasonable trial, titrated, and of appropriate length* of oxybutynin IR, tolterodine OR solifenacin are not tolerated.

*an appropriate trial is considered to be of 12 weeks duration.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated October 2018

Health and Community Services

Oxybutynin XL (Ditropan XL 5mg, 10mg, and Uromax CR 10mg, CR 15mg tablets)

For the treatment of overactive bladder (not stress incontinence) after a reasonable trial, titrated, and of appropriate length* of oxybutynin IR, tolterodine AND solifenacin are not tolerated.

*an appropriate trial is considered to be of 12 weeks duration.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2018

Health and Community Services

PALBOCICLIB (IBRANCE) 75MG, 100MG AND 125MG CAPSULES

In combination with an aromatase inhibitor (e.g., letrozole) for the treatment of estrogen receptor positive, HER2 negative advanced breast cancer in postmenopausal women who:

- have not received prior therapy for metastatic disease, and
- are not resistant to (neo)adjuvant non-steroidal aromatase inhibitor (NSAI) therapy, and
- do not have active or uncontrolled metastases to the central nervous system.

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. Resistance is defined as disease progression occurring during or within 12 months following (neo)adjuvant NSAI therapy.
3. Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Notes:

- Sequential use of palbociclib and everolimus will not be reimbursed.
- Approval period: 12 months

Updated May 2018

Health and Community Services

PALIPERIDONE PALMITATE (INVEGA SUSTENNA 50mg/0.5ml, 75 mg/0.75ml, 100 mg/mL, 150 mg/1.5 mL, INVEGA TRINZA 175mg/0.875ml, 63mg/1.315, 350 mg/1.75ml, 525 mg/2.625ml)

For the treatment of schizophrenia and related psychotic disorders (not dementia related) in patients:

- who are non-adherent to an oral antipsychotic.

OR

- who are currently receiving a long-acting injectable antipsychotic and require a switch to another injectable.

Please visit the following link if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2018

Health and Community Services

Pantoprazole magnesium (Tecta 40mg)

Pantoprazole magnesium doses ≤ 40mg daily (20mg and 40mg tablets tablets) are listed as regular benefits.

Doses above 40mg daily require special authorization.

Requests for pantoprazole 40mg BID will only be considered if there has been inadequate response to an 8 week trial of pantoprazole 40mg OD dosing for the indications listed below:

Indication and Diagnostic Information	Maximum Approval Period	
Symptomatic GERD or other reflux-associated indication (i.e. non-cardiac chest pain).	Considered for short-term (8 weeks) approval	
Erosive/ulcerative esophagitis or Barrett's esophagus	Considered for long term approval	
Peptic Ulcer Disease (PUD): Confirmed Gastric/duodenal ulcers	Considered for up to 12 weeks	
Zollinger-Ellison Syndrome	Considered for long term approval	
Gastro-duodenal protection (ulcer prophylaxis) for high risk patients (e.g. high risk NSAID users).	Considered for one year with reassessment.	
H pylori eradication	Regimen	Drugs and dose
	Bismuth quadruple (PBMT)	PPI standard dose BID[a] Metronidazole 500 mg tid to qid Tetracycline 500 mg QID Bismuth subsalicylate[b]
	Non bismuth quadruple therapy	PPI standard dose BID[a] Metronidazole 500 mg tid to qid Amoxicillin 1000 mg bid Clarithromycin 500 mg bid
	PAC triple therapy (same as HP PAC)	PPI standard dose BID[a] Amoxicillin 1000 mg bid Clarithromycin 500 mg bid
	PMC triple therapy	PPI standard dose BID[a] Metronidazole 500 mg tid to qid

		Clarithromycin 500 mg bid
	PAM triple therapy	PPI standard dose BID[a] Amoxicillin 1000 mg bid Metronidazole 500 mg tid to qid
	A second treatment will be considered providing that at least a four-week period has elapsed since the end of the previous treatment and that retreatment within a three month period uses a different antibiotic regimen. Additional treatments within one year will require diagnostic confirmation of the continued presence of H. pylori. Additional treatments within one year will require diagnostic confirmation of the continued presence of H. pylori. *A PPI at BID dosing will be reimbursed with special authorization as part of an approved H. pylori eradication regimen for 14 days.	

a. Standard dose PPI: lansoprazole 30 mg, omeprazole 20 mg, pantoprazole 40 mg, and rabeprazole 20mg.
b. Bismuth subsalicylate (Pepto Bismol) 262 mg 2 tablets four times daily.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated March 2018

Health and Community Services

Pantoprazole sodium (Pantoloc 20mg, 40mg tablet & generics)

Pantoprazole sodium doses ≤ 40mg daily (20mg and 40mg tablets tablets) are listed as regular benefits.

Doses above 40mg daily require special authorization.

Requests for pantoprazole 40mg BID will only be considered if there has been inadequate response to an 8 week trial of pantoprazole 40mg OD dosing for the indications listed below:

Indication and Diagnostic Information	Maximum Approval Period	
Symptomatic GERD or other reflux-associated indication (i.e. non-cardiac chest pain).	Considered for short-term (8 weeks) approval	
Erosive/ulcerative esophagitis or Barrett's esophagus	Considered for long term approval	
Peptic Ulcer Disease (PUD): Confirmed Gastric/duodenal ulcers	Considered for up to 12 weeks	
Zollinger-Ellison Syndrome	Considered for long term approval	
Gastro-duodenal protection (ulcer prophylaxis) for high risk patients (e.g. high risk NSAID users).	Considered for one year with reassessment.	
H pylori eradication	Regimen	Drugs and dose
	Bismuth quadruple (PBMT)	PPI standard dose BID[a] Metronidazole 500 mg tid to qid Tetracycline 500 mg QID Bismuth subsalicylate[b]
	Non bismuth quadruple therapy	PPI standard dose BID[a] Metronidazole 500 mg tid to qid Amoxicillin 1000 mg bid Clarithromycin 500 mg bid
	PAC triple therapy (same as HP PAC)	PPI standard dose BID[a] Amoxicillin 1000 mg bid Clarithromycin 500 mg bid
	PMC triple therapy	PPI standard dose BID[a] Metronidazole 500 mg tid to qid

		Clarithromycin 500 mg bid
	PAM triple therapy	PPI standard dose BID[a] Amoxicillin 1000 mg bid Metronidazole 500 mg tid to qid
	A second treatment will be considered providing that at least a four-week period has elapsed since the end of the previous treatment and that retreatment within a three month period uses a different antibiotic regimen. Additional treatments within one year will require diagnostic confirmation of the continued presence of H. pylori. Additional treatments within one year will require diagnostic confirmation of the continued presence of H. pylori. *A PPI at BID dosing will be reimbursed with special authorization as part of an approved H. pylori eradication regimen for 14 days.	

a. Standard dose PPI: lansoprazole 30 mg, omeprazole 20 mg, pantoprazole 40 mg, and rabeprazole 20mg.
b. Bismuth subsalicylate (Pepto Bismol) 262 mg 2 tablets four times daily.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated March 2018

Health and Community Services

Pazopanib hydrochloride (Votrient 200mg tablet)

As a first-line treatment for patients with advanced or metastatic clear cell renal carcinoma and good performance status (ECOG 0-1).

OR

For patients with advanced or metastatic clear cell renal carcinoma who, based on the mutual assessment of the treating physician and the patient, are unable to tolerate ongoing use of an effective dose of sunitinib.

Approval period: 12 months

Dosing: 800 mg daily

Renewals will be considered for patients who do not have evidence of disease progression AND who have not developed unacceptable toxicities that require discontinuation of pazopanib.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated September 2014

Health and Community Services

Peginterferon alfa -2a (PEGASYS 180 MCG/0.5 ML SYRNGE/ProClick Auto Injector, PEGASYS 180MCG/ML VIAL,)

Hepatitis B:

For the treatment of **HBeAg negative** Chronic Hepatitis B in patients with compensated liver disease, liver inflammation and evidence of viral replication (both cirrhotic and non-cirrhotic) with demonstrated **intolerance or failure to lamivudine** therapy.

- Written request of a hepatologist or other specialist in this area.
- Maximum duration of coverage, **48 weeks**.

Hepatitis C:

For the treatment of individuals with (Peginterferon/RBV–treatment naïve) chronic hepatitis C (upon request from internal medicine specialist/ hepatologist/other appropriate specialist).

- Initial coverage of 24 weeks will be approved for all patients. Coverage for an additional 24 weeks will be approved for patients with HVC genotypes other than 2 or 3.
- A positive HCV RNA assay after 24 weeks of therapy is an indication to stop therapy.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated September 2014

Health and Community Services

Peginterferon alfa -2a + Ribavirin (Pegasys RBV)

For the treatment of individuals with (Peginterferon/RBV –treatment naïve) chronic hepatitis C (upon request from internal medicine specialist/ hepatologist/other appropriate specialist).

- Initial coverage of 24 weeks will be approved for all patients. Coverage for an additional 24 weeks will be approved for patients with HVC genotypes other than 2 or 3.
- A positive HCV RNA assay after 24 weeks of therapy is an indication to stop therapy.
- For the treatment of patients with chronic hepatitis C genotype 1 infection (HCV RNA positive) in combination with telaprevir.

  Note: Coverage will be approved for up to a total of 48 weeks in combination with telaprevir.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated May 2014

Health and Community Services

Peginterferon alfa-2b + Ribavirin (Pegetron , Pegetron Redipen & Pegetron Clear Click 50mcg injection and 200mg capsule, 80mcg injection and 200mg capsule 100mcg injection and 200mg capsule, 120mcg injection and 200mg capsule 150mcg injection and 200mg capsule)

Requests will be considered from internal medicine specialist/ hepatologist/other appropriate specialist

- For the treatment of peginterferon and ribavirin treatment-naïve chronic hepatitis C (HCV RNA positive) patients.

Note: Initial coverage of 24 weeks will be approved for all patients. Coverage for an additional 24 weeks will be approved for patients with HCV genotypes other than 2 and 3. A positive HCV RNA assay after 24 weeks of therapy is an indication to stop treatment.

- For the treatment of patients with chronic hepatitis C genotype 1 infection (HCV RNA positive) in combination with telaprevir.

Note: Coverage will be approved for up to a total of 48 weeks in combination with telaprevir.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated May 2014

Health and Community Services

PERAMPANEL (FYCOMPA 2mg, 4mg, 6mg, 8mg, 12mg tablets)

As an adjunctive therapy in the management of partial-onset seizures, in patients with epilepsy who are not satisfactorily controlled with conventional therapy, if the following clinical criteria and condition are met:

Clinical criteria:

- Patients are currently receiving two or more antiepileptic drugs
- Less costly anti-epileptic drugs (AEDs) are ineffective or not appropriate

Condition:
Patients are under the care of a physician experienced in the treatment of epilepsy

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated May 2014

Health and Community Services

Pilocarpine (Salagen 5mg tablet)

- For the treatment of the symptoms of xerostomia due to salivary gland hypofunction caused by radiotherapy for cancer of the head and neck, in addition to treatment with topical lubricants, etc.

- For the treatment of Sjogren's syndrome where symptomatic treatment of topical lubricants, etc., fail to provide satisfactory control of symptoms.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2010

Newfoundland Labrador

Health and Community Services

Pioglitazone HCL (Actos 15mg, 30mg, and 45mg tablets and generics)

For the treatment of type II diabetes in patients who are inadequately controlled on a combination of a sulfonylurea and metformin, at maximum dosages, or in whom these agents are contraindicated or not tolerated.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2010

Newfoundland Labrador
Health and Community Services

PIRFENIDONE (ESBRIET 267 MG CAPSULE, 267 MG TABLET, 801 MG TABLET)

Adult patients with a diagnosis of mild to moderate idiopathic pulmonary fibrosis (IPF):

- Diagnosis confirmed by a respirologist and a high-resolution CT scan within the previous 24 months.
- All other causes of restrictive lung disease (e.g. collagen vascular disorder or hypersensitivity pneumonitis) should be excluded.
- Mild to moderate IPF is defined as forced vital capacity (FVC) greater than or equal to 50% of predicted.
- Patient is under the care of a physician with experience in IPF.

Initial approval period: 7 months (allow 4 weeks for repeat pulmonary function tests).

Initial renewal criteria (at 6 months):
Patients must NOT demonstrate progression of disease defined as an absolute decline in percent predicted FVC of ≥10% from initiation of therapy until renewal (initial 6 month treatment period). If a patient has experienced progression as defined above, then the results should be validated with a confirmatory pulmonary function test conducted 4 weeks later.

Approval period: 6 months

Second and subsequent renewals (at 12 months and thereafter):
Patients must NOT demonstrate progression of disease defined as an absolute decline in percent predicted FVC of ≥10% within any 12 month period. If a patient has experienced progression as defined above, then the results should be validated with a confirmatory pulmonary function test conducted 4 weeks later.

Approval period: 12 months

Exclusion Criteria:
Combination use of Esbriet (pirfenidone) and Ofev (nintedanib) will not be funded.

Notes:
Patients who have experienced intolerance or failure to Esbriet (pirfenidone) or Ofev (nintedanib) will be considered for the alternate agent provided that the patient continues to meet the above coverage criteria.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/forms/pdf/Pirfenidone_Nintedanib.pdf

Updated April 2018

Health and Community Services

Pomalidomide (Pomalyst) 1mg, 2mg, 3mg and 4mg

For patients with relapsed and/or refractory multiple myeloma who have previously failed at least two treatments, including lenalidomide* and

- Have failed bortezomib**or
- Have contraindication or intolerance to bortezomib

And

- Have demonstrated disease progression on the last treatment

*In all cases patients should have failed lenalidomide. Includes lenalidomide that may have been received in the maintenance setting.
**Includes patients who have previously received a course of bortezomib during which there was no disease progression, but are not eligible for bortezomib re-treatment at time of disease relapse.

Approval Period: 6 months

Recommended Dose: 4mg daily on day 1 to 21 in combination with dexamethasone 40mg on days 1, 8, 15 and 22 of a 28 day cycle until disease progression

Renewal requires physician reassessment and request.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated May 2015

Health and Community Services

PONATINIB (ICLUSIG) 15mg tablets

For the treatment of patients with chronic phase, accelerated phase or blast phase chronic myeloid leukemia (CML) or Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) and with ECOG performance status 0-2 for whom other tyrosine kinase inhibitor (TKI) therapy is not appropriate, including CML or Ph+ ALL that is T315i mutation positive or where there is resistance or intolerance to prior TKI therapy. Treatment should continue until unacceptable toxicity or disease progression.

Other TKI therapy is not considered appropriate in the following circumstances:

- for treatment of patients who have confirmed T315i mutation positive disease, independent of previous TKI therapy

- for the treatment of patients with chronic phase, accelerated phase or blast phase CML, or Ph+ ALL who have resistance/disease progression after at least two prior lines of TKI therapy where Iclusig would be available as third line TKI option, or who have intolerance to prior TKI therapy.

Initial Approval Period: 3 months

Approval Period with Hematological Response: 12 months

Recommended Starting Dose: 45mg once daily

Dose may be reduced to 15mg daily with major cytogenetic response (MCyR).

Renewal requests require assessment of hematologic and cytogenetic response.

Please visit the following link if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2018

Newfoundland Labrador

Health and Community Services

PREGABALIN generic 25mg, 50mg, 75mg, 150mg, 225mg, 300mg CAPSULE

- For the treatment of neuropathic pain associated with diabetic peripheral neuropathy (DPN), post herpetic neuralgia (PHN) and spinal cord injury in patients who have failed an adequate trial with a tricyclic antidepressant (e.g., nortriptyline, imipramine, desipramine, amitriptyline)

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated October 2013

Health and Community Services

PROPIVERINE HCL (MICTORYL PEDIATRIC 5 MG TABLET)

For the treatment of overactive bladder with symptoms of urgency incontinence and/or urinary frequency and urgency in pediatric patients under 18 years of age.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated September 2018

Health and Community Services

Quinagolide (Norprolac 0.075mg, 0.150mg)

For the treatment of hyperprolactinemic disorders in patients who have failed to respond or are intolerant to treatment with bromocriptine.

Please note that coverage may be considered WITHOUT a Special Authorization request as long as the beneficiary's medication history in the NLPDP database shows the prior use of bromocriptine, Dostinex, Norprolac within the past year.

If there is no history of a previous claim for bromocriptine, Dostinex, Norprolac, the normal Special Authorization Process will be required.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated January 2012

Health and Community Services

Rabeprazole (Pariet 10mg, 20mg EC tablets and generics)

Rabeprazole doses ≤ 20mg daily (10mg and 20mg tablets) are listed as regular benefits.

Doses above 20mg daily require special authorization.

Requests for rabeprazole 20mg BID will only be considered if there has been inadequate response to an 8 week trial of rabeprazole 20mg OD dosing for the indications listed below:

Indication and Diagnostic Information	Maximum Approval Period
Symptomatic GERD or other reflux-associated indication (i.e. non-cardiac chest pain).	Considered for short-term (8 weeks) approval
Zollinger-Ellison Syndrome	Considered for long term approval
Peptic Ulcer Disease (PUD): Confirmed Gastric/duodenal ulcers	Considered for up to 12 weeks
H. pylori eradication	H. Pylori Eradication: • H. Pylori eradication, in conjunction with clarithromycin and metronidazole/amoxicillin, at BID dosing for a 7 day period. • A second treatment will be considered providing that at least a four-week period has elapsed since the end of the previous treatment and that retreatment within a three month period uses a different antibiotic regimen. Additional treatments within one year will require diagnostic confirmation of the continued presence of H. pylori. Additional treatments within one year will require diagnostic confirmation of the continued presence of H. pylori. *A PPI at BID dosing will be reimbursed with special authorization as part of an approved H. pylori eradication regimen for 7 days.
Gastro-duodenal protection (ulcer prophylaxis) for high risk patients (e.g. high risk NSAID users).	Considered for one year with reassessment.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated March 2018

Newfoundland Labrador

Health and Community Services

Raloxifene (Evista & generics)

- For the treatment of postmenopausal osteoporosis associated with documented fragility fracture when bisphosphonates are not tolerated or contraindicated.

- For the treatment of postmenopausal osteoporosis without documented fractures when patient at high 10-year fracture risk (based on age, sex and T-score, see Appendix 1 below for fracture risk table) and bisphosphonates are not tolerated or contraindicated.

Appendix 1

10 Year Absolute Fracture Risk based on BMD

Age (yrs)	WOMEN		
	Low Risk < 10%	Moderate Risk 10% - 20%	High Risk > 20%
50	> - 2.3	- 2.3 to - 3.9	<- 3.9
55	> - 1.9	- 1.9 to - 3.4	< - 3.4
60	> - 1.4	- 1.4 to - 3.0	< - 3.0
65	> - 1.0	- 1.0 to – 2.6	< - 2.6
70	> - 0.8	- 0.8 to – 2.2	< - 2.2
75	> - 0.7	- 0.7 to – 2.1	< - 2.1
80	> - 0.6	- 0.6 to – 2.0	< - 2.0
85	> - 0.7	- 0.7 to – 2.2	< - 2.2

Age (yrs)	MEN		
	Low Risk < 10%	Moderate Risk 10% - 20%	High Risk > 20%
50	>-3.4	≤-3.4	---
55	>-3.1	≤-3.1	---
60	>-3.0	≤-3.0	---
65	>-2.7	≤-2.7	---
70	>-2.1	-2.1 to -3.9	<-3.9
75	>-1.5	-1.5 to -3.2	<-3.2
80	>-1.2	-1.2 to -3.0	<-3.0
85	>-1.3	-1.3 to -3.3	<-3.3

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2010

Newfoundland Labrador

Health and Community Services

RANIBIZUMAB (LUCENTIS 2.3 MG/0.23 ML VIAL)

Neovascular (wet) age-related macular degeneration (AMD):

- A diagnosis of neovascular (wet) age-related macular degeneration (AMD);
    - Ocular Coherence Tomography (OCT) is recognized by the NLPDP as a relevant diagnostic test for wet AMD;
- Evidence of recent (< 3months) disease progression (e.g. blood vessel growth, as indicated by either fluorescein angiography, OCT or recent visual acuity changes);
- A corrected Visual acuity between 6/12 and 6/96;
    - Patients falling outside of the proposed VA criterion can be considered by the NLPDP on a case-by-case basis.
- A lesion whose size is less than or equal to 12 disc areas in its greatest linear dimension;
- When there is no permanent structural damage to the central fovea.

Any NLPDP beneficiary, who meets the above criteria, will have their drug plan coverage limited to a maximum of 15 vials used to treat the better seeing affected eye.

<u>Criteria for Exclusion</u>:

- Patients who have “permanent retinal damage”, as defined by the Royal College of Ophthalmology guidelines, including any future amendments.

Diabetic Macular edema:

For the treatment of visual impairment due to diabetic macular edema meeting all of the following criteria:

- clinically significant diabetic macular edema for whom laser photocoagulation is also indicated, **and**
- a hemoglobin A1c of less than 11%, **and**
- drug plan coverage limited to **nine vials per patient**

Macular edema secondary to retinal vein occlusion:

For the treatment of visual impairment due to macular edema secondary to retinal vein occlusion in patients meeting both of the following criteria:

- clinically significant macular edema secondary to non-ischemic branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO), not previously treated with a vascular endothelial growth factor (VEG-F) inhibitor
- drug plan coverage will be limited to **24 months duration** AND not to exceed **10 vials** for non-ischemic branch retinal vein occlusion (BRVO) or **12 vials** for patients with central retinal vein occlusion (CRVO).

Exclusion: Coverage is not considered for clients who have reached NLPDP coverage limits on another ophthalmic antineovascularization agent.

Note: For DME and wet AMD, coverage can be considered for switching between ophthalmic antineovascularization agents if coverage limit has not been reached. Coverage will be for the number of vials remaining within the coverage limit.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/lucentis_sa_form.pdf

Updated September 2015

Health and Community Services

REGORAFENIB (STIVARGA) 40 MG TABLET

For patients with metastatic and/or unresectable gastrointestinal stromal tumors (GIST) who have had disease progression on, or intolerance to, imatinib and sunitinib; AND patient has ECOG ≤ 1.

Approval period: 24 weeks

Dosing: 160 mg daily for 3 weeks, followed by 1 week off treatment

Renewals will be considered for patients who are expected to have continued clinical benefit AND who have not developed unacceptable toxicities that require discontinuation of regorafenib.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated October 2014

Health and Community Services

Repaglinide (Gluconorm 0.5, 1, 2mg tablets & generics)

For patients who have failed to respond to or have experienced hypoglycemia from benefit sulfonylureas.

Please note: Please note that coverage may be considered WITHOUT a Special Authorization request as long as the beneficiary's medication history in the NLPDP database has had a paid (non-reversed) claim for Gluconorm (repaglinide), glimepiride, gliclizide, tolbutamide, chlorpropamide or glyburide in the past year.

If there is no history of a previous claim for glimepiride, gliclizide, tolbutamide, chlorpropamide or glyburide the normal Special Authorization Process will be required.

To facilitate this process a specific **Oral Diabetes Medications Special Authorization Form** has been developed and can be found at:
http://www.health.gov.nl.ca/health/forms/pdf/oral_diabetes.pdf

Updated January 2012

Health and Community Services

RIBAVIRIN (IBAVYR 200mg, 400mg, 600mg)

For use within a combination therapy regimen for the treatment of chronic hepatitis C, in accordance with the specific eligibility criteria for approved agents, used to treat this condition.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated August 2016

Health and Community Services

RIFABUTIN (MYCOBUTIN)

For the prevention of disseminated *Mycobacterium avium* complex (MAC) disease in patients with advanced HIV infection.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

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Updated June 2012

Health and Community Services

RIFAXIMIN (ZAXINE 550 MG TABLET)

For reducing the risk of overt hepatic encephalopathy (HE) recurrence (i.e., 2 or more episodes), if the following clinical criteria are met:

Clinical Criteria:

- Patients are unable to achieve adequate control of HE recurrence with maximal tolerated dose of lactulose alone.
- Must be used in combination with maximal tolerated doses of lactulose.
- For patients not maintained on lactulose, information is required regarding the nature of the patient's intolerance to lactulose.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated April 2016

Health and Community Services

RILPIVIRINE (EDURANT 25 MG TABLET)

For the treatment of human immunodeficiency virus type 1 (HIV-1) infection in treatment-naive patients, when used in combination with other antiretroviral agents.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated April 2012

Health and Community Services

Riluzole (Rilutek 50mg & generics)

For the treatment of amyotrophic lateral sclerosis (ALS) or Lou Gehrig's Disease, when initiated by a neurologist with expertise in the management of ALS, when the patient has:

- Probable or definite diagnosis of ALS as defined by the World Federation of Neurology criteria.
- ALS symptoms for less than five years.
- FVC > 60% predicted upon initiation of therapy
- No tracheostomy for invasive ventilation.

Coverage will be reviewed every six months.
Coverage cannot be renewed once the patient has a tracheostomy for the purpose of invasive ventilation or mechanical ventilation.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated February 2015

Health and Community Services

RIOCIGUAT (ADEMPAS 0.5 mg, 1 mg, 1.5 mg, 2 mg and 2.5 mg tablets)
(DIN numbers 02412764, 02412772, 02412799, 02412802 and 02412810)

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).

Should be prescribed by a clinician with experience in the diagnosis and treatment of CTEPH.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated June 2015

Health and Community Services

Risedronate (Actonel 30mg tablets and generics)

- For the treatment of Paget's Disease.

Coverage will be limited to a 2 month approval.

Risedronate (Actonel 5mg and 35mg tablets and generics)

- For the treatment of osteoporosis associated with documented fracture.
- For the treatment of osteoporosis without documented fracture when a patient has a high 10 year fracture risk (based on age, sex and T-score, **see Appendix 1 below for fracture risk table**).
- As prophylaxis of corticosteroid induced osteoporosis in patient who will be or have been on systemic corticosteroid therapy for > 3 months.

Please note:
Alendronate 10mg & 70mg is open benefit for beneficiaries 65 years of age and older regardless of plan.

Appendix 1

10 Year Absolute Fracture Risk based on BMD

Age (yrs)	WOMEN		
	Low Risk < 10%	Moderate Risk 10% - 20%	High Risk > 20%
50	> - 2.3	- 2.3 to - 3.9	<- 3.9
55	> - 1.9	- 1.9 to - 3.4	< - 3.4
60	> - 1.4	- 1.4 to - 3.0	< - 3.0
65	> - 1.0	- 1.0 to – 2.6	< - 2.6
70	> - 0.8	- 0.8 to – 2.2	< - 2.2
75	> - 0.7	- 0.7 to – 2.1	< - 2.1
80	> - 0.6	- 0.6 to – 2.0	< - 2.0
85	> - 0.7	- 0.7 to – 2.2	< - 2.2

Age (yrs)	MEN		
	Low Risk < 10%	Moderate Risk 10% - 20%	High Risk > 20%
50	>-3.4	≤-3.4	---
55	>-3.1	≤-3.1	---
60	>-3.0	≤-3.0	---
65	>-2.7	≤-2.7	---
70	>-2.1	-2.1 to -3.9	<-3.9
75	>-1.5	-1.5 to -3.2	<-3.2
80	>-1.2	-1.2 to -3.0	<-3.0
85	>-1.3	-1.3 to -3.3	<-3.3

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated January 2016

Health and Community Services

Risperidone (Risperdal Consta 12.5mg/vial, 25/mg/vial, 37.5mg/vial and 50mg/vial)

For the treatment of schizophrenia and related psychotic disorders (not dementia related) in patients:

- who are non-adherent to an oral antipsychotic.

OR

- who are currently receiving a long-acting injectable antipsychotic and require a switch to another injectable.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated December 2016

Health and Community Services

Risperidone (Risperdal M-tab 0.5mg, 1mg, 2mg, 3mg, 4mg & generics)

- For the treatment of schizophrenia and related psychotic disorders in patients unable to be treated with the regular oral risperidone formulation.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated December 2016

Health and Community Services

Rituximab (Rituxan 100mg and 500mg for intravenous injection)

Rheumatoid Arthritis:

For the treatment of adult patients with severe active rheumatoid arthritis who have failed to respond to an adequate trial with an anti-TNF agent.

Clinical Notes:

- Rituximab will not be reimbursed concomitantly with anti-TNF agents.
- Approval for re-treatment with rituximab will only be considered for patients who have achieved a response, followed by a subsequent loss of effect and, after an interval of no less than six months from the previous dose.

Polyangiitis:

For the induction of remission in patients with severely active granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA) who have a severe intolerance or other contraindication to cyclophosphamide, or who have failed an adequate trial of cyclophosphamide.

Clinical Notes:

- Rituximab will not be reimbursed concomitantly with anti-TNF agents.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated May 2014

Newfoundland Labrador

Health and Community Services

RIVAROXABAN (XARELTO 10mg, 15mg, 20mg tablet)

For prophylaxis of venous thromboembolism following total hip replacement (THR) surgery for up to 35 days, as an alternative to low molecular weight heparins (LMWH).

For prophylaxis of venous thromboembolism following total knee replacement (TKR) surgery for up to 14 days, as an alternative to low molecular weight heparins (LMWH).

- **The recommended daily dose is 10mg.**

Please visit the link below if you require our special authorization form:
http://www.health.gov.nl.ca/health/forms/pdf/Thromboembolism_Prevention_Following_Surgery.pdf

For the prevention of stroke and systemic embolism in at-risk patients with non-valvular atrial fibrillation for whom:

- Anticoagulation is inadequate following a at least a two month trial on warfarin; **or**
- Warfarin is contraindicated or not possible due to inability to regularly monitor through International Normalized Ratio (INR) testing (i.e. no access to INR testing services at a laboratory, clinic, pharmacy, and at home).

The following patient groups are excluded from coverage for rivaroxaban for atrial fibrillation:

- Patients with impaired renal function (creatinine clearance or estimated glomerular filtration rate <30 mL/min) **OR**
- Patients 75 years of age or older without documented stable renal function **OR**
- Patients with hemodynamically significant rheumatic valvular heart disease, especially mitral stenosis **OR**
- Patients with prosthetic heart valves.

Notes:

1. At-risk patients with atrial fibrillation are defined as those with a $CHADS_2$ score of ≥ 1. Although the ROCKET-AF trial included patients with higher $CHADS_2$ scores (≥ 2), other landmark studies with the other newer oral anticoagulants demonstrated a therapeutic benefit in patients with a $CHADS_2$ score of 1. Prescribers may consider an antiplatelet regimen or oral anticoagulation for patients with a $CHADS_2$ score of 1.
2. 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).

3. 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 rivaroxaban product monograph).
4. Documented stable renal function is defined as creatinine clearance or estimated glomerular filtration rate that is maintained for at least 3 months (i.e. 30-49 mL/min for 15 mg once daily dosing or ≥ 50 mL/min for 20 mg once daily dosing).
5. There is currently no data to support that rivaroxaban provides adequate anticoagulation in patients with rheumatic valvular disease or those with prosthetic heart valves, rivaroxaban is not recommended in these populations.
6. Patients starting rivaroxaban should have ready access to appropriate medical services to manage a major bleeding event.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/atrial_fibrillation_medication_request.pdf

For the treatment of deep vein thrombosis (DVT) or pulmonary embolism (PE)

Approval Period: Up to six (6) months

Notes:

- The recommended dose of rivaroxaban for patients initiating treatment is 15 mg twice daily for 3 weeks, followed by 20 mg once daily.
- Drug plan coverage for rivaroxaban is an alternative to heparin/warfarin for up to 6 months. When used for greater than 6 months, rivaroxaban is more costly than heparin/warfarin. As such, patients with an intended duration of therapy greater than 6 months should be considered for initiation on heparin/warfarin.
- Since renal impairment can increase bleeding risk, it is important to monitor renal function regularly. Other factors that increase bleeding risks should also be assessed and monitored (see product monograph).

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated October 2014

Health and Community Services

Rivastigmine (Exelon 1.5mg, 3mg, 4.5mg, 6mg and 2mg/ml oral solution & generics)

For the treatment of patients with mild to moderate dementia who meet the following criteria:

- A Mini-Mental State Examination (MMSE) score of 10 to 30 AND;
- A Functional Assessment Staging Test (FAST) score of 4 to 5; and

Initial requests for reimbursement will be considered for a 6 month approval; subsequent requests may be considered for a maximum 12 months approval.

FAST		STAGE FUNCTIONAL IMPAIRMENT DUE TO COGNITIVE DEFICIT (NOT PHYSICAL)
4	Mild	IADLs: needs assistance (Instrumental Activities of Daily Living include complex tasks such as managing money and medications, shopping, cooking, driving, housekeeping, using telephone)
5	Moderate	Re-wearing clothes; requires assistance in such basic tasks of daily life as choosing proper clothing. Patient can no longer function independently
6	Moderately Severe	ADLs: needs assistance, especially with dressing and bathing (i.e. unable to bathe properly; inability to handle the mechanics of toileting); eventually experiences urinary and fecal incontinence (Activities of Daily Living include dressing, washing, toileting, feeding, mobility)
7	Severe	Non-verbal, non-ambulatory

Adapted from: Reisberg, B. Functional Assessment Staging (FAST). Psychopharmacology Bulletin 1988;24(4):653-9

To facilitate this process specific **Cholinesterase Inhibitor Special Authorization Forms** have been developed and can be found at:
http://www.health.gov.nl.ca/health/forms/pdf/Donepezil_Galantamine_Rivastigmine.pdf

Updated February 2017

Health and Community Services

Rizatriptan benzoate (Maxalt 5 and 10mg tablets & generics, 5 and 10mg wafers)

Coverage is provided as an open benefit up to 6 doses / 30 days[1]

Consideration is given for > 6 doses / 30 days for patients with >3 migraines/month despite prophylactic therapy.

- Coverage will be limited to a maximum of 12 doses / 30 days.

[1]Reimbursement will be available for a maximum quantity of 6 triptan doses per 30 days regardless of the agent(s) used within the 30 day period..

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated April 2016

Health and Community Services

ROTIGOTINE (NEUPRO TRANSDERMAL PATCH 24 HOURS 1mg/24 hour, 2mg/24 hour, 3mg/24 hour, 4mg/24 hour, 6mg/24 hour, 8mg/24 hour)

For adjunctive treatment of patients with advanced stage Parkinson's disease who are currently receiving a levodopa-decarboxylase inhibitor combination.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated December 2017

Newfoundland Labrador

Health and Community Services

RUFINAMIDE (BANZEL 100mg, 200mg, 400mg TABLET)

For the adjunctive treatment of seizures associated with Lennox-Gastaut syndrome in children 4 years and older and adults who meet all of the following criteria:

- Are under the care of a physician experienced in treating Lennox-Gastaut syndrome associated seizures, and
- Are currently receiving two or more antiepileptic drugs, and
- In whom less costly antiepileptic drugs are ineffective or not appropriate.

BANZEL is not indicated for the treatment of any other type of seizure disorder.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated May 2014

Health and Community Services

Ruxolitinib (Jakavi) 5mg, 10mg, 15mg, 20mg

For patients with intermediate to high risk symptomatic Myelofibrosis (MF) as assessed using the Dynamic International Prognostic Scoring System (DIPSS) Plus or patients with symptomatic splenomegaly. Patients should have ECOG performance status ≤3 and be either previously untreated or refractory to other treatment.

Approval Period: 6 months

Recommended Dose: 5 to 25 mg twice daily

Renewals will be considered for patients who are responding and benefiting from treatment.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated May 2015

Health and Community Services

SACUBITRIL/VALSARTAN (ENTRESTO) 24MG-26MG, 49MG-51MG, 97MG-103MG

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% AND
- Patient has NYHA class II to III symptoms despite at least four weeks of treatment with a stable dose of an angiotensin-converting enzyme inhibitor (ACEI) or an angiotensin II receptor antagonist (ARB) AND
- In combination with a beta blocker AND
- Other recommended therapies (if tolerable)

Clinical Notes:

- Patients should be under the case of a specialist experienced in the treatment of heart failure for patient selection, titration follow-up and monitoring.
- 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.

Updated June 2018

Health and Community Services

SALMETEROL (Serevent 50mcg/dose Diskhaler and 50mcg/dose Diskus)

Reversible Obstructive Airway Disease (Asthma):

For treatment of moderate to severe asthma in patients in whom:

- are compliant with inhaled corticosteroids at optimal doses; and
- require additional symptom control, (e.g., cough, awakening at night, missing activities such as school, work or social activities because of asthma symptoms); and
- require increasing amounts of short-acting $beta_2$-agonists, indicative of poor control

Chronic Obstructive Pulmonary Disease (COPD):

- 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 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 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.

Please visit the link below if you require our Chronic Obstructive Pulmonary Disease special authorization form:
http://www.health.gov.nl.ca/health/prescription/Chronic_Obstructive_Pulmonary_Disease_Form_2017.pdf

Updated November 2015

Health and Community Services

SAXAGLIPTIN / METFORMIN (KOMBOGLYZE 2.5mg-500mg, 2.5mg-850mg, 2.5mg-1000mg)

For the treatment of type 2 diabetes in patients who are already stabilized on therapy with metformin, a sulfonylurea and saxagliptin to replace the individual components of saxagliptin and metformin **and** for whom insulin is not an option.

To facilitate this process a specific **Oral Diabetes Medications Special Authorization Form** has been developed and can be found at:
http://www.health.gov.nl.ca/health/forms/pdf/oral_diabetes.pdf

Updated July 2015

Newfoundland Labrador

Health and Community Services

SAXAGLIPTIN (ONGLYZA 2.5mg, 5mg)

For the treatment of type 2 diabetes in addition to metformin and a sulfonylurea for patients with inadequate glycemic control on metformin and a sulfonylurea **and** for whom insulin is not an option.

To facilitate this process a specific **Oral Diabetes Medications Special Authorization Form** has been developed and can be found at:
http://www.health.gov.nl.ca/health/forms/pdf/oral_diabetes.pdf

Updated July 2015

Health and Community Services

SECUKINUMAB (COSENTYX 150mg/ml injection syringe, 300mg dose kit (two (2) subcutaneous injections of 150 mg)

Chronic Plaque Psoriasis:

For adult patients with chronic, severe, debilitating 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 to, or unable to access phototherapy.

Clinical Notes:

- Initial approval for a maximum of 12 weeks.
- Response must be assessed prior to week 12 and further doses provided only for responders.
- Continuation of therapy beyond 12 weeks will be based on response:
  - Achievement of a ≥ 75% reduction in Psoriasis Area Severity Index (PASI) score, **or**
  - A ≥ 50% reduction in PASI with a ≥ 5 point improvement in the Dermatology Life Quality Index (DLQI) **or**
  - A significant reduction in BSA, involved with consideration of important regions such as the face, hands, or genital region.
- Ongoing coverage for maintenance therapy should only be provided for responders, as noted above.

Claim Notes:

- Initial approval for a maximum of 12 weeks.
- Coverage may be approved as follows: initial dosing of 300 mg doses at Weeks 0, 1, 2 and 3, followed by monthly maintenance dosing of 300 mg doses starting at Week 4. If response criteria are met at 12 weeks, approval will be continued to a maximum dose of 300mg every month thereafter up to one year.
- Must be prescribed by a dermatologist
- Concurrent use of biologics will not be approved.

To facilitate this process, a specific **Chronic Plaque Psoriasis Special Authorization Form** has been developed and can be found at:
http://www.health.gov.nl.ca/health/prescription/chronic_plaque_psoriasis_meds_coverage_request.pdf

Psoriatic Arthritis:

For patients with active psoriatic arthritis who meet all of the following criteria:

- Have at least three active and tender joints.
- Have not responded to an adequate trial of two DMARDs or have an intolerance or contraindication to DMARDs.

Claim Notes:

- Must be prescribed by a rheumatologist.
- Combined use of more than one biologic DMARD will not be reimbursed.
- Initial approval: the recommended dose is 150 mg by subcutaneous injection with initial dosing at Weeks 0, 1, 2, 3, and 4 followed by monthly maintenance dosing.
- If a patient is an anti-TNFalpha inadequate responder and continues to have active psoriatic arthritis, consider using the 300 mg dose.
- For psoriatic arthritis patients with coexistent moderate to severe plaque psoriasis, use the dosing and administration recommendations for plaque psoriasis (i.e. 300 mg at weeks 0, 1, 2, and 3, followed by monthly maintenance dosing starting at week 4).
- Initial Approval: 6 months.
- Renewal Approval: 1 year.
    - Requests for renewal can be reassessed for yearly coverage dependent on achieving improvement in symptoms of at least 20% (20% improvement in the American College of Rheumatology response criteria (ACR 20) or response using the Psoriatic Arthritis Response criteria).

To facilitate this process, specific RA Medication Special Authorization Forms have been developed and can be found at:
http://www.health.gov.nl.ca/health/prescription/ra_meds_initiation.pdf
http://www.health.gov.nl.ca/health/prescription/ra_meds_continuation_request.pdf

Ankylosing spondylitis:

For the treatment of patients with moderate to severe ankylosing spondylitis (e.g. Bath AS Disease Activity Index (BASDAI) score $\geq$ 4 on 10 point scale) who:

- have axial symptoms***** and who have failed to respond to the sequential use of at least 2 NSAIDs at the optimum dose for a minimum period of 3 months observation or in whom NSAIDs are contraindicated,

OR

- have peripheral symptoms and who have failed to respond to, or have contraindications to, the sequential use of at least 2 NSAIDs at the optimum dose for a minimum period of 3 months observation and have had an inadequate response to an optimal dose or maximal tolerated dose of a DMARD.

Renewal Requests:

- 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 internist.
- Combined use of more than one biologic DMARD will not be reimbursed.
- Approvals will be for 150 mg at Weeks 0, 1, 2 and 3, followed by monthly maintenance dosing of 150 mg doses starting at Week 4
- Initial Approval: 6 months.
- Renewal Approval: 1 year

To facilitate this process specific RA Medications Special Authorization Forms have been developed and can be found at:
http://www.health.gov.nl.ca/health/prescription/ra_meds_initiation.pdf
http://www.health.gov.nl.ca/health/prescription/ra_meds_continuation_request.pdf

Updated March 2018

Health and Community Services

SELEXIPAG (UPTRAVI 200mg, 400mg, 600mg, 800mg, 1000mg, 1200mg, 1400mg, 1600mg)

For the long-term treatment of idiopathic pulmonary arterial hypertension (PAH), heritable PAH, PAH associated with connective tissue disorders, and PAH associated with congenital heart disease, in adult patients with World Health Organization (WHO) functional class (FC) II to III to delay disease progression, if the following clinical criterion and conditions are met:

- Inadequate control with a first- and second-line PAH therapy
- Prescribed by a clinician with experience in the diagnosis and treatment of PAH

NOTE: Combination therapy with prostacyclin or prostacyclin analogs therapies will NOT be covered

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated March 2018

Health and Community Services

SEVELAMER HCL (RENAGEL 800 MG TABLET)

For the management of hyperphosphatemia (serum phosphate greater than 1.8 mmol/L) in patients with end-stage renal disease (eGFR < 15 mL/min) who have:

- Inadequate control of phosphate levels on a calcium based phosphate binder, OR
- Hypercalcemia (corrected for albumin), OR
- calciphylaxis (calcific arteriolopathy)

Claim Notes:

- Initial Approval: 6 months.
- Renewal Approval: 1 year. Confirmation of improvement of phosphate levels is required (lab values must be provided).
- Request from a nephrologist or an internist within a dialysis unit.

To facilitate this process a specific **Sevelamer Special Authorization Form** has been developed and can be found at:
http://www.health.gov.nl.ca/health/prescription/sevelamer_specauth_form.pdf

Updated January 2017

Newfoundland Labrador

Health and Community Services

Sildenafil (Revatio 20mg & generics)

Idiopathic Pulmonary Arterial Hypertension (IPAH) functional class III:

- For the treatment of patients with World Health Organizaton (WHO) functional class III idiopathic pulmonary arterial hypertension (IPAH) who do not demonstrate vasoreactivity on testing or who do demonstrate vasoreactivity on testing but fail a trial of calcium channel blockers (CCB) or are intolerant to CCB.

Pulmonary Arterial Hypertension (PAH) secondary to connective tissue disease (functional class III):

- For the treatment of patients with World Health Organization (WHO) functional class III pulmonary hypertension associated with connective tissue disease who do not respond to conventional therapy.

Diagnosis of PAH should be confirmed by right heart catheterization.

Written request of a PAH specialist only.

Dose of Sildenafil will be limited to 20mg three times daily.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2010

Health and Community Services

SIMEPREVIR (GALEXOS 150 MG CAPSULE)

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

Claim Note:
Claims that exceed the maximum claim amount of $9,999.99 must be divided and submitted as separate transactions on different days. Please note: A single professional fee will be paid per 30 day supply.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated June 2015

Health and Community Services

Sitagliptin (Januvia 25mg, 50mg, 100mg tablet)

For the treatment of type 2 diabetes as a third drug **added** to metformin **and** a sulfonylurea for patients with inadequate glycemic control on metformin and a sulfonylurea **AND** in whom insulin is not an option.

To facilitate this process a specific **Oral Diabetes Medications Special Authorization Form** has been developed and can be found at:
http://www.health.gov.nl.ca/health/forms/pdf/oral_diabetes.pdf

Updated April 1, 2016

Health and Community Services

Sitagliptin/metformin (Janumet 50-500mg, 50-850mg & 50-1000mg tablets, Janumet XR 50mg/1000mg)

For the treatment of type 2 diabetes in patients with inadequate glycemic control on metformin and a sulfonylurea and in whom insulin is not an option AND who are already stabilized on therapy with metformin, a sulfonylurea and sitagliptan, to replace the individual components of sitagliptan and metformin in these patients.

To facilitate this process a specific **Oral Diabetes Medications Special Authorization Form** has been developed and can be found at:
http://www.health.gov.nl.ca/health/forms/pdf/oral_diabetes.pdf

Updated April 2016

Health and Community Services

SODIUM BICARBONATE 500mg tablets

For the treatment of metabolic acidosis in patients with chronic kidney disease who have a serum bicarbonate (CO_2) < 22mmol/L.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated January 2017

Health and Community Services

SODIUM CHLORIDE 7% (HYPER-SAL 7%, NEBUSAL 7%)

NHP# 80029414, NHP# 80029758

For use in patients with cystic fibrosis (CF) to help reduce pulmonary exacerbations and improve lung function.

Notes:
The combination of HyperSal **or** Nebusal **and** Pulmozyme will not be reimbursed.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated November 2015

Health and Community Services

SODIUM PHENLUBUTYRATE (PHEBURANE 483 MG/G GRANULES)

For the chronic management of urea cycle disorders (UCD).

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated March 2018

Health and Community Services

SOFOSBUVIR (SOVALDI 400 MG TABLET)

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

	Approval Period and Regimen
Genotype 2 • Without cirrhosis • With compensated cirrhosis	12 weeks in combination with ribavirin (RBV)
Genotype 3 • Without cirrhosis • With compensated cirrhosis	24 weeks in combination with RBV
Genotype 3 • Without cirrhosis	12 weeks in combination with daclatasvir
Genotype 3 • With compensated or decompensated cirrhosis • Post-liver transplant without cirrhosis or with compensated cirrhosis	12 weeks in combination with daclatasvir and ribavirin

Patients must meet ALL of the following criteria:

- Prescribed by a hepatologist, gastroenterologist, or infectious disease specialist (or other physician experienced in treating a patient with hepatitis C infection)
- Lab-confirmed hepatitis C genotype 2 and 3
- Quantitative HCV RNA value within the last 6 months
- Fibrosis stage F2 or greater (Metavir scale or equivalent) or Fibrosis stage less than F2 and at least one of the following poor prognostic factors:
    - Co-infected with HIV or hepatitis B virus
    - Post-organ transplant (liver and/or non-liver transplant)
    - Extra-hepatic manifestations
    - Chronic kidney disease stage 3, 4 or 5 as defined by the National Kidney Foundation Kidney Disease Outcomes Quality Initiative
    - Co-existent liver disease with diagnostic evidence of fatty liver disease (e.g., non-alcoholic steatohepatitis)
    - Patients with diabetes being treated with antihyperglycemic medications
    - Women of childbearing age who are planning a pregnancy within the next 12 months

Clinical Notes:

1. Treatment-experienced is defined as patients who have been previously treated with a peginterferon/ribavirin regimen, and have not experienced an adequate response.
2. 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.
3. Extra-hepatic manifestations include but are not limited to: symptomatic vasculitis associated with HCV-related mixed cryoglobulinaemia, HCV immune complex-related nephropathy and non-Hodgkin B cell lymphoma, porphyria cutanea tarda, lichen planus, and glomerulonephritis.
4. Chronic kidney disease stage 3, 4 or 5 includes patients with glomerular filtration rate (GFR) <60 mL/min/1.73m2 for ≥ 3 months.
5. Special Authority requests for patients with fibrosis stage less than F2 and fatty liver disease must include a confirmation that ultrasound imaging has been done with diagnosis of fatty liver disease.
6. Compensated cirrhosis is defined as a Child-Turcotte-Pugh (CTP) score of 5 to 6 (Class A).
7. Decompensated cirrhosis is defined as a CTP score of 7 or above (Class B or C). Special Authority requests for patients with decompensated cirrhosis must include a clinical history or ultrasound imaging diagnosis, laboratory test reports and fibrosis score test performed in the last 12 months. Acceptable methods include liver biopsy, transient elastography (FibroScan) and serum biomarker panels (such as AST-to-Platelet Ratio Index (APRI) or Fibrosis-4 (FIB-4) score) either alone or in combination. Supporting documentation must be submitted.
8. Re-treatment for direct-acting antivirals failures will be considered on a case-by-case basis under the formulary exception process.

Claim Note:

- Claims that exceed the maximum claim amount of $9,999.99 must be divided and submitted as separate transactions on different days.
- Please note: A single professional fee will be paid per 30 day supply.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/forms/pdf/hepatitis_C_treatment_request.pdf

Updated August 2017

Health and Community Services

SOFOSBUVIR/VELPATASVIR (EPCLUSA 400 MG-100 MG TABLET)

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

	Approval Period and Regimen
Genotypes 1, 2, 3, 4, 5, 6 or mixed genotypes • Patients with compensated cirrhosis • Patients without cirrhosis	12 weeks
Genotypes 1, 2, 3, 4, 5, 6 or mixed genotypes • Patients with decompensated cirrhosis	12 weeks in combination with ribavirin

Patients must meet all of the following criteria:

- Prescribed by a hepatologist, gastroenterologist, or infectious disease specialist (or other physician experienced in treating a patient with hepatitis C infection).
- Lab-confirmed hepatitis C genotype 1, 2, 3, 4, 5, 6 or mixed genotypes
- Quantitative HCV RNA value within the last 6 months
- Fibrosis stage

Clinical Notes:

1) Treatment-experienced is defined as a patient who has been previously treated with a peginterferon/ribavirin regimen, including regimens containing HCV protease inhibitors and who has not experienced an adequate response.
2) 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.
3) Compensated cirrhosis is defined as a Child-Turcotte-Pugh (CTP) score of 5 to 6 (Class A).
4) Re-treatment for direct-acting antivirals failures will be considered on a case-by-case basis under the formulary exception process.

Claim Notes:

Claims that exceed the maximum claim amount of $9,999.99 must be divided and submitted as separate transactions on different days.
Please note: A single professional fee will be paid per 30 day supply.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/forms/pdf/hepatitis_C_treatment_request.pdf

Updated September 2018

Health and Community Services

SOFOSBUVIR/VELPATASVIR/VOXILAPREVIR (VOSEVI) 400MG/100MG/100MG TABLET)

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

	Approval Period
Genotypes 1, 2, 3, 4, 5, 6 or mixed genotypes • Patients with compensated cirrhosis • Patients without cirrhosis	12 weeks

Patients must meet all of the following criteria:

- Prescribed by a hepatologist, gastroenterologist, or infectious disease specialist (or other physician experienced in treating a patient with hepatitis C infection).
- Lab-confirmed hepatitis C genotype 1, 2, 3, 4, 5, 6 or mixed genotypes
- Quantitative HCV RNA value within the last 6 months

Clinical Notes:

1) Treatment experienced is defined as a patient who has been previously treated with an NS5A inhibitor for genotype 1, 2, 3, 4, 5 or 6 or sofosbuvir without an NS5A inhibitor for genotype 1, 2, 3 or 4 and who has not experienced an adequate response.
2) Compensated cirrhosis is defined as a Child-Turcotte-Pugh (CTP) score of 5 to 6 (Class A).
3) Re-treatment for sofosbuvir-velpatasvir-voxilaprevir treatment failures will be considered on a case-by-case basis under the formulary exception process.

Claim Notes:

Claims that exceed the maximum claim amount of $9,999.99 must be divided and submitted as separate transactions on different days.
Please note: A single professional fee will be paid per 30 day supply.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/forms/pdf/hepatitis_C_treatment_request.pdf

Updated September 2018

Health and Community Services

Sorafenib (Nexavar 200mg tablets)

Hepatocellular carcinoma:

For the treatment of advanced hepatocellular carcinoma is considered under the following criteria:
Initial approval criteria:

- For patients with Child-Pugh Class A advanced hepatocellular carcinoma; and
- Have ECOG status 0,1, or 2; and
- Have either progressed on trans-arterial chemoembolization (TACE) or are not suitable for the TACE procedure.

Initial approval period: 3 months

Renewal criteria:

- Documentation of radiography and/or scan results indicating no progression.

Approval period for renewal: 3 months

- Not reimbursed if used with induction or adjuvant intent along with other curative-intent treatments.
- Not reimbursed if for maintenance therapy after trans-arterial chemoembolization.
- Not reimbursed if patients have Child-Pugh B or Child-Pugh C cirrhosis.

Metastatic clear-cell renal carcinoma:

For patients with histologically confirmed metastatic clear-cell renal-cell carcinoma AND

- the disease had progressed after prior cytokine therapy (i.e.interferon) within the previous 8 months locally advanced/metastatic renal cell (clear cell); and
- patient has a performance status of 0 or 1 on the basis of the Eastern Cooperative Oncology Group criteria; and
- with favorable to intermediate risk disease according to the Memorial Sloan-Kettering Cancer Center (MSKCC) prognostic score*.

Initial approval period: 1 year

Renewal criteria: Written confirmation from the clinical that the patient has benefited from therapy and is expected to continue to do so; Renewal: 1 year

* The Memorial Sloan-Kettering Cancer Center (MSKCC) Prognostic Score categorizes patients into three risk groups according to the number of pre-treatment risk factors present: Favourable = none; Intermediate = one or two; Poor = three or more. Pre-treatment risk factors:

- Low Karnofsky performance status (<80%)
- Lactate Dehydrogenase level greater than 1.5 times the upper limit of normal
- Hemoglobin level below the lower limit of normal
- High corrected serum calcium level (>10 mg/dL or 2.5 mmol/L)
- Interval of less than 1 year between diagnosis and treatment

Reference: Motzer RJ, Bacik J, Murphy BA et al. Interferon-alfa as a comparative treatment for clinical trials of new therapies against advanced renal cell carcinoma. J Clin Oncol 2002;20;289-96.

Please visit the following link if you require our standard special authorization form: http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated August 2013

Health and Community Services

STIRIPENTOL (DIACOMIT 250mg, 500mg CAPSULE, 250og, 500mg POWDER PACKET)

DIN 02398958, 02398966, 02398974 and 02398982

For use in combination with clobazam and valproate as adjunctive therapy of refractory generalized tonic-clonic seizures in patients with severe myoclonic epilepsy in infancy (Dravet syndrome), whose seizures are not adequately controlled with clobazam and valproate alone.

The patient must be under the care of a neurologist or a pediatrician.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated October 2015

Health and Community Services

Sumatriptan nasal spray (Imitrex 5mg, 20mg nasal spray)

For the treatment of patients with acute migraine attacks who have an intolerance or insufficient response to all triptans listed as regular benefits (e.g. almotriptan, rizatriptan, sumatriptan, zolmitriptan).

Coverage limited to 6 doses / 30 days[1]

- More than 6 doses / 30 days considered for patients with >3 migraines/month on average despite prophylactic therapy (up to a maximum of 12 doses / 30 days).

[1]Reimbursement will be available for a maximum quantity of 6 triptan doses per 30 days regardless of the agent(s) used within the 30 day period.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated May 2018

Health and Community Services

Sumatriptan sc injection (Imitrex 12mg/ml injection):

For the treatment of patients with acute migraine attacks who have an intolerance or insufficient response to all triptans listed as regular benefits (e.g. almotriptan, rizatriptan, sumatriptan, zolmitriptan).

Coverage limited to 6 doses / 30 days[1]

- More than 6 doses / 30 days considered for patients with >3 migraines/month on average despite prophylactic therapy (up to a maximum of 12 doses / 30 days).

[1]Reimbursement will be available for a maximum quantity of 6 triptan doses per 30 days regardless of the agent(s) used within the 30 day period.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

May 2018

Health and Community Services

Sumatriptan (Imitrex 50mg, 100mg tablet, Imitrex DF 50mg, 100mg, and generics)

Coverage is provided as an open benefit up to 6 doses / 30 days[1]

Coverage limited to 6 doses / 30 days[1]

- More than 6 doses / 30 days considered for patients with >3 migraines/month on average despite prophylactic therapy (up to a maximum of 12 doses / 30 days).

[1]Reimbursement will be available for a maximum quantity of 6 triptan doses per 30 days regardless of the agent(s) used within the 30 day period.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated May 2018

Health and Community Services

Sunitinib (Sutent 12.5mg, 25mg and 50mg capsules)

Unresectable or recurrent/metastatic GIST:

For patients with histologically proven unresectable or recurrent/metastatic GIST who have failed or are unable to tolerate imatinib therapy.

Approval period: 6 months

Recommended Dose: 50mg once daily, on a schedule of 4 weeks on treatment followed by 2 weeks off.

Response to Sunitinib therapy should be reassessed every six months and therapy should be discontinued when there is objective evidence of disease progression.

Sunitinib will not be funded concomitantly with imatinib.

Metastatic Renal Cell Carcinoma (MRCC):

For the first-line treatment of metastatic renal cell carcinoma (MRCC) for patients with favorable to intermediate risk disease according to the Memorial Sloan-Kettering Cancer Center (MSKCC) prognostic score*. Requests for coverage should include pre-treatment risk factors.

Approval period: 12 months

Recommended Dose: 50mg once daily, on a schedule of 4 weeks on treatment followed by 2 weeks off.

Renewal criteria:

- Written confirmation from the clinical physician that the patient has benefited from therapy and is expected to continue to do so.

* The Memorial Sloan-Kettering Cancer Center (MSKCC) Prognostic Score categorizes patients into three risk groups according to the number of pre-treatment risk factors present:
Favourable = none; Intermediate = one or two; Poor = three or more.
Pre-treatment risk factors:
• Low Karnofsky performance status (<80%)
• Lactate Dehydrogenase level greater than 1.5 times the upper limit of normal
• Hemoglobin level below the lower limit of normal
• High corrected serum calcium level (>10 mg/dL or 2.5 mmol/L)
• Interval of less than 1 year between diagnosis and treatment

Reference: Motzer RJ, Bacik J, Murphy BA et al. Interferon-alfa as a comparative treatment for clinical trials of new therapies against advanced renal cell carcinoma. J Clin Oncol 2002;20;289-96.

Pancreatic Neuroendocrine Tumor (pNET):

For the treatment of patients with progressive, unresectable, well or moderately differentiated, locally advanced or metastatic pancreatic neuroendocrine tumors (pNET) with good performance status (ECOG 0-2), until disease progression.

Note: Patients whose disease progresses on sunitinib are not eligible for funded treatment with everolimus for pNET.

Approval Period: 12 months

Recommended Dose: 37.5mg daily until disease progression or development of unacceptable toxicity requiring discontinuation of sunitinib

Renewals will be considered for patients who do not have evidence of disease progression AND who have not developed unacceptable toxicities that require discontinuation of sunitinib.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated February 2014

Health and Community Services

Tacrolimus (Protopic 0.03%, 0.1% ointment)

Protopic 0.1%:

For the intermittent use for moderate to severe atopic dermatitis in adults who have:

- failed or are intolerant to a site appropriate strength of corticosteroid therapy (i.e., low potency on face versus intermediate to high potency for trunk and extremities).

Protopic 0.03%:

For children greater than 2 years of age with refractory* atopic dermatitis for a 12 month period.

*failure to improve after adequate hydration of the skin and traditional topical corticosteroid therapy.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2010

Health and Community Services

Tazarotene (Tazorac 0.05%, 0.1% gel)

- For use in psoriasis therapy when conventional therapies (high potency steroids) have been ineffective or are inappropriate.

- For the treatment of acne when conventional therapies with benefit topical agents have failed.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2010

Health and Community Services

Temozolomide (Temodal 5, 20, 100, 140mg, 180mg, 250mg capsules & generics)

For the treatment of adult patients with glioblastoma multiforme or anaplastic astrocytoma and documented evidence of recurrence or progression after standard therapy (resection, radiotherapy, and chemotherapy).

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2010

Health and Community Services

Tenofovir (Viread 300mg tablets & generics)

HIV Infection:

- For the treatment of adult patients with HIV infection who have experienced adverse events or virologic failure with nucleoside reverse transcriptase inhibitors.

Chronic Hepatitis B:

- For the treatment of chronic hepatitis B infection in patients with cirrhosis documented on radiologic or histologic grounds **AND**
- A HBV DNA concentration above 200IU/ml.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated September 2017

Health and Community Services

TERBINAFINE (LAMISIL and generic brands)

250mg tablet

- Treatment of onychomycosis
- Treatment of dermatophyte infection unresponsive to other treatments or unlikely to respond to other treatments due to the site or severity of the infection.

Claim Notes:

- Approval limits payment for 6 weeks for the treatment of fingernail mycosis.
- Approval limits payment for 12 weeks for the treatment of toenail mycosis.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated April 2016

Health and Community Services

TERIFLUNOMIDE (AUBAGIO 14MG TABLET)

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.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated March 2015

Health and Community Services

Testosterone topical (Androgel 2.5mg & 5mg sachets, Testim 1% gel, Androderm 25mg/24hr, 50mg/24hr patch)

For the treatment of congenital and acquired primary or secondary hypogonadism in males with a specific diagnosis of:

> **Primary:** Cryptorchidism, Klinefelter's, orichidectomy, and other established causes.
>
> **Secondary:** Pituitary-hypothalamic injury due to tumors, trauma, radiation.

Testosterone deficiency should be clearly demonstrated by clinical features and confirmed by two separate biochemical tests before initiating any T therapy.

Older males with non-specific symptoms of fatigue, malaise or depression who have low testosterone (T) levels do not satisfy these criteria.

Limited to 5 g/day gel or 5 mg patch.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2010

Health and Community Services

Testosterone Undecanoate (Andriol 40mg capsule and generics)

For the treatment of congenital and acquired primary or secondary hypogonadism in males with a specific diagnosis of:

> **Primary:** Cryptorchidism, Klinefelter's, orichidectomy, and other established causes.
>
> **Secondary:** Pituitary-hypothalamic injury due to tumors, trauma, radiation.

Testosterone deficiency should be clearly demonstrated by clinical features and confirmed by two separate biochemical tests before initiating any T therapy.

Older males with non-specific symptoms of fatigue, malaise or depression who have low testosterone (T) levels do not satisfy these criteria.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2010

Health and Community Services

Thyrotropin alpha (Thyrogen 0.9mg/ml)

For preparation prior to radioiodine ablation in patients who have undergone thryroidectomy for papillary or follicular thyroid cancer.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2010

Health and Community Services

TICAGRELOR (BRILINTA 90 MG TABLET)

To be taken in combination with ASA 75 mg -150mg daily[a] for patients with acute coronary syndrome (i.e. ST elevation myocardial infarction (STEMI), non-ST elevation myocardial infarction (NSTEMI), or unstable angina (UA), as follows:

STEMI[b,c]

- STEMI patients undergoing primary PCI

NSTEMI or UA[b,c]

- Presence of high risk features irrespective of intent to perform revascularization:
  - High GRACE risk score (>140)
  - High TIMI risk score (5-7)
  - Second ACS within 12 months
  - Complex or extensive coronary artery disease e.g. diffuse three vessel disease
  - Definite documented cerebrovascular or peripheral vascular disease
  - Previous CABG

OR

- Undergoing PCI + high risk angiographic anatomy[d]

Notes:

(a) Co-administration of ticagrelor with high maintenance dose ASA (>150 mg daily) is not recommended.

(b) In the PLATO study more patients on ticagrelor experienced non CABG related major bleeding than patients on clopidogrel, however, there was no difference between the rate of overall major bleeding, between patients treated with ticagrelor and those treated with clopidogrel. As with all other antiplatelet treatments the benefit/risk ratio of antithrombotic effect vs. bleeding complications should be evaluated.

(c) Ticagrelor is contraindicated in patients with active pathological bleeding, in those with a history of intracranial hemorrhage and moderate to severe hepatic impairment.

(d) High risk angiographic anatomy is defined as any of the following: left main stenting, high risk bifurcation stenting (i.e., two-stent techniques), long stents ≥ 38 mm or overlapping stents, small stents ≤ 2.5 mm in patients with diabetes.

Approval will be for a maximum of 12 months.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/forms/Ticagrelor_Form.pdf

Updated February 2015

Health and Community Services

Tinzaparin sodium (Innohep 10000U, 20000U vial, 3500U, 8000U, 10,000U, 12000U, 16000U syringe)

- For treatment of acute Venous Thromboembolism (VTE)
  - coverage is limited to 7 to 10 days while establishing a therapeutic INR
  - extended treatment of recurrent VTE may be considered in patients with treatment failure on therapeutic doses of warfarin. Coverage will be limited to a 3 month period.

- For the prevention of VTE following:
  - total hip replacement (THR) surgery or hip fracture surgery (maximum coverage up to 35 days)
  - total knee replacement (TKR) surgery (maximum coverage up to 10 days)

- For prophylaxis, coverage is limited to patients with concomitant anticoagulation syndromes, or in patients who have failed to reach therapeutic INR while on oral anticoagulant therapy.
  - Coverage will be limited to a 3 month period.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/forms/pdf/Thromboembolism_Prevention_Following_Surgery.pdf

Updated March 2016

Health and Community Services

TIOTROPIUM / OLODATEROL (INSPIOLTO RESPIMAT 2.5-2.5ug)

Chronic Obstructive Pulmonary Disease (COPD):

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:

- 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 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 LABA or LAAC.

Please visit the link below if you require our Chronic Obstructive Pulmonary Disease special authorization form:
http://www.health.gov.nl.ca/health/prescription/Chronic_Obstructive_Pulmonary_Disease_Form_2017.pdf

Updated July 2016

Health and Community Services

TIOTROPIUM (SPIRIVA 18ug CAPSULES, SPIRIVA RESPIMAT 2.5ug INHAL)

Chronic Obstructive Pulmonary Disease (COPD):

- 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 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 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.

Please visit the link below if you require our Chronic Obstructive Pulmonary Disease special authorization form:
http://www.health.gov.nl.ca/health/prescription/Chronic_Obstructive_Pulmonary_Disease_Form_2017.pdf

Updated June 2016

Health and Community Services

Tipranavir (Aptivus 250mg capsule)

To be used as an alternate Protease Inhibitor (PI's) as part of a HIV treatment regimen in the treatment of adult patients with HIV-1 infection who are:

- treatment experienced and
- have demonstrated failure to multiple PI's and in whom no other PI is a treatment option.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2010

Health and Community Services

TOBRAMYCIN (TOBI 300 MG/5ML SOLUTION for INHALATION)
TOBRAMYCIN (TOBI PODHALER 28 MG POWDER for INHALATION)

- For the management of patients with moderate to severe* chronic Pseudomonas aeruginosa infections, in Cystic Fibrosis (CF) patients aged 6 years and older, when used as cyclic treatment (28-day cycles),

AND

- The patient has had a hypersensitivity reaction (e.g. edema, respiratory distress, serum sickness, anaphylaxis) to a non-medicinal ingredient contained in the interchangeable generic tobramycin product.

*Moderate to severe CF is defined as FEV1 of 25-75%.

Please note:

- Generic brands are available as an open benefit
- Restricted to patients eligible under the Select Needs Program.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated November 2016

Health and Community Services

TOCILIZUMAB (ACTEMRA 162 MG/0.9 ML SYRINGE)

Rheumatoid Arthritis

For the treatment of severely active rheumatoid arthritis, in combination with methotrexate or other disease-modifying antirheumatic drugs (DMARDs), in adult patients who are refractory or intolerant to:

- Methotrexate (oral or parenteral) at a dose of ≥ 20 mg weekly (≥15mg if patient is ≥65 years of age) for a minimum of 12 weeks, followed by methotrexate in combination with at least two other DMARDs, such as hydroxychloroquine and sulfasalazine, for a minimum of 12 weeks;

Or

- Initial use of triple DMARD therapy with methotrexate in combination with at least two other DMARDs, such as hydroxychloroquine and sulfasalazine, for a minimum of 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 may take up to 24 weeks, however if no improvement is seen after 12 weeks of triple DMARD use, therapy should be changed.
- If the patient is intolerant to triple DMARD therapy, then dual therapy with DMARDs (methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) must be considered.
- Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above.
- Intolerant is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs. The nature of intolerance(s) must be clearly documented.

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:
    - Subcutaneous injection: Initial approvals will be for 162mg every other week for patients <100kg, with a maximum maintenance dose escalation to weekly dosing permitted. Patients ≥100kg will be approved for 162mg every week, with no dose escalation permitted.

Please visit the following link if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/ra_meds_initiation.pdf
http://www.health.gov.nl.ca/health/prescription/ra_meds_continuation_request.pdf

TOCILIZUMAB (ACTEMRA 80mg/4ml, 200mg/10ml, 400mg/20ml intravenous infusion)

Rheumatoid Arthritis

For the treatment of severely active rheumatoid arthritis, in combination with methotrexate or other disease-modifying antirheumatic drugs (DMARDs), in adult patients who are refractory or intolerant to:

- Methotrexate (oral or parenteral) at a dose of ≥ 20 mg weekly (≥15mg if patient is ≥65 years of age) for a minimum of 12 weeks, followed by methotrexate in combination with at least two other DMARDs, such as hydroxychloroquine and sulfasalazine, for a minimum of 12 weeks;

or

- Initial use of triple DMARD therapy with methotrexate in combination with at least two other DMARDs, such as hydroxychloroquine and sulfasalazine, for a minimum of 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 may take up to 24 weeks, however if no improvement is seen after 12 weeks of triple DMARD use, therapy should be changed.
- If the patient is intolerant to triple DMARD therapy, then dual therapy with DMARDs (methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) must be considered.
- Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above.
- Intolerant is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs. The nature of intolerance(s) must be clearly documented.

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:
  - Tocilizumab: 4mg/kg/dose once every 4 weeks followed by an increase to 8 mg/kg/dose based on clinical response.

To facilitate this process specific **RA Medication Special Authorization Forms** have been developed and can be found at:
http://www.health.gov.nl.ca/health/prescription/ra_meds_initiation.pdf
http://www.health.gov.nl.ca/health/prescription/ra_meds_continuation_request.pdf

Systemic Juvenile Idiopathic Arthritis (sJIA):

For the treatment of active systemic juvenile idiopathic arthritis (sJIA), in patients 2 years of age or older, who have responded inadequately to non-steroidal anti-inflammatory drugs (NSAIDs) and systemic corticosteroids (with or without methotrexate) due to intolerance or lack of efficacy.

Clinical Notes:

- Coverage will be approved for a dose of 12 mg/kg for patients weighing less than 30kg or 8 mg/kg for patients weighing greater than or equal to 30kg to a maximum of 800mg, administered every two weeks.
- Continued coverage will be dependent on a positive patient response as determined by a pediatric rheumatologist.

Claim Notes:

- Must be prescribed by, or in consultation with, a pediatric rheumatologist.
- Initial approval period: 16 weeks
- Renewal period: 1 year

Polyarticular Juvenile Idiopathic Arthritis (pJIA):

For the treatment of children (age 2-17) with polyarticular juvenile rheumatoid arthritis who have:

- not responded to an adequate trial with one or more disease modifying antirheumatic drug (DMARD) for at least 3 months, OR has experience intolerance to DMARDs

Claim Note:

- Must be prescribed by a rheumatologist who is familiar with the use of DMARDs and/or biologic DMARDs in children.
- Intravenous infusion: Approvals will be for 10mg/kg for patients <30kg or 8mg/kg for patients ≥ 30kg, to a maximum of 800mg, administered every four weeks.
- Initial approval period: 16 weeks
- Renewal Approval: 1 year. Confirmation of continued response is required.

To facilitate this process specific **RA Medication Special Authorization Forms** have been developed and can be found at:
http://www.health.gov.nl.ca/health/prescription/ra_meds_initiation.pdf
http://www.health.gov.nl.ca/health/prescription/ra_meds_continuation_request.pdf

Updated July 2016

Health and Community Services

TOFACITINIB (XELJANZ 5 MG TABLET)

Rheumatoid Arthritis (RA):

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) for a minimum of 12 weeks, followed by methotrexate in combination with at least two other DMARDs, such as hydroxychloroquine and sulfasalazine, for a minimum of 12 weeks;

or

- Initial use of triple DMARD therapy with methotrexate in combination with at least two other DMARDs, such as hydroxychloroquine and sulfasalazine, for a minimum of 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 may take up to 24 weeks, however if no improvement is seen after 12 weeks of triple DMARD use, therapy should be changed.
- If the patient is intolerant to triple DMARD therapy, then dual therapy with DMARDs (methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) must be considered.
- Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above.
- Intolerant is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs. The nature of intolerance(s) must be clearly documented.

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:
    - TOFACITINIB: Maximum daily dosage not to exceed 10 mg (i.e., 5 mg twice daily)

To facilitate this process, specific **RA Medication Special Authorization Forms** have been developed and can be found at:
http://www.health.gov.nl.ca/health/prescription/ra_meds_initiation.pdf
http://www.health.gov.nl.ca/health/prescription/ra_meds_continuation_request.pdf

Updated April 2017

Health and Community Services

TRAMETINIB (MEKINIST) 0.5mg, 2mg tablets

First-line BRAF-mutation targeted treatment (i.e. patients may be treatment naïve or previously treated with checkpoint inhibitor immunotherapy and/or chemotherapy) with Tafinlar Mekinist (Dabrafenib Trametinib) combination therapy for patients with BRAF V600 mutation positive, unresectable or metastatic melanoma and who have an ECOG performance status of 0 or 1. If brain metastases are present, patients should be asymptomatic or have stable symptoms. Treatment should continue until disease progression.

OR

First-line BRAF-mutation targeted treatment (i.e. patients may be treatment naïve or previously treated with checkpoint inhibitor immunotherapy and/or chemotherapy) with Mekinist monotherapy for patients with BRAF V600 mutation positive, unresectable or metastatic melanoma and who have an ECOG performance status of 0 or 1. If brain metastases are present, patients should be asymptomatic or have stable symptoms. Treatment should continue until disease progression.

Approval period: 6 months

Dosing: 2mg once daily

Renewals will be considered for patients who do not have evidence of disease progression AND who have not developed unacceptable toxicities that require discontinuation of trametinib.

NOTE: Trametinib, or the combination of Dabrafenib and Trametinib, is not approved in patients who have progressed on prior BRAF targeted therapy.
Patients who received combination of Dabrafenib and Trametinib are not eligible for coverage of any other BRAF targeted therapy as a subsequent line of therapy following disease progression (e.g., monotherapy with Dabrafenib, Trametinib or Vemurafenib).
Patients who experience toxicity to combination therapy, but without disease progression, will be eligible for coverage of either Dabrafenib or Trametinib as monotherapy if clinically appropriate or Vemurafenib.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated February 2017

Health and Community Services

Treprostinil (Remodulin 1mg/ml, 2.5mg/ml, 5mg/ml & 10mg/ml)

For patients with primary pulmonary hypertension or pulmonary hypertension secondary to collagen vascular disease, with New York Heart Association class lll or lV disease who have:

- failed to respond to non-prostanoid therapies, **and**:
- who are not candidates for epoprostenol therapy because of:
    - prior recurrent complications with central line access (infec/thrombosis) **or**
    - inability to operate the complicated delivery system of epoprostenol, **or**
    - they reside in an area without ready access to medical care, which could complicate problems associated with an abrupt interruption of epoprostenol therapy.

Please visit the following link if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2010

Newfoundland Labrador

Health and Community Services

TROSPIUM CHLORIDE (TROSEC 20mg)

For the treatment of overactive bladder (not stress incontinence) after a reasonable trial, titrated, and of appropriate length* of oxybutynin IR, tolterodine OR solifenacin are not tolerated.

*an appropriate trial is considered to be of 12 weeks duration.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated October 2018

Health and Community Services

TROSPIUM CHLORIDE (TROSEC 20mg)

For the treatment of overactive bladder (not stress incontinence) after a reasonable trial, titrated, and of appropriate length* of oxybutynin IR, tolterodine AND solifenacin are not tolerated.

*an appropriate trial is considered to be of 12 weeks duration.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated March 2018

Health and Community Services

ULIPRISTAL (FIBRISTAL 5 MG TABLET)

For the treatment of moderate to severe signs and symptoms of uterine fibroids in adult women of reproductive age, who are eligible for surgery, under the following conditions:

- the duration of treatment will not exceed three months, per patient, per lifetime
- the patient is under the care of a physician experienced in the management of gynecological conditions such as uterine fibroids

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2016

Health and Community Services

UMECLIDINIUM/VILANTEROL (ANORO ELLIPTA 62.5-25ug INHALER)

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:

- 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-2 agonist (LABA) or long-acting anticholinergic therapy (LAAC).

Please visit the link below if you require our Chronic Obstructive Pulmonary Disease special authorization form:
http://www.health.gov.nl.ca/health/prescription/Chronic_Obstructive_Pulmonary_Disease_Form_2017.pdf

Updated October 2015

Health and Community Services

UMECLIDINIUM BROMIDE (INCRUSE ELLIPTA 62.5 MCG INHALATION DEVICE)

- 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 exacerbations(s) and an inadequate response to LABA/ICS or LAAC. NOTE: Combination therapy of single agent long-acting bronchodilator inhalers, e.g., LABA, LAAC, will not be considered.

Clinical Notes:

1. Moderate to severe COPD is defined by spirometry as a 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 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 (Combivent Respimat)

   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.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2016

Health and Community Services

URSODIOL (URSO 250mg TABLET, URSO DS 500mg TABLET & generics)

- For dissolution of gallstones in patients who cannot undergo a cholecystectomy.
- For management of cholestactic liver disease such as primary biliary cirrhosis.

Please visit the following link if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated August 2016

Health and Community Services

USTEKINUMAB (STELARA 45mg/0.5ml, 90mg/ml solution for subcutaneous injection)

For adult patients with chronic severe, debilitating 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 to methotrexate and cyclosporine;
- Failure to respond to, intolerant to, or unable to access phototherapy.

Requests for renewal must include information demonstrating an adequate response, defined as:

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

Claim Notes:

- Must be prescribed by a dermatologist.
- Combined use of more than one biologic DMARD will not be reimbursed.
- Approvals will be for 90 mg given at weeks 0, 4 and 16, then every 12 weeks thereafter.
- Initial Approval: 16 weeks.
- Renewal Approval: 1 year.

To facilitate this process a specific **Chronic Plaque Psoriasis Special Authorization Form** has been developed and can be found at:
http://www.health.gov.nl.ca/health/prescription/chronic_plaque_psoriasis_meds_coverage_request.pdf

Updated February 2018

Health and Community Services

VALGANCICLOVIR (VALCYTE 450mg TABLET& generics)

- For the prevention of cytomegalovirus (CMV) disease in solid organ transplant in patients as high-risk (Donor positive/Recipient negative).
    - Coverage will be for a maximum of 90 days.

- For the treatment of cytomegalovirus (CMV) retinitis in HIV-positive patients, upon the request of an infectious disease specialist only.
    - Coverage will be for a maximum of 90 days.

- For the treatment of patients with cytomegalovirus (CMV) infection who have received a solid organ transplant.
    - Coverage will be for a maximum of 90 days post-transplant.
    - Requests from specific transplant centers for longer durations will be considered based on their standard protocols.

Please visit the following link if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated November 2015

Health and Community Services

VEDOLIZUMAB (ENTYVIO 300mg VIAL for IV infusion)

Ulcerative Colitis

- For the treatment of adult patients with moderately to severely active ulcerative colitis (UC) who have a partial Mayo score > 4, and a rectal bleeding subscore ≥ 2 and are:
- refractory or intolerant to conventional therapy (i.e. 5-ASA for a minimum of 4 weeks, and prednisone ≥ 40mg daily for two weeks or IV equivalent for one week); or
- corticosteroid dependent (i.e. cannot be tapered from corticosteroids without disease recurrence; or have relapsed within three months of stopping corticosteroids; or require two or more courses of corticosteroids within one year.)

Renewal requests must include information demonstrating the beneficial effects of the treatment, specifically:

- a decrease in the partial Mayo score ≥ 2 from baseline, and
- a decrease in the rectal bleeding subscore ≥1.

Clinical Notes:

- Consideration will be given for patients who have not received a four week trial of aminosalicylates if disease is severe (partial Mayo score > 6).
- 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 gastroenterologist or physician with a specialty in gastroenterology.
- Combined use of more than one biologic DMARD will not be reimbursed.
- Initial Approval: 3 infusions of 300mg at week 0, 2 & 6.
- Discontinue therapy in patients who show no evidence of therapeutic benefit by Week 10.
- **The maximum approved dose is 300mg at 0, 2, and 6 weeks then every 8 weeks.**

To facilitate this process a specific Anti-TNF agents for Crohn's disease Special Authorization Form has been developed and can be found at:
http://www.health.gov.nl.ca/health/forms/pdf/IBD.pdf

Crohn's Disease

- For the treatment of adult patients with moderately to severely active* Crohn's disease (CD) with contraindications to or not achieving remission with glucocorticosteroids **AND** immunosuppressive therapy.
    - Initial request must include current Crohn's Disease Activity Index (CDAI) or the Harvey Bradshaw Index Assessment (HBI) score.

Claim Notes:

- Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology.

- Concurrent use of other biologic DMARDS not approved.
- Initial Approval: 3 infusions of 300mg at week 0, 2 & 6.
- Renewal Approval: Continued coverage dependent on evidence of response using criteria such the 100 point reduction in Crohn's Disease Activity Index (CDAI) or the Harvey-Bradshaw Index Assessment (HBI) with a score of 5 or less or a decrease in score of 4 or more.
- Discontinue therapy in patients who show no evidence of therapeutic benefit by Week 14.
- **The maximum approved dose is 300mg at 0, 2, and 6 weeks then every 8 weeks.**

To facilitate this process a specific **Inflammatory Bowel Disease Special Authorization Form** has been developed and can be found at:
http://www.health.gov.nl.ca/health/forms/pdf/IBD.pdf

Updated August 2017

Health and Community Services

VEMURAFENIB (ZELBORAF) 240MG TABLETS

As a first-line therapy for patients presenting with BRAF V600 mutation-positive unresectable stage IIIC or IV melanoma or for patients who develop metastatic disease. Patients should have good performance status (ECOG ≤ 1), and, if brain metastases are present, the metastases must have been previously treated and be stable.

OR

In combination with cobimetinib, for the treatment of patients with previously untreated BRAF V600 mutation-positive unresectable stage III or stage IV melanoma who have a good performance status. Treatment should continue until unacceptable toxicity or disease progression. If brain metastases are present, patients should be asymptomatic or have stable symptoms.

Approval period: 6 months

Dosing: 960mg twice daily

Renewals will be considered for patients who do not have evidence of disease progression. AND who have not developed unacceptable toxicities that require discontinuation of vemurafenib.

NOTE: Vemurafenib, or the combination of Cobimetinib and Vemurafenib, is not approved in patients who have progressed on prior BRAF targeted therapy.
Patients who received combination of Cobimetinib and Vemurafenib are not eligible for coverage of any other BRAF targeted therapy as a subsequent line of therapy following disease progression (e.g., monotherapy with Dabrafenib, Trametinib or Vemurafenib).
Patients who experience toxicity to combination therapy but without disease progression will be eligible for coverage of either Vemurafenib as monotherapy if clinically appropriate or Dabrafenib and/or Trametinib as combination therapy or as monotherapy

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated June 2017

Health and Community Services

VIGABATRIN (SABRIL 500mg tablet, 500mg POWDER IN PACKET)

- For the adjunctive management of epilepsy in those patients who do not respond to alternative treatment combinations, or in who other drug combinations have not been tolerated.
- For the management of infantile spasms.

Claim Note:

- The maximum approved dose will be 4g/day

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated January 2017

Health and Community Services

VISMODEGIB (Erivedge) 150mg

For patients with metastatic basal cell carcinoma (BCC) or with locally advanced BCC (including patients with basal cell nevus syndrome, i.e. Gorlin syndrome) who have measurable metastatic disease or locally advanced disease, which is considered inoperable or inappropriate for surgery and inappropriate for radiotherapy; AND

- Patient 18 years or age or older; AND
- Patient has ECOG ≤ 2

Approval period: 9 months

Dosing: 150 mg daily

Renewals will be considered for patients who do not have evidence of disease progression AND who have not developed unacceptable toxicities that require discontinuation of vismodegib.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated October 2014

Health and Community Services

Voroconazole (VFend 50mg, 200mg tablets)

- For culture proven invasive candidiasis with documented resistance to fluconazole.

- Upon the request of an infectious diseases physician, respiratory medicine physician, or other physician with specific expertise in invasive aspergillosis for the treatment of invasive aspergillosis.

Please visit the following link if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2010

Health and Community Services

Wet Nebulization Coverage Criteria (Ipratropium, salbutamol, ipratropium/salbutamol, sodium cromoglycate, budesonide nebules and generics)

Wet nebulization solutions will be approved upon the written request of a physician for those patients who meet the following criteria:

- Adult patients with a vital capacity of 900 ml or less.
- Patients with a respiratory rate greater than 25 breaths per minute.
- Patients who have demonstrated they cannot follow instructions, cannot hold the spacer device or cannot hold the device long enough to actuate it, **OR**
- Other situations as deemed appropriate, on a case by case basis.

Please note: Coverage will not be provided for the concurrent use of nebules and inhalers, with the exception of salbutamol inhaler for rescue therapy. Concurrent use will result in discontinuation of nebulized solution coverage.

Please visit the following link if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2010

Health and Community Services

Zafirlukast (Accolate 20mg tablet)

For the treatment of asthma in patients uncontrolled on optimal doses of inhaled corticosteroids* necessitating the frequent use of beta-agonists for symptom control.

*Optimal defined as: >400mcg/day budesonide
>250mcg/day HFA- beclomethasone
>250mcg/day fluticasone
>200mcg/day mometasone
>400mcg/day ciclesonide

Please visit the following link if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated February 2015

Health and Community Services

Zanamivir (Relenza 5mg Diskhaler)

For beneficiaries residing in long-term care facilities* during an influenza outbreak situation and further to the recommendation of a Medical Officer of Health:

- For treatment of long-term care facility residents with clinically suspected or lab confirmed influenza A or B **AND** there is suspected or confirmed oseltamivir resistance **or** in patients where oseltamivir is contraindicated.

  A clinically suspected case is one in which the patient meets the criteria of influenza-like illness and there is confirmation of influenza A or B circulating within the facility or surrounding community

- For prophylaxis of long-term care residents where the facility has an influenza A or B outbreak **AND** there is suspected or confirmed oseltamivir resistance **or** in patients where oseltamivir is contraindicated.
  - Prophylaxis should be continued until the outbreak is over. An outbreak is declared over 7 days after the onset of the last case in the facility

* *Long-term care facility* refers to a licensed nursing home.

Please visit the following link if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2010

Health and Community Services

Ziprasidone (Zeldox 20mg, 40mg, 60mg & 80mg)

For the treatment of schizophrenia and related psychotic disorders (not dementia related) in patients:

- with a history of inadequate response or intolerance to at least one less expensive antipsychotic agent

OR

- who have a contraindication to less expensive options.

Please visit the following link if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated December 2016

Health and Community Services

Zolmitriptan (Zomig 2.5mg, Rapiment tablets and generics)

Coverage is provided as an open benefit up to 6 doses / 30 days[1]

Consideration is given for > 6 doses / 30 days for patients with >3 migraines/month despite prophylactic therapy.

- Coverage will be limited to a maximum of 12 doses / 30 days.

[1]Reimbursement will be available for a maximum quantity of 6 triptan doses per 30 days regardless of the agent(s) used within the 30 day period.

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http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated April 2016

Health and Community Services

ZOLMITRIPTAN nasal spray (ZOMIG 2.5 MG/DOSE nasal spray)

For the treatment of patients with acute migraine attacks who have an intolerance or insufficient response to all triptans listed as regular benefit (e.g. almotriptan, rizatriptan, sumatriptan, zolmitriptan).

Coverage limited to 6 doses / 30 days[1]

- More than 6 doses / 30 days considered for patients with >3 migraines/month on average despite prophylactic therapy (up to a maximum of 12 doses / 30 days).

[1]Reimbursement will be available for a maximum quantity of 6 triptan doses per 30 days regardless of the agent(s) used within the 30 day period.

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Updated May 2018