Appendix III – Criteria for Coverage of Exception Status Drugs

Coverage of exception status drugs will be approved according to the following criteria upon review of a prescriber's written request. Forms for Exception Status Drug request, which may be used to facilitate the approval process can be found at https://novascotia.ca/dhw/pharmacare/exception-status-drugs.asp.

As an alternative to sending a written request to the Pharmacare office, certain exception status drugs have been assigned criteria codes. To allow for on-line payment of these drugs, the criteria code may be provided by the prescriber on the prescription or confirmed by the pharmacist. The use of these codes offers the prescriber and the pharmacist access to immediate coverage for patients who clearly meet the exception status criteria. The criteria codes are indicated within the following exception criteria.

ABATACEPT *(Orencia 125mg/mL Prefilled Syringe and 250mg/vial Injection)*

- For the treatment of severely active rheumatoid arthritis, in combination with methotrexate or other disease-modifying antirheumatic drugs (DMARDs), in adult patients who are refractory or intolerant to:
    - Methotrexate (oral or parenteral) at a dose of ≥ 20 mg weekly (≥15mg if patient is ≥65 years of age), or use in combination with another DMARD, for a minimum of 12 weeks;

      AND
    - Methotrexate in combination with at least two other DMARDs, such as hydroxychloroquine and sulfasalazine, for a minimum of 12 weeks.

Clinical Notes:

- For patients who do not demonstrate a clinical response to oral methotrexate, or who experience gastrointestinal intolerance, a trial of parenteral methotrexate must be considered.
- Optimal treatment response to DMARDs may take up to 24 weeks, however coverage of a biologic therapy can be considered if no improvement is seen after 12 weeks of triple DMARD use.
- If patient factors (e.g. intolerance) prevent the use of triple DMARD therapy, these must be described and dual therapy with DMARDs must be tried.
- Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above.
- Intolerant is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs. The nature of intolerance(s) must be clearly documented.

Claim Notes:

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

NOTE: Exception status drugs for Drug Assistance for Cancer Patients are indicated by an asterisk (*).

*ABIRATERONE ACETATE *(Zytiga 250mg and 500mg Tablet)*

ASYMPTOMATIC OR MILDLY SYMPTOMATIC PATIENTS

- In **combination with prednisone** for **asymptomatic or mildly symptomatic** metastatic CRPC patients after failure of androgen deprivation therapy (including an LHRH agonist/antagonist or orchiectomy) who have not received prior chemotherapy for metastatic CRPC and have ECOG PS 0 or 1.
- Abiraterone would be an **alternative** to enzalutamide and **not sequential** therapy in this asymptomatic or mildly symptomatic patient population.

SYMPTOMATIC (POST-DOCETAXEL CHEMOTHERAPY) PATIENTS

- In **combination with prednisone** for metastatic CRPC patients with ECOG PS of 0-2 and progression after previous treatment with docetaxel.
- Abiraterone would be an **alternative** to enzalutamide and **not sequential** therapy in this symptomatic post docetaxel chemotherapy setting.

RETREATMENT

- Use of abiraterone in the post-docetaxel setting is **not permitted** if previously used in the pre-chemotherapy setting.

ABOBOTULINUMTOXIN-A *(Dysport Therapeutic 300U and 500U Vial)*

- For the treatment of cervical dystonia (spasmodic torticollis) in adults.
- For the treatment of upper and lower limb focal spasticity in adults.
- For the treatment of lower limb spasticity in pediatric patients 2 years of age and older.

ACAMPROSATE *(Campral 333mg Tablet)*

- For treatment in patients who have been abstinent from alcohol for at least four days and who have contraindications to naltrexone (i.e., acute hepatitis, liver failure or currently receiving opioids).

ACLIDINIUM BROMIDE *(Tudorza Genuair 400mcg powder for Inhalation)*

- For the treatment of moderate to severe chronic obstructive pulmonary disease (COPD) as defined by spirometry;

  OR
- For the treatment of COPD in patients with an inadequate response to short acting bronchodilators.
- Combination therapy with a long-acting beta-$_2$ agonist /inhaled corticosteroid (LABA/ICS) and a long acting anticholinergic (LAAC) inhaler will be considered in patients with: moderate to severe COPD, as defined by spirometry, a history of COPD exacerbation(s) and an inadequate response to LABA/ICS or LAAC.

Clinical Notes:

- Moderate to severe COPD is defined by spirometry as a post bronchodilator FEV1 < 60% predicted and FEV1/FVC ratio of < 0.70. Spirometry reports from any point in time will be accepted.

  If spirometry cannot be obtained, reasons must be clearly explained and other evidence of COPD severity provided, i.e., Medical Research Council (MRC) Dyspnea Scale Score of at least Grade 3.

  MRC Grade 3 is described as: walks slower than people of same age on the level because of shortness of breath from COPD or has to stop for breath when walking at own pace on the level.
- 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.

- COPD exacerbation is defined as an increase in symptoms requiring treatment with antibiotics and/or systemic (oral or intravenous) corticosteroids.

Notes:

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

ACLIDINIUM/FORMOTEROL *(Duaklir Genuair 12µg/400µg metered dose for Inhalation)*

- 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).

ADALIMUMAB *(Humira 40mg/vial Injection)*

- See **Anti-Tumor Necrosis Factor (TNF) Agents**

ADEFOVIR DIPIVOXIL *(Hepsera 10mg Tablet)*

- In combination with lamivudine in patients who:
  - Have developed failure to lamivudine (increase in HBV DNA of ≥1 log10iu/mL over the nadir measured on two separate occasions within an interval of at least one month, after the first 3 months of lamivudine therapy); AND
  - When failure to lamivudine is not due to poor adherence to therapy.
- Coverage approved for 1 year.

*AFATINIB DIMALEATE *(Giotrif 20mg, 30mg, 40mg Tablet)*

- 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.

*ALECTINIB *(Alecensaro 150mg Capsule)*

- For the **first line treatment** of patients with locally advanced or metastatic anaplastic lymphoma kinase (ALK) positive non-small cell lung cancer (NSCLC).
- For the treatment of patients with locally advanced or metastatic anaplastic lymphoma kinase (ALK) positive non-small cell lung cancer (NSCLC) who have disease progression on, or intolerance to crizotinib.

Claim Notes:

- Patients should have a good performance status and treatment should be continued until disease progression or unacceptable toxicity.
- If alectinib is chosen as first-line therapy, ceritinib is not funded as a subsequent line of therapy.
- Alectinib is not funded following two prior ALK inhibitor therapies (e.g. crizotinib followed by ceritinib)
- Claims for Alecensaro 150mg capsule that exceed the maximum claim amount of $9,999.99 must be divided and submitted as separate transactions using the DIN first and then the following PIN:
    - 00904400

ALEMTUZUMAB *(Lemtrada 12mg/1.2mL (10mg/mL) concentrated solution for IV infusion in single-use vials)*

- For the management of adult patients with relapsing-remitting multiple sclerosis (RRMS), with active disease defined by clinical and imaging features, who have had an inadequate response to interferon beta or other disease-modifying therapies, if the following clinical criteria are met:
    - At least two attacks (first episode or relapse) in the previous two years, with at least one attack in the previous year;
    - At least one relapse while on at least six months of a disease modifying therapy within the last 10 years;
    - An Expanded Disability Status Scale (EDSS) score of five (5) or less;
    - Prescribed by a specialist with experience in the treatment of multiple sclerosis.

Claim Notes:

- A maximum of two years of therapy (i.e. two treatment courses; 8 vials) will be reimbursed.
- Claims for Lemtrada 12mg/1.2mL (10mg/mL concentrated solution for IV infusion in single-use vials that exceed the maximum claim amount of $9,999.99 must be divided and submitted as separate transactions using the DIN first and then the following PINs:
    - 00904161
    - 00904162
    - 00904163
    - 00904164
    - 00904165
    - 00904166
    - 00904167
    - 00904196
    - 00904197

ALGLUCOSIDASE ALFA *(Myozyme 50mg Powder for Injection)*

- For the treatment of infantile onset Pompe disease in patients who have had the onset of symptoms and confirmed cardiomyopathy before the age of 12 months; AND
- Participation in the long-term evaluation of the efficacy of treatment by periodic medical assessment as outlined in the monitoring of therapy guidelines.
- Initial approval is for 6 months. Continued coverage will be based on evaluation of the efficacy of treatment by regular medical assessment as outlined in the monitoring and discontinuation of therapy guidelines (available from the Pharmacare Office upon request).

ALIROCUMAB *(Praluent 75 mg/mL and 150 mg/mL Prefilled Syringe and 75 mg/mL and 150 mg/mL Prefilled Pen)*

- For the treatment of heterozygous familial hypercholesterolemia (HeFH) in adult patients who require additional lowering of low-density lipoprotein cholesterol (LDL-C) if the following criteria are met:
    - Definite or probable diagnosis of HeFH using the Simon Broome or Dutch Lipid Network criteria or genetic testing; and
    - Patient is unable to reach LDL-C target (less than 2.0 mmol/L or at least a 50% reduction in LDL-C from untreated baseline) despite confirmed adherence to at least 3 months of continuous treatment with:
        - high-dose statin (e.g., atorvastatin 80 mg, rosuvastatin 40 mg) in combination with ezetimibe; or
        - ezetimibe alone if high dose statin is not possible due to rhabdomyolysis, contraindication or intolerance
- **Initial renewal criteria:**
    - A reduction in LDL-C of at least 40% from baseline or has reached a target LDL-C less than 2.0 mmol/L.
- **Subsequent renewal criteria:**
    - The patient continues to maintain a reduction in LDL- C of at least 40% from baseline or has reached a target LDL-C less than 2.0 mmol/L.

Clinical Notes:

- LDL-C levels must be provided.
- Intolerance to high dose statin will be considered if patient has developed documented, myopathy or abnormal biomarkers (i.e. creatinine kinase greater than 5 times the upper limit of normal) after trial of at least two statins and
    - for each statin, dose reduction was attempted rather than statin discontinuation, and intolerance was reversible upon statin discontinuation, but reoccurred with statin re-challenge where clinically appropriate; and
    - at least one statin was initiated at the lowest daily starting dose; and
    - other known causes of intolerance or abnormal biomarkers have been ruled out.
- For patients who cannot take a statin due to an intolerance or contraindication, details must be provided (ie. confirmed rhabdomyolysis, active liver disease, unexplained persistent elevations of serum transaminases exceeding three times the upper limit of normal).
- For patients who cannot take ezetimibe due to an intolerance or contraindication, details must be provided.

Claim Notes:

- Maximum dose approved: 300mg every 4 weeks

NOTE: Exception status drugs for Drug Assistance for Cancer Patients are indicated by an asterisk (*).

- Initial approval: 6 months
- Renewal approval: 1 year

ALLERGEN IMMUNOTHERAPY *(Allergy Serum, Pollinex-R Injection)*

- For immunotherapy with specific, standardized allergenic material, administered in high-dose schedules for carefully selected patients with a diagnosis of:
    - IgE mediated anaphylactic reactions to insect stings; or
    - Severe, seasonal (lasting two or more years) or perennial IgE dependent allergic rhinoconjunctivitis when optimal drug therapy and allergen avoidance have not been sufficiently effective in controlling symptoms; or
    - IgE mediated allergic asthma, specifically where there is a clear temporal association between exposure and signs and symptoms of asthma and when optimal drug therapy and avoidance measures have not been sufficiently effective in controlling symptoms.

Note:

- The allergy serum must be dispensed from a pharmacy on prescription from a prescriber. Initial authorization is for two years, and can be continued for up to five years if improvement is noted.

ALMOTRIPTAN *(Axert 6.25mg, 12.5mg Tablet and generic brands)*

- See **Selective $5HT_1$ - Receptor Agonists**

AMBRISENTAN *(Volibris 5mg, 10mg Tablet and generic brands)*

- For the treatment of patients with at least Class III pulmonary arterial hypertension (PAH), either idiopathic or associated with connective tissue disease who have failed therapy with sildenafil or who have contraindications to sildenafil.
- Diagnosis must be confirmed by right heart catheterization.
- Request must be from a PAH specialist.

ANAGRELIDE *(Agrylin 0.5mg Capsule and generic brands)*

NOVA SCOTIA SENIORS' PHARMACARE PROGRAM

- For the treatment of essential thrombocythemia (ET) in patients who have:
    - Failed hydroxyurea therapy (does not provide sufficient platelet reduction); or
    - Intolerable side effects from hydroxyurea therapy.

COMMUNITY SERVICES PHARMACARE PROGRAMS

- For the treatment of essential thrombocythemia (ET) as an alternative to hydroxyurea.

ANTI-TUMOR NECROSIS FACTOR (TNF) AGENTS *(Adalimumab, Certolizumab Pegol, Etanercept, Golimumab, Infliximab, Ixekizumab)*

ANKYLOSING SPONDYLITIS (ADALIMUMAB, ETANERCEPT, GOLIMUMAB, INFLIXIMAB)

- For the treatment of patients with moderate to severe ankylosing spondylitis (Bath AS Disease Activity Index (BASDAI) score ≥4 on 10 point scale) who:
    - Have axial symptoms[1] and who have failed to respond to the sequential use of at least 2 NSAIDs at the optimum dose for a minimum period of 3 months observation, or in whom NSAIDs are contraindicated; OR
    - 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.
- Must be prescribed by a rheumatologist or prescriber with a specialty in rheumatology.
- Requests for renewal must include information showing the beneficial effects of the treatment, specifically:
    - A decrease of at least 2 points on the BASDAI scale, compared with the pre-treatment score; OR
    - Patient and expert opinion of an adequate clinical response as indicated by a significant functional improvement (measured by outcomes such as HAQ or "ability to return to work").

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

Initial coverage duration and maximum dosage approved:

Adalimumab	• initial period 6 months, maximum dose of 40mg every two weeks and not in combination with other anti-TNF agents
Etanercept	• initial period 6 months, maximum dose of 50mg per week and not in combination with other anti-TNF
Golimumab	• initial period 16 weeks, maximum dose 50mg per month and not in combination with other anti-TNF
Infliximab	• initial coverage period 6 months, maximum dose 5mg/kg at 0, 2, and 6 weeks then every 6-8 weeks thereafter and not in combination with other anti-TNF agents

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

For etanercept-naïve patients whose etanercept therapy is initiated after November 1, 2017, a biosimilar will be the product that is approved.

ANKYLOSING SPONDYLITIS (CERTOLIZUMAB PEGOL)

- For the treatment of adult patients with moderate to severe ankylosing spondylitis (Bath AS Disease Activity Index (BASDAI) score ≥4 on 10 point scale) who:
    - Have axial symptoms[1] and who have failed to respond to the sequential use of at least 2 NSAIDs at the optimum dose for a minimum period of 3 months observation, or in whom NSAIDs are contraindicated; OR
    - 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.

- Must be prescribed by a rheumatologist or prescriber with a specialty in rheumatology.
- Requests for renewal must include information showing the beneficial effects of the treatment, specifically:
    - A decrease of at least 2 points on the BASDAI scale, compared with the pre-treatment score; OR
    - Patient and expert opinion of an adequate clinical response as indicated by a significant functional improvement (measured by outcomes such as HAQ or "ability to return to work").

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

Initial coverage duration and maximum dosage approved:

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

CROHN'S DISEASE (ADALIMUMAB)

- For patients with moderate to severely active Crohn's disease and are:
    - Refractory or have contraindications to an adequate course of 5-aminosalicylic acid and corticosteroids and other immunosuppressive therapy;
    - Initial reimbursement is restricted to an induction dose of 160mg followed by 80mg;
    - Clinical response to be assessed twelve weeks after the first induction dose and maintenance therapy approved in responders only at a dose not exceeding 40mg every two weeks.

CROHN'S DISEASE (INFLIXIMAB)

- For treatment of Crohn's disease in patients with moderate to severe active disease refractory to 5-ASA products AND glucocorticoids (e.g.,prednisone) AND immunosuppressive therapy (azathioprine or 6-mercaptopurine or methotrexate)[1].
    - Initial approval of infliximab will be for a single infusion of 5mg/kg/dose. A second infusion may be warranted in patients not responding to the first infusion or in patients responding initially but then worsening before maintenance therapy is effective. Request for approval beyond induction therapy will be considered on a case by case basis.
    - In patients with fistulizing disease who have actively draining perianal or enterocutaneous fistula(e) that have recurred or persisted despite a course of appropriate antibiotic therapy (e.g., metronidazole +/- ciprofloxacin for a minimum of 3 weeks) AND immunosuppressive therapy (azathioprine or 6-mercaptopurine or methotrexate)[1].
    - Initial approval is for three infusions of infliximab of 5mg/kg/dose at 0, 2 and 6 week intervals.

1. Patients who are very ill and not candidates for surgery may qualify for infliximab therapy without a trial of AZA, 6-MP or MTX, as they may require a more rapid onset of response.

Note:

- Requires a written request by a gastroenterologist or physician with a specialty in gastroenterology.

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

For pediatric patients whose infliximab therapy is initiated after October 1, 2019, an infliximab biosimilar will be

the product approved.

HIDRADENITIS SUPPURATIVA (ADALIMUMAB)

- For the treatment of adult patients with active moderate to severe hidradenitis suppurativa (HS) who have not responded to conventional therapy and who meet all of the following criteria:
    - A total abscess and nodule count of 3 or greater
    - Lesions in at least two distinct anatomic areas, one of which must be Hurley Stage II or III
    - An inadequate response to a 90-day trial of oral antibiotics

Initial renewal criteria:

- Requests for renewal should provide objective evidence of a treatment response, defined as at least a 50% reduction in abscess and inflammatory nodule count with no increase in abscess or draining fistula count relative to baseline at week 12.

Subsequent renewal criteria:

- Requests for renewal should provide objective evidence of the preservation of treatment effect (i.e. the current abscess and inflammatory nodule count and draining fistula count should be compared to the count prior to initiating treatment with adalimumab).

Claim Notes:

- Must be prescribed by a dermatologist or physician with experience in the treatment of HS.
- Approvals will be for a maximum of 160mg followed by 80mg two weeks later, then 40mg every week beginning four weeks after the initial dose.
- Initial Approval: 12 weeks
- Renewal Approval: 1 year

JUVENILE RHEUMATOID ARTHRITIS (ETANERCEPT)

- 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 have intolerance to DMARDs, and do not have a contraindication to etanercept.

POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (ADALIMUMAB)

- For the treatment of polyarticular juvenile idiopathic arthritis (pJIA) with the following criteria:
    - For patients aged 4-17 years with moderately or severe pJIA who have had a inadequate response to one or more disease-modifying anti-rheumatic drugs (DMARDs); and
    - Treatment must be initiated by a rheumatologist who is familiar with the use of DMARDs and/or biologic DMARDs in children.

PSORIASIS (ADALIMUMAB, ETANERCEPT, INFLIXIMAB, IXEKIZUMAB)

- For patients with severe, debilitating chronic plaque psoriasis who meet all of the following:
    - Body surface area (BSA) involvement of >10% and/or significant involvement of the face, hands, feet or genitals;
    - Failure to, contraindication to or intolerant of methotrexate and cyclosporine;
    - Failure to, intolerant of or unable to access phototherapy;
    - Written request of a dermatologist or prescriber with a specialty in dermatology.
- Continued coverage is dependent on evidence of improvement, specifically:
    - A >75% reduction in the Psoriasis Area and Severity Index (PASI) score; or

- A >50% reduction in PASI with a >5-point improvement in DLQI (Dermatology Life Quality Index); or
- Significant reduction in BSA involved, with consideration of important regions such as the face, hands, feet or genitals.

Clinical Note:

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

Claim Note:

- Concurrent use of biologics not approved.

Initial duration and maximum dosage approved:

Adalimumab	▪ initial approval for a maximum of 16 weeks ▪ maximum dosage for ongoing coverage is 40mg every two weeks
Etanercept	▪ initial approval for a maximum of 12 weeks ▪ maximum dosage approved: 50mg biweekly for the initial 12 weeks then 50mg weekly thereafter
Infliximab	▪ initial approval for a maximum of 12 weeks ▪ dosage restricted to infliximab 5mg/kg 0, 2 and 6 weeks then every 8 weeks
Ixekizumab	▪ initial approval for a maximum of 12 weeks. Renewal approval: 1 year. ▪ approvals will be for 160 mg at week 0, followed by 80 mg at weeks 2, 4, 6, 8, 10, and 12 then 80 mg every four weeks.

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

PSORIATIC ARTHRITIS (ADALIMUMAB, CERTOLIZUMAB PEGOL, ETANERCEPT, GOLIMUMAB, INFLIXIMAB, IXEKIZUMAB)

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

Clinical Notes:

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

Claim Notes:

- Must be prescribed by a rheumatologist.
- Combined use of more than one biologic DMARD will not be reimbursed.
- Renewal approval: 1 year. Confirmation of continued response required.

Initial coverage duration and maximum dosage approved:

Adalimumab	▪ initial period 3 months, maximum dose of 40mg every two weeks
Certolizumab pegol	▪ initial coverage period 3 months. ▪ Loading dose of 400mg at Weeks 0, 2 and 4. ▪ maximum maintenance dose of 200mg every 2 weeks or alternatively, 400mg every 4 weeks, and not in combination with other anti-TNF agents.
Etanercept	▪ initial period 3 months, maximum dose of 50mg per week
Golimumab	▪ initial period 3 months, maximum dose 50mg per month
Infliximab	▪ initial period 3 months, maximum dose 5mg/kg 0, 2 and 6 weeks then every 8 weeks
Ixekizumab	▪ initial approval for a maximum of 12 weeks. ▪ approvals will be for 160mg at week 0, followed by 80mg every 4 weeks.

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

RHEUMATOID ARTHRITIS (ADALIMUMAB, CERTOLIZUMAB PEGOL, ETANERCEPT, GOLIMUMAB, INFLIXIMAB)

- For the treatment of severely active rheumatoid arthritis, in combination with methotrexate or other disease-modifying antirheumatic drugs (DMARDs), in adult patients who are refractory or intolerant to:
    - methotrexate (oral or parenteral) at a dose of ≥ 20 mg weekly (≥15mg if patient is ≥65 years of age), or use in combination with another DMARD, for a minimum of 12 weeks;

      AND
    - methotrexate in combination with at least two other DMARDs, such as hydroxychloroquine and sulfasalazine, for a minimum of 12 weeks.

Clinical Notes:

- For patients who do not demonstrate a clinical response to oral methotrexate, or who experience gastrointestinal intolerance, a trial of parenteral methotrexate must be considered.
- Optimal treatment response to DMARDs may take up to 24 weeks, however coverage of a biologic therapy can be considered if no improvement is seen after 12 weeks of triple DMARD use.
- If patient factors (e.g. intolerance) prevent the use of triple DMARD therapy, these must be described and dual therapy with DMARDs must be tried.
- Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above.
- Intolerant is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs. The nature of intolerance(s) must be clearly documented.

Claim Notes:

- Must be prescribed by a rheumatologist.

NOTE: Exception status drugs for Drug Assistance for Cancer Patients are indicated by an asterisk (*).

- 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
Certolizumab pegol	▪ 400mg at weeks 0, 2 and 4 weeks, then 200mg every 2 weeks (or 400mg every 4 weeks) with no dose escalation permitted
Etanercept	▪ 25mg twice a week or 50mg once a week with no dose escalation permitted
Golimumab	▪ 50mg once a month with no dose escalation permitted
Infliximab (Remicade)	▪ 3mg/kg/dose at 0, 2 and 6 weeks, then every 8 weeks thereafter
Infliximab (Inflectra)	▪ 3mg/kg/dose at 0, 2 and 6 weeks, then every 8 weeks thereafter

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

For etanercept-naïve patients whose etanercept therapy is initiated after November 1, 2017, a biosimilar will be the product that is approved.

ULCERATIVE COLITIS (ADALIMUMAB, GOLIMUMAB, INFLIXIMAB)

- For the treatment of patients with moderately to severely active ulcerative colitis who have a partial Mayo score > 4, and a rectal bleeding subscore ≥ 2 and are:
    - refractory or intolerant to conventional therapy (i.e. 5-ASA for a minimum of 4 weeks, and prednisone ≥ 40mg daily for two weeks or IV equivalent for one week); OR
    - corticosteroid dependent (i.e. cannot be tapered from corticosteroids without disease recurrence; or have relapsed within three months of stopping corticosteroids; or require two or more courses of corticosteroids within one year.)
- Renewal requests must include information demonstrating the beneficial effects of the treatment, specifically:
    - a decrease in the partial Mayo score ≥ 2 from baseline, AND
    - a decrease in the rectal bleeding subscore ≥ 1.

Clinical Notes:

- Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above.
- Intolerant is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs. The nature of intolerance(s) must be clearly documented.
- Patients with severe disease do not require a trial of 5-ASA

Claim Notes:

- Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology.
- Combined use of more than one biologic DMARD will not be reimbursed.
- Initial Approval: 16 weeks.
- Renewal Approval: 1 year.

NOTE: Exception status drugs for Drug Assistance for Cancer Patients are indicated by an asterisk (*).

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

For pediatric patients whose infliximab therapy is initiated after October 1, 2019, an infliximab biosimilar will be the product approved.

APIXABAN *(Eliquis, 2.5mg, 5mg Tablet)*

TOTAL KNEE/HIP REPLACEMENT (ELIQUIS 2.5MG TABLET)

- For the prophylaxis of venous thromboembolism following total knee replacement surgery for up to 14 days, as an alternative to low molecular weight heparins. **[Criteria Code 14]**
- For the prophylaxis of venous thromboembolism following total hip replacement surgery for up to 35 days, as an alternative to low molecular weight heparins. **[Criteria Code 35]**

Notes:

- The total duration of therapy includes the period during which doses are administered post-operatively in an acute care (hospital) setting, and the approval period is for the balance of the total duration after discharge.
- The first dose is typically administered 12 to 24 hours after surgery, assuming adequate hemostasis has been achieved.
- The ADVANCE clinical trial program did not evaluate the efficacy or safety of sequential use of molecular weight heparin followed by apixaban for the prophylaxis of VTE. Due to the current lack of evidence for sequential use, coverage is not intended for this practice.
- Clinical judgment is warranted to assess the increased risk for VTE and/or adverse effects in patients with a history of previous VTE, myocardial infarction, transient ischemic attack or ischemic stroke; a history of intraocular or intracerebral bleeding; a history of gastrointestinal disease with gastrointestinal bleeding; moderate or severe renal insufficiency (estimated creatinine clearance <30 mL/min); severe liver disease; concurrent use of other anticoagulants; or age greater than 75 years.
- Apixaban has not been studied in clinical trials in patients undergoing hip fracture surgery, and is not recommended in these patients.

DEEP VEIN THROMBOSIS/PULMONARY EMBOLISM (ELIQUIS 2.5MG, 5MG TABLET)

- **Inclusion Criteria:**
  - For the treatment of deep vein thrombosis (DVT) or pulmonary embolism (PE)
  - Approval Period: Up to six (6) months

Notes:

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

****[Criteria Code 32]** will be used to allow the 5mg strength to pay (max 56 tablets), which will allow patients to start therapy while awaiting ESD approval for the six months of therapy.

NOTE: Exception status drugs for Drug Assistance for Cancer Patients are indicated by an asterisk (*).

NON-VALVULAR ATRIAL FIBRILLATION (AF) (ELIQUIS 2.5MG, 5MG TABLET):

- **Inclusion Criteria:**
    - At-risk patients with non-valvular atrial fibrillation (AF) who require apixaban for the prevention of stroke and systemic embolism AND in whom:
        - anticoagulation is inadequate following at least a 2-month trial on warfarin; OR
        - anticoagulation with warfarin is contraindicated or not possible due to inability to regularly monitor via International Normalized Ratio (INR) testing (i.e. no access to INR testing services at a laboratory, clinic, pharmacy, and at home).
- **Exclusion Criteria:**
    - Patients with impaired renal function (creatinine clearance or estimated glomerular filtration rate < 25 mL/min) OR > 75 years of age and without documented stable renal function OR hemodynamically significant rheumatic valvular heart disease, especially mitral stenosis; OR prosthetic heart valves.

Notes:

- At risk patients with non valvular atrial fibrillation are defined as those with a CHADS2 score of ≥ 1. Prescribers may consider an antiplatelet regimen or oral anticoagulation for patients with CHADS2 score of ≥ 1.
- Inadequate anticoagulation is defined as INR testing results that are outside the desired INR range for at least 35% of the tests during the monitoring period (i.e. adequate anticoagulation is defined as INR test results that are within the desired INR range for at least 65% of the tests during the monitoring period).
- Documented stable renal function is defined as creatinine or estimated glomerular filtration rate maintained for at least 3 months.
- Dosing: the usual recommended dose is 5mg twice daily; a reduced dose of apixaban 2.5mg twice daily is recommended for patients with at least two [2] of the following: age > 80 years, body weight < 60kg, or serum creatinine >133 micromole/litre.
- 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).
- 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.

APOMORPHINE *(Movapo 30mg/3mL Prefilled Pen)*

- For the acute, intermittent treatment of hypomobility “off” episodes (“end-of-dose wearing off” and unpredictable “on/off” episodes) in patients with advanced Parkinson’s disease (PD), if the following criteria are met:
    - Apomorphine should only be used as adjunctive therapy in patients who are receiving optimized PD therapy (levodopa and derivatives and dopaminergic agonists) and still experiencing “off” episodes.

Clinical Notes:

- Patients should be under the care of a physician with experience in the diagnosis and management of PD.
- If the patient is not a good candidate for treatment with dopaminergic agonists, please provide detail as to why (i.e., those with cognitive impairment and impulsivity).

NOTE: Exception status drugs for Drug Assistance for Cancer Patients are indicated by an asterisk (*).

*APREPITANT *(Emend 80mg, 125mg Capsule and Tri-Pack Capsule)*

- In combination with a 5-HT3 antiemetic and dexamethasone for the prevention of acute and delayed nausea and vomiting in patients receiving:
    - highly emetogenic chemotherapy, OR
    - moderately emetogenic chemotherapy who have had inadequate symptom control using a 5-HT3 antagonist and dexamethasone in a previous cycle.

Clinical Notes:

- Highly emetogenic chemotherapy (HEC) may include, but is not limited to: cisplatin regimens, anthracycline and cyclophosphamide combination regimens, and regimens containing carmustine, mechlorethamine, streptozocin, dacarbazine and cyclophosphamide ≥ 1500mg/m2.
- Patients who receive carboplatin-based regimens with AUC ≥ 4 are also eligible to receive aprepitant in combination with a 5-HT3 antiemetic and dexamethasone for the primary prevention of acute and delayed nausea and vomiting.

ARIPIPRAZOLE *(Abilify 2mg, 5mg, 10mg, 15mg, 20mg and 30mg Tablet and generic brands)*

- For the treatment of schizophrenia and related psychotic disorders (not dementia related) in patients with a history of failure, intolerance, or contraindication to at least one less expensive antipsychotic agent.

ARIPIPRAZOLE *(Abilify Maintena 300mg and 400mg Prolonged Release Injectable Suspension)*

- For the maintenance treatment of schizophrenia and related psychotic disorders (not dementia related) in patients who are not adherent to an oral antipsychotic; OR
- Who are currently receiving a long-acting injectable antipsychotic and require an alternative long acting injectable antipsychotic.

ARTIFICIAL TEARS, PRESERVATIVE FREE *(Celluvisc, Refresh, Refresh Plus, Refresh Tears, Tears Naturale Free)*

- For patients with a diagnosis of dry eye requiring frequent daily doses of artificial tears, to prevent sensitivity to preservatives or in patients in whom preservative sensitivity is suspected;
- Written request from an ophthalmologist or optometrist confirming the diagnosis will be required to initiate coverage.

ASENAPINE *(Saphris 5mg and 10mg SL Tablet)*

- For the acute treatment of manic or mixed episodes associated with bipolar I disorder as either:
    - monotherapy, after a trial of lithium or divalproex sodium has failed, and trials of less expensive atypical antipsychotic agents have failed due to intolerance or lack of response;
    - co-therapy with lithium or divalproex sodium, after trials of less expensive atypical antipsychotic agents have failed due to intolerance or lack of response.

*AXITINIB *(Inlyta 1mg and 5mg Tablet)*

- As second line therapy for the treatment of patients with metastatic renal cell carcinoma after failure of prior therapy with either a cytokine or tyrosine kinase inhibitor.

Renewal Criteria:

- Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.

Clinical Notes:

- Patients must have a good performance status.
- Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Notes:

- Sequential use of axitinib and everolimus will not be reimbursed. Exceptions may be considered in cases of intolerance or contraindication without disease progression.
- Initial approval period: 6 months.
- Renewal period: 1 year.

*AZITHROMYCIN *(Zithromax POS 100mg/5mL, 200mg/5mL and 250mg, 600mg Tablet and generic brands)*

- The treatment of infections requiring a macrolide antibiotic when the patient has a documented intolerance to clarithromycin. **[Criteria Code 02]**
- The treatment of chlamydia trachomatis as a single dose of 1g. **[Criteria Code 05]**
- The treatment and prevention of mycobacterium avium complex (MAC). **[Criteria Code 06]**
- The treatment of infections requiring a macrolide antibiotic when the patient is taking medications that would significantly interact with erythromycin/clarithromycin. **[Criteria Code 07]**

BENRALIZUMAB *(Fasenra 30mg/mL Prefilled Syringe)*

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

Initial Discontinuation Criteria:

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

Subsequent Discontinuation Criteria:

- Baseline asthma control questionnaire score achieved after the first 12 months of therapy has not been maintained subsequently, OR

NOTE: Exception status drugs for Drug Assistance for Cancer Patients are indicated by an asterisk (*).

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

Clinical Notes:

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

Claim Notes:

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

*BENZYDAMINE HCL *(0.15% Oral Rinse)*

- For oncology patients only.

BETAHISTINE *(Serc 16mg, 24mg Tablet and generic brands)*

- For the symptomatic treatment of recurrent episodes of vertigo associated with Meniere's disease.

BOSENTAN *(Tracleer 62.5mg, 125mg Tablet and generic brands)*

- Written initial request from a pulmonary arterial hypertension (PAH) specialist only.
- Diagnosis of PAH should be confirmed by right heart catheterization.
- **IPAH (functional class III and IV):**
    - For the treatment of patients with 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.
- **PAH secondary to scleroderma, congenital heart disease or HIV (functional class III and IV):**
    - For the treatment of patients with 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.

NOTE: Exception status drugs for Drug Assistance for Cancer Patients are indicated by an asterisk (*).

*BOSUTINIB *(Bosulif 100mg and 500mg Tablet)*

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

BREXPIPRAZOLE *(Rexulti 0.25mg, 0.5mg, 1mg, 2m, 3mg and 4mg Tablet)*

- For the treatment of schizophrenia and related psychotic disorders (not dementia related) in adult patients with a history of intolerance or inadequate response to at least one less expensive antipsychotic agent, or who have a contraindication to less expensive agents.

BRIVARACETAM *(Brivlera 10mg, 25mg, 50mg, 75mg, 100mg Tablet)*

- For the adjunctive treatment of refractory partial-onset seizures (POS) in patients who are currently receiving two or more antiepileptic drugs, and who have had an inadequate response or intolerance to at least three other antiepileptic drugs.

Claim Notes:

- The patient must be under the care of a physician experienced in the treatment of epilepsy.
- Any combination of lacosamide, perampanel, eslicarbazepine, levetiracetam or brivaracetam will not be reimbursed.

BRODALUMAB *(Siliq 210mg/1.5 mL Prefilled Syringe)*

- For patients with severe, debilitating chronic plaque psoriasis who meet all of the following:
    - Body surface area (BSA) involvement of >10% and/or significant involvement of the face, hands, feet or genitals;
    - Failure to, contraindication to or intolerant of methotrexate and cyclosporine;
    - Failure to, intolerant of or unable to access phototherapy;
    - Written request of a dermatologist or prescriber with a specialty in dermatology.
- Continued coverage is dependent on evidence of improvement, specifically:
    - A >75% reduction in the Psoriasis Area and Severity Index (PASI) score; or
    - A >50% reduction in PASI with a >5-point improvement in DLQI (Dermatology Life Quality Index); or
    - Significant reduction in BSA involved, with consideration of important regions such as the face, hands, feet or genitals.

Clinical Note:

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

Claim Notes:

- Concurrent use of biologics not approved.
- Initial approval for a maximum of 12 weeks. Renewal approval: 1 year.
- Approvals will be for 210mg at week 0, 1, 2, followed by 210mg every two weeks.

NOTE: Exception status drugs for Drug Assistance for Cancer Patients are indicated by an asterisk (*).

*BUDESONIDE *(Pulmicort Nebuamps 0.125mg/mL, 0.25mg/mL, 0.5mg/mL Suspension)*

- See **Wet Nebulization Solutions**

BUPROPION *(Zyban 150mg Tablet)*

- See **Smoking Cessation Therapies**

BUTORPHANOL *(10mg/mL Nasal Spray)*

- For the treatment of migraine, upon the request of a neurologist, prescriber with a specialty in neurology or a specialist in pain management, when conventional forms of therapy are ineffective or inappropriate.

CABERGOLINE *(Dostinex 0.5mg Tablet and generic brands)*

- For the treatment of micro- or macro-adenoma of the pituitary after failure of bromocriptine (as determined by prolactin levels) or if bromocriptine is not tolerated.

CALCIPOTRIOL *(Dovonex 50mcg/g Ointment)*

- For the treatment of psoriasis when conventional therapies have been ineffective or inappropriate.

CALCIPOTRIOL/BETAMETHASONE DIPROPIONATE *(Dovobet 0.5mg/g/50mcg/g Gel and Enstilar 50mcg/g/ 0.5mg/g Aer Foam)*

- For the treatment of body and scalp psoriasis after failure of a topical steroid and a vitamin D analogue as single agents.

CANAGLIFLOZIN *(Invokana 100mg and 300mg Tablet)*

- For the treatment of Type II diabetes for patients with:
    - Inadequate glycemic control on metformin and a sulfonylurea; and
    - For whom insulin is not an option.

Note:

- 200mg is not a recognized dose; as such a dose of two 100mg tablets will not be funded.

CANAKINUMAB *(Ilaris 150mg/1mL Solution for Injection and 150 mg/mL Powder for Solution)*

- For the treatment of active systemic juvenile idiopathic arthritis, in patients 2 years of age or older, who have an inadequate response or intolerance to systemic corticosteroids (with or without methotrexate) and tocilizumab.

Clinical Note:

- Intolerance is defined as a serious adverse effect as described in the product monograph. The nature of the intolerance(s) must be clearly documented.

Claim Notes:

- Must be prescribed by, or in consultation with, a rheumatologist, who is familiar with the use of biologic DMARDs in children.
- Combined used of more than one biologic DMARD will not be reimbursed.
- Approvals will be for 4 mg/kg for patients > 9 kg, to a maximum of 300mg, administered every four weeks.
- Initial approval period: 16 weeks.

- Renewal approval period: 1 year. Confirmation of continued response is required.
- Claims that exceed $9,999.99 must be divided and submitted as separate transactions using the DIN first and then the following PIN:
    - 00903809

CARVEDILOL *(Coreg 3.125mg, 6.25mg, 12.5mg, 25mg Tablet and generic brands)*

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

*CERITINIB *(Zykadia 150mg Capsule)*

- For the treatment of patients with locally advanced or metastatic anaplastic lymphoma kinase (ALK) positive non-small cell lung cancer (NSCLC) who experience disease progression on, or intolerance to crizotinib.

Claim Notes:

- Patients should have a good performance status and treatment should be continued until disease progression or unacceptable toxicity
- If alectinib is chosen as first-line therapy, ceritinib is not funded as a subsequent line of therapy.
- Disease progression on any other ALK inhibitor in the second-line setting after crizotinib, precludes the use of ceritinib as a subsequent line of therapy.

CERTOLIZUMAB PEGOL *(Cimzia 200mg/mL SC Injection and 200mg/mL Autoinjector Prefilled Pen)*

- See **Anti-Tumor Necrosis Factor (TNF) Agents**

CETIRIZINE *(Reactine 10mg and 20mg Tablet and generic brands)*

- For chronic urticaria, defined as the presence of hives or lesions for longer than six weeks, which has responded to treatment with cetirizine.

CHOLINESTERASE INHIBITORS (ChEI) *(Donepezil, Galantamine, Rivastigmine)*

- For the treatment of patients with mild to moderate dementia who meet the following criteria:
    - A Mini-Mental Statement Examination (MMSE) score of 10 to 30;

      AND
    - A Functional Assessment Staging Test (FAST) score of 4 to 5.
- Initial requests for reimbursement will be considered for a 4 month approval; subsequent requests may be considered for a maximum 12 months approval.

CINACALCET *(Sensipar 30mg, 60mg and 90mg Tablet and generic brands)*

- For the treatment of patients with chronic kidney disease on dialysis with severe secondary hyperparathyroidism who:
    - are not responding to optimal doses of Vitamin D analogues or phosphate binders (calcium or non-calcium based) AND are either not a surgical candidate due to surgical or anesthetic risk OR awaiting kidney transplant;
    - in addition laboratory findings must confirm serum phosphate >1.8mmol/L, serum calcium ≥2.2mmol/L and iPTH >88pmol/L on more than one occasion at least 6 weeks apart;
    - ongoing laboratory investigations must include serum calcium, albumin, phosphorous weekly for three

weeks and iPTH every 6 weeks.

- Coverage for cinacalcet will be renewed if there is a greater than 30% decrease in iPTH after at least 3 months with escalating dose, indicating the patient is responding.
- Approval period 12 months, provided there has been a greater than 30% decrease in iPTH as stated above.

CIPROFLOXACIN, OPHTHALMIC *(Ciloxan 0.3% Ophthalmic Solution and generic brands and Ointment)*

- See **Fluoroquinolones, Ophthalmic**

*CIPROFLOXACIN, ORAL *(Cipro 100mg/mL Oral Liquid and 250mg, 500mg, 750mg Tablet and generic brands)*

- See **Fluoroquinolones, Oral**

*CIPROFLOXACIN XL, ORAL *(Cipro XL 1000mg Tablet)*

- For the oral treatment of gram-negative infections in complicated urinary tract infections, for which other oral agents are not effective or available. **[Criteria Code 10]**
- For the oral treatment of acute uncomplicated pyelonephritis. **[Criteria Code 11]**

CIPROFLOXACIN & DEXAMETHASONE, OTIC *(Ciprodex Otic Suspension)*

- For the treatment of patients with acute otitis media with otorrhea through tympanostomy tubes; or with known or suspected tympanic membrane perforation with otorrhea. **[Criteria Code 01]**
- For the treatment of patients with acute otitis externa in the presence of a tympanostomy tube or with known or suspected perforation of the tympanic membrane. **[Criteria Code 02]**

*CODEINE, SUSTAINED RELEASE *(Codeine Contin 50mg, 100mg, 150mg and 200mg Tablet)*

- For the treatment of mild to moderate chronic pain syndrome, if pain has been controlled by doses less than 200mg q12h.
- Patients may be considered candidates if they are achieving good pain control from immediate-release plain codeine preparations but prefer the convenience of a long-acting preparation, or if they are achieving good pain control from acetaminophen or ASA plus codeine preparations but are limited by the acetaminophen content to no greater than 12 tablets per day.
- Not insured for the treatment of acute pain (e.g., post-operative pain).

*CRIZOTINIB *(Xalkori 200mg and 250mg Capsule)*

- As a first or second-line therapy for patients with ALK-positive advanced non-small cell lung cancer with ECOG performance status ≤ 2.

CROMOGLYCATE SODIUM *(pms-Sodium Cromoglycate1% Nebulizer Solution)*

- See **Wet Nebulization Solutions**

*CYANOCOBALAMIN, INJECTION *(Cyanocobalamin, Vitamin B12 100mcg/mL and 1000mcg/mL Injection)*

- For the treatment of documented cyanocobalamin deficiency, when the oral route is inappropriate or contraindicated. (Criteria applies to all Programs.)

*CYANOCOBALAMIN, ORAL *(Vitamin B12 500mcg and 1,000mcg Tablet)*

- For the treatment of documented cyanocobalamin deficiency in recipients of the Community Services Pharmacare Program, Family Pharmacare Program and Drug Assistance for Cancer Patients; oral cyanocobalamin is fully insured for Seniors' Pharmacare Program.

*CYANOCOBALAMIN, ORAL IN COMBINATION *(Vitamin B12 1000mcg SL Tablet with Folic Acid)*

- For the treatment of documented cyanocobalamin deficiency in recipients of the Community Services Pharmacare Program, Family Pharmacare Program and Drug Assistance for Cancer Patients; oral cyanocobalamin is fully insured for Seniors' Pharmacare Program.

CYSTEAMINE BITARTRATE *(Procysbi 25mg and 75mg Capsule)*

- For the treatment of infantile nephropathic cystinosis with documented cystinosin (lysosomal cystine transporter) gene mutation.

Claim Notes:

- Must be prescribed by, or in consultation with, a prescriber with experience in the diagnosis and management of cystinosis
- Claims for Procysbi 75mg capsule that exceed the maximum claim amount of $9,999.99 must be divided and submitted as separate transactions using the DIN first and then the following PINs:
    - 00904354
    - 00904355

DABIGATRAN *(Pradaxa 110mg and 150mg Capsule and generic brands)*

- **Inclusion Criteria:**
    - At-risk[1] patients with non-valvular atrial fibrillation (AF) who require dabigatran for the prevention of stroke and systemic embolism AND in whom:
        - anticoagulation is inadequate[2] following a reasonable trial[3] on warfarin;
          OR
        - anticoagulation with warfarin is contraindicated or not possible due to inability to regularly monitor via International Normalized Ratio (INR) testing (i.e. no access to INR testing services at a laboratory, clinic, pharmacy, and at home).
- **Exclusion Criteria:**
    - Patients with impaired renal function[4] (creatinine clearance or estimated glomerular filtration rate < 30mL/min) OR ≥ 75 years of age and without documented stable renal function[5] OR hemodynamically significant rheumatic valvular heart disease[6], especially mitral stenosis; OR prosthetic heart valves.

* Please Note: Patients starting dabigatran should have ready access to appropriate medical services to manage a major bleeding event.

1. At risk patients with non valvular atrial fibrillation are defined as those with a CHADS2 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. A reasonable trial on warfarin is defined as at least two months of therapy.
4. 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 Pradaxa® (dabigatran) Product Monograph).

NOTE: Exception status drugs for Drug Assistance for Cancer Patients are indicated by an asterisk (*).

5. Documented stable renal function is defined as creatinine clearance or estimated glomerular filtration rate that is maintained for at least three months (i.e. 30-49mL/min for 110mg twice daily dosing or ≥ 50 mL/min for 150 mg twice daily dosing).
6. 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.

*DABRAFENIB *(Tafinlar 50mg and 75mg Capsule)* AND TRAMETINIB *(Mekinist 0.5mg and 2mg Tablet)*

- Dabrafenib-trametinib combination therapy as a first-line BRAF-mutation targeted treatment for patients with BRAF V600 mutation positive, unresectable or metastatic melanoma and who have an ECOG performance status of 0 or 1. Treatment should continue until disease progression. If brain metastases are present, patients should be asymptomatic or have stable symptoms.
- In the event that a patient is initiated on dabrafenib-trametinib combination therapy and has to discontinue one agent due to toxicity, dabrafenib or trametinib monotherapy as a BRAF-mutation targeted treatment for patients with BRAF V600 mutation positive, unresectable or metastatic melanoma and who have an ECOG performance status of 0 or 1, will be funded, should that be the chosen treatment option. Treatment should continue until disease progression. If brain metastases are present, patients should be asymptomatic or have stable symptoms. For clarity, initiation of treatment with dabrafenib or trametinib monotherapy will not be funded.

DAPAGLIFLOZIN *(Forxiga 5mg and 10mg Tablet)*

- For the treatment of Type II diabetes when:
    - Added on to metformin for patients:
        - who have inadequate glycemic control on metformin; and
        - who have a contraindication or intolerance to a sulfonylurea; and
        - for whom insulin is not an option.
- Added on to a sulfonylurea for patients:
    - Who have inadequate glycemic control on a sulfonylurea; and
        - who have a contraindication or intolerance to metformin; and
        - for whom insulin is not an option.

DAPAGLIFLOZIN AND METFORMIN HYDROCHLORIDE *(Xigduo 5mg/850mg and 5mg/1000mg Tablet)*

- For the treatment of Type II diabetes for patients:
    - who are already stabilized on therapy with dapagliflozin and metformin to replace the individual components of dapagliflozin and metformin; and
    - for whom insulin is not an option

Claim Note:

- Must have met criteria for dapagliflozin.

NOTE: Exception status drugs for Drug Assistance for Cancer Patients are indicated by an asterisk (*).

*DARBEPOETIN *(Aranesp Syringe Injection)*

- For the treatment of transfusion dependent patients with hematologic malignancies who have a baseline anemia of ≤ 90g/L and whose transfusion requirements are ≥ 2 units of packed red blood cells per month over 3 months
- Initial approval for 12 weeks with the documentation of dose, hemoglobin and therapeutic outcome (number of transfusions).
- Approval of further 12 week cycles are dependent on evidence of satisfactory clinical response or reduced treatment requirement to less than 2 units of PRBC monthly.

Note:

- Specialized request forms are used to request coverage for darbepoetin.

DARIFENACIN *(Enablex 7.5mg, 15mg Tablet)*

- See **OAB Medications**

*DASATINIB *(Sprycel 20mg, 50mg, 70mg, 100mg Tablet)*

- As a single agent for the treatment of adults with chronic, accelerated or blast phase chronic myelogenous leukemia (CML) and Philadelphia chromosome acute lymphoblastic leukemia (Ph⊕ ALL) with resistance or intolerance to prior therapy including imatinib.
- Coverage approved for 6 months.

DEFERASIROX *(Exjade 125mg, 250mg, 500mg Tablet for Suspension and generic brands)*

- For the treatment of patients who require iron chelation and deferoxamine is contraindicated.

DEFERIPRONE *(Ferriprox 100mg/mL Solution and 1000mg Tablet)*

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

*DENOSUMAB *(Prolia 60mg/mL Prefilled Syringe)*

- For the treatment of osteoporosis in postmenopausal women and in men who meet the following criteria:
    - Have a contraindication to oral bisphosphonates; and
    - High risk for fracture, or refractory or intolerant to other available osteoporosis therapies.

Clinical Notes:

- Refractory is defined as a fragility fracture or evidence of a decline in bone mineral density below pre-treatment baseline levels, despite adherence for one year to other available osteoporosis therapies.
- High fracture risk is defined as:
    - Moderate 10-year fracture risk (10% to 20%) as defined by the Canadian Association of Radiologists and Osteoporosis Canada (CAROC) tool or the World Health Organization's Fracture Risk Assessment (FRAX) tool with a prior fragility fracture; or
    - High 10-year fracture risk (≥ 20%) as defined by the CAROC or FRAX tool.

*DENOSUMAB *(Xgeva 120mg/1.7mL Solution)*

- As a single agent for the prevention of skeletal related events (SREs) for metastatic castrate resistant prostate

cancer (CRPC) patients with one or more documented bone metastases and ECOG performance status (PS) 0-2.

DIENOGEST *(Visanne 2mg 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.

DIMETHYL FUMARATE *(Tecfidera 120mg and 240mg DR Capsule)*

- 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).
- **Exclusion:**
    - 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.

DIPYRIDAMOLE & ASA *(Aggrenox 200/25mg Capsule and generic brands)*

- For the secondary prevention of ischemic stroke/transient ischemic attack (TIA) in patients who have experienced a recurrent thrombotic event (stroke, symptoms of TIA) while taking ASA.

DONEPEZIL *(Aricept 5mg, 10mg Tablet and generic brands)*

- See **Cholinesterase Inhibitors (ChEI)**

DULOXETINE *(Cymbalta 30mg, 60mg Capsule and generic brands)*

- For the treatment of chronic pain in patients who have had an inadequate response or intolerance to at least one first-line agent.

Clinical Note:

- First-line agents include tricyclic antidepressants for chronic neuropathic pain and non-steroidal anti-inflammatory drugs for chronic non-neuropathic pain.

Claim Note:

- The maximum dose reimbursed is 60mg daily.

EDOXABAN *(Lixiana 15mg, 30mg, 60mg Tablet)*

DEEP VEIN THROMBOSIS/PULMONARY EMBOLISM

Inclusion Criteria:

- For the treatment of deep vein thrombosis (DVT) or pulmonary embolism (PE)
- Approval Period: Up to six (6) months
- **[Criteria Code 36]** will be used to allow the 30mg or 60mg strengths to pay (max 30 tablets), which will allow patients to start therapy while awaiting ESD approval for the six months of therapy.

Notes:

- The recommended dose of edoxaban for patients initiating DVT or PE treatment is 60mg once daily following the initial use of a parenteral anticoagulant for five to ten days. A reduced dose of edoxaban 30mg once daily is recommended for patients with one or more of the following clinical factors: moderate renal impairment (creatinine clearance (CrCl) 30-50 mL/min, low body weight ≤60kg, or concomitant use of P-glycoprotein (P-gp) inhibitors except amiodarone and verapamil.
- Drug plan coverage for edoxaban is an alternative to heparin/warfarin for up to 6 months. When used greater than 6 months, edoxaban is more costly than heparin/warfarin. As such, patient with an intended duration of therapy greater than 6 months should be considered for initiation on heparin/warfarin.
- Since renal impairment can increase bleeding risk, it is important to monitor renal function regularly. Other factors that increase bleeding risks should also be assessed and monitor (see edoxaban product monograph).

NON-VALVULAR ATRIAL FIBRILLATION (AF)

Inclusion Criteria:

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

Exclusion Criteria:

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

Notes:

- At risk patients with non-valvular atrial fibrillation are defined as those with a CHADS2 score of ≥ 1. Prescribers may consider an antiplatelet regimen or oral anticoagulation for patients with CHADS2 score of ≥ 1.
- Inadequate anticoagulation is defined as INR testing results that are outside the desired INR range for at least 35% of the tests during the monitoring period (i.e. adequate anticoagulation is defined as INR test results that are within the desired INR range for at least 65% of the tests during the monitoring period).
- A reasonable trial on warfarin is defined as at least two months of therapy.
- The usual recommended dose is 60mg once daily. A reduced dose of edoxaban 30mg once daily is recommended for patients with one or more of the following clinical factors: moderate renal impairment (creatinine

clearance (CrCl) 30-50 mL/min, low body weight ≤60kg, or concomitant use of P-glycoprotein (P-gp) inhibitors except amiodarone and verapamil.

- Since renal impairment can increase bleeding risk, renal function should be regularly monitored. Other factors that increase bleeding risk should also be assessed and monitored (see edoxaban Product Monograph).
- There is currently no data to support that edoxaban provides adequate anticoagulation in patients with rheumatic valvular disease or those with prosthetic heart valves, so edoxaban is not recommended in these populations.

ELBASVIR/GRAZOPREVIR *(Zepatier 50mg/100mg Tablet)*

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

	Approval 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 4 ▪ Treatment-naïve ▪ Treatment-experienced prior relapsers	▪ 12 weeks
Genotype 1a ▪ Treatment-experienced on-treatment virologic failures	▪ 16 weeks in combination with ribavirin
Genotype 4 ▪ Treatment-experienced on-treatment virologic failures	▪ 16 weeks in combination with ribavirin

- **Patients must also meet all of 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);
  - Lab-confirmed hepatitis C genotype 1 or 4;
  - Quantitative HCV RNA value within the last 6 months;
  - Fibrosis stage must be provided.

Clinical Notes:

1. Treatment-experienced is defined as a patient who has been previously treated with a peginterferon/ribavirin (PegIFN/RBV) based regimen, 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 regimen, including regimens containing HCV protease inhibitors (for genotype 1), and who has not experienced adequate response, including a null response, partial response, 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. Re-treatment for direct-acting antiviral failures will be considered on a case-by-case basis.

Claim Notes:

- Claims that exceed the maximum claim amount of $9,999.99 must be divided and submitted as separate transactions using the DIN first and then the following PINs:
  - 00904237
  - 00904238
- Claims will be limited to a 28-day supply.

EMPAGLIFLOZIN *(Jardiance 10mg and 25mg Tablet)*

- For the treatment of Type 2 diabetes mellitus for patients with:
  - inadequate glycemic control on metformin and a sulfonylurea; and
  - for whom insulin is not an option

  OR
- As an adjunct to diet, exercise, and standard care therapy to reduce the incidence of cardiovascular death in patients with type 2 diabetes mellitus and established cardiovascular disease (details must be provided as per clinical note below) who have:
  - inadequate glycemic control despite an adequate trial of metformin

Clinical Notes:

- Established cardiovascular disease is defined as one of the following (details must be provided):
  - History of myocardial infarction (MI)
  - Multi-vessel coronary artery disease in two or more major coronary arteries (irrespective of revascularization status)
  - Single-vessel coronary artery disease with significant stenosis and either a positive non-invasive stress test or discharged from hospital with a documented diagnosis of unstable angina within 12 months prior to selection.
  - Last episode of unstable angina >2 months prior with confirmed evidence of coronary multi-vessel or single-vessel disease.
  - History of ischemic or hemorrhagic stroke.
  - Occlusive peripheral artery disease.

EMPAGLIFOZIN/METFORMIN HYDROCHLORIDE *(Synjardy 5mg/500mg, 5mg/850mg, 5mg/1000mg, 12.5mg/500mg, 12.5mg/850mg and 12.5mg/1000mg Tablet)*

- For the treatment of type 2 diabetes mellitus in patients who are already stabilized on therapy with empagliflozin and metformin, to replace the individual components of empagliflozin and metformin. Patients must meet coverage criteria for empagliflozin.

EMTRICITABINE/TENOFOVIR DISOPROXIL FUMARATE *(Truvada 200mg/ 300mg Tablet and generic brands)*

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.

Note regarding daily versus "on-demand" dosing:

- As stated in the Canadian Guideline, **daily** emtricitabine/tenofovir disoproxil fumarate (TDF/FTC) is currently the PrEP regimen of choice because it has been the most widely evaluated in high quality studies, and "on-demand" dosing is currently an off-label use of TDF/FTC in Canada. The on-demand regimen requires taking the drug 24 hours before sexual activity, every 24 hours during the sexual activity, and 24 hours after the last sexual encounter. A randomized placebo-controlled trial among MSM in France and Montreal found high efficacy among men who had frequent sex and who regularly took an average of 4 pills per week. These results suggest an on-demand strategy may be less effective for MSM who have less frequent sex because consistent pill use is important to achieve high levels of drugs in the body. A subsequent sub-study found that an on-demand strategy

(median 9.5 pills/month) remained highly effective for MSM having infrequent sex (median 5x/month). The implication is that on demand' PrEP compared with daily, continuous PrEP may decrease the cost of drugs while preventing similar numbers of infections. However, study of how on-demand PrEP would work in "real life" settings outside of a placebo-controlled trial are required.

ENTACAPONE *(Comtan 200mg Tablet and generic brands)*

- For the treatment of Parkinson's disease as adjunctive therapy in patients who are not well controlled and are experiencing significant "wearing off" symptoms despite optimal therapy with a levodopa and a decarboxylase inhibitor.

ENTECAVIR *(Baraclude 0.5mg Tablet and generic brands)*

- For the treatment of chronic hepatitis B infection in patients with:
  - documented cirrhosis on radiologic or histologic grounds; AND
  - a HBV DNA concentration above 2000iu/mL.

*ENZALUTAMIDE *(Xtandi 40mg Capsule)*

ASYMPTOMATIC OR MILDLY SYMPTOMATIC PATIENTS

- As a **single agent treatment** for **asymptomatic or mildly symptomatic** metastatic CRPC patients after failure of androgen deprivation therapy (including an LHRH agonist/antagonist or orchiectomy) who have not received prior chemotherapy for metastatic CRPC, ECOG PS 0-1 and no risk for seizures.
- Enzalutamide would be an **alternative** to abiraterone and **not sequential** therapy in this asymptomatic or mildly symptomatic patient population.

SYMPTOMATIC (POST-DOCETAXEL CHEMOTHERAPY) PATIENTS

- As a **single agent treatment** for metastatic CRPC patients with ECOG PS 0-2, no risk for seizures and progression **after previous treatment with docetaxel.**
- Enzalutamide would be an **alternative** to abiraterone and **not sequential** therapy in this symptomatic post docetaxel chemotherapy setting.

RETREATMENT

- Use of enzalutamide in the post docetaxel setting is **not permitted** if previously used in the pre-chemotherapy setting.

EPINEPHRINE *(Allerject 0.15mg/0.15mL, 0.3mg/0.3mL Injection, Epipen 1:1000 and Epipen Jr. 1:2000 Injection)*

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

Note:

- Regular benefit, but with a quantity limit of two injections per fiscal year. Additional units require an exception status request.

EPLERENONE *(Inspra 25mg, 50mg Tablet and generic brands)*

- For patients >55 years with mild to moderate HF on standard HF treatments with EF≤ 30% (or ≤35% if QRS duration >130ms) and recent (6 months) hospitalization for CV disease or with elevated BNP or NT-proBNP levels.

Notes:

- Requests will be considered from practitioners with a specialty in cardiology.
- Patients must be on optimal therapy with an angiotensin-converting–enzyme (ACE) inhibitor, an angiotensin-receptor blocker (ARB), or both and a beta-blocker (unless contraindicated) at the recommended dose or maximal tolerated dose.

***ERLOTINIB** *(Tarceva 100mg and 150mg Tablet and generic brands)*

- For the first-line treatment of patients with EGFR mutation positive locally advanced or metastatic NSCLC with a good performance status.
- For the treatment of patients with locally advanced or metastatic NSCLC after failure of at least one prior chemotherapy regimen and whose EGFR mutation status is positive or unknown.

Renewal Criteria:

- Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.

Claim Notes:

- Use of erlotinib precludes the use of any other EGFR inhibitor as a subsequent line of therapy.
- Approval period: 6 months
- In the absence of disease progression and in the event of severe toxicity within the first 12 weeks of therapy, a switch to another approved EGFR inhibitor may be allowed.

***ERYTHROPOIETIN** *(Eprex Multidose Vial and Syringe Injection)*

- For the treatment of transfusion dependent patients with hematologic malignancies who have a baseline anemia of $\leq$ 90g/L and whose transfusion requirements are $\geq$ 2 units of packed red blood cells per month over 3 months
- Initial approval for 12 weeks with the documentation of dose, hemoglobin and therapeutic outcome (number of transfusions).
- Approval of further 12 week cycles are dependent on evidence of satisfactory clinical response or reduced treatment requirement to less than 2 units of PRBC monthly.
- If transfusion requirements increase to $\geq$ 2 units/ month (over a 3 month period), one dose increase may be attempted (maximum dose 60,000iu per week).

Note:

- Specialized request forms are used to request coverage for erythropoietin.

ESLICARBAZEPINE *(Aptiom 200mg, 400mg, 600mg and 800mg Tablet)*

- As adjunctive treatment for patients with refractory partial-onset seizures who meet all of the following criteria:
    - are under the care of a 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.

Note:

- Any combination of lacosamide, perampanel or eslicarbazepine will not be reimbursed.

*ESTRADIOL *(Estrogel Topical Gel)*

- For the treatment of menopausal symptoms in women who cannot tolerate the oral forms of hormone replacement therapy.

ETANERCEPT *(Brenzys 50 mg/mL Prefilled Pen and 50 mg/mL Prefilled Syringe)*

For etanercept-naïve patients whose etanercept therapy is initiated after November 1, 2017, a biosimilar will be the product that is approved for the following indications.

ANKYLOSING SPONDYLITIS

- For the treatment of patients with moderate to severe ankylosing spondylitis (Bath AS Disease Activity Index (BASDAI) score ≥4 on 10 point scale) who:
    - have axial symptoms and who have failed to respond to the sequential use of at least 2 NSAIDs at the optimum dose for a minimum period of 3 months observation, or in whom NSAIDs are contraindicated; OR
    - have peripheral symptoms and who have failed to respond to, or have contraindications to, the sequential use of at least 2 NSAIDs at the optimum dose for a minimum period of 3 months observation and have had an inadequate response to an optimal dose or maximal tolerated dose of a DMARD.

Notes:

- Must be prescribed by a rheumatologist or prescriber with a specialty in rheumatology.
- 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").
- Initial coverage period 6 months, maximum dose 50mg per week and not in combination with other anti-TNF agents.
- Patients with recurrent uveitis (2 or more episodes within 12 months) as a complication of axial disease, do not require a trial of 2 NSAIDs.

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), or
    - use in combination with another DMARD, for a minimum of 12 weeks; **AND**

- methotrexate in combination with at least two other DMARDs, such as hydroxychloroquine and sulfasalazine, for a minimum of 12 weeks.

Clinical Notes:

- For patients who do not demonstrate a clinical response to oral methotrexate, or who experience gastrointestinal intolerance, a trial of parenteral methotrexate must be considered.
- Optimal treatment response to DMARDs may take up to 24 weeks, however coverage of a biologic therapy can be considered if no improvement is seen after 12 weeks of triple DMARD use.
- If patient factors (e.g. intolerance) prevent the use of triple DMARD therapy, these must be described and dual therapy with DMARDs must be tried.
- Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above.
- Intolerant is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs. The nature of intolerance(s) must be clearly documented.

Claim Notes:

- Must be prescribed by a rheumatologist.
- Combined use of more than one biologic DMARD will not be reimbursed.
- Initial Approval: 6 months.
- Renewal Approval: 1 year. Confirmation of continued response is required.
- Maximum Dosage Approved: 50mg once per week with no dose escalation permitted.

ETANERCEPT *(Enbrel 25mg Powder For Injection and 50mg/mL Injection)*

- See **Anti-Tumor Necrosis Factor (TNF) Agents**

ETANERCEPT *(Erelzi 25mg/0.5 ml and 50mg/ml Prefilled Syringe and 50mg/ml Prefilled Autoinjector)*

For etanercept-naïve patients whose etanercept therapy is initiated after November 1, 2017, a biosimilar will be the product that is approved.

ANKYLOSING SPONDYLITIS

- For the treatment of patients with moderate to severe ankylosing spondylitis (Bath AS Disease Activity Index (BASDAI) score ≥4 on 10-point scale) who:
  - have axial symptoms and who have failed to respond to the sequential use of at least 2 NSAIDs at the optimum dose for a minimum period of 3 months' observation, or in whom NSAIDs are contraindicated; OR
  - have peripheral symptoms and who have failed to respond to, or have contraindications to, the sequential use of at least 2 NSAIDs at the optimum dose for a minimum period of 3 months' observation and have had an inadequate response to an optimal dose or maximal tolerated dose of a disease modifying antirheumatic drug (DMARD).

Notes:

- Must be prescribed by a rheumatologist or prescriber with a specialty in rheumatology.
- Requests for renewal must include information showing the beneficial effects of the treatment, specifically:
  - a decrease of at least 2 points on the BASDAI scale, compared with the pre-treatment score; OR

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

- Initial coverage period 6 months, maximum dose 50mg per week and not in combination with other anti-TNF agents.
- Patients with recurrent uveitis (2 or more episodes within 12 months) as a complication of axial disease, do not require a trial of 2 NSAIDs.

RHEUMATOID ARTHRITIS

- For the treatment of severely active rheumatoid arthritis, in combination with methotrexate (MTX) or other DMARDs, in adult patients who are refractory or intolerant to:
  - MTX (oral or parenteral) at a dose of ≥ 20 mg weekly (≥15mg if patient is ≥65 years of age), or use in combination with another DMARD, for a minimum of 12 weeks AND
  - MTX 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 MTX, or who experience gastrointestinal intolerance, a trial of parenteral MTX must be considered.
- Optimal treatment response to DMARDs may take up to 24 weeks, however coverage of a biologic therapy can be considered if no improvement is seen after 12 weeks of triple DMARD use.
- If patient factors (e.g. intolerance) prevent the use of triple DMARD therapy, these must be described and dual therapy with DMARDs must be tried.
- Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above.
- Intolerant is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs. The nature of intolerance(s) must be clearly documented.

Claim Notes:

- Must be prescribed by a rheumatologist.
- Combined use of more than one biologic DMARD will not be reimbursed.
- Initial Approval: 6 months.
- Renewal Approval: 1 year. Confirmation of continued response is required.
- Maximum Dosage Approved: 25mg twice a week or 50mg once a week with no dose escalation permitted.

POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS

- For the treatment of polyarticular juvenile idiopathic arthritis (pJIA) with the following criteria:
  - For patients aged 4-17 years with moderate or severe pJIA who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs (DMARDs); and
  - Treatment must be initiated by a rheumatologist who is familiar with the use of DMARDs and/or biologic DMARDs in children.

*EVEROLIMUS *(Afinitor 2.5mg, 5mg, and 10mg Tablet)*

METASTATIC RENAL CELL CARCINOMA (RCC)

- As a single agent for metastatic renal cell carcinoma (RCC) patients with documented clear cell histology who have a Karnofsky performance status 70% or higher after progression or intolerance to the VEGF multi-targeted tyrosine kinase inhibitors (TKIs), (e.g., sunitinib, pazopanib and/or sorafenib).

HORMONE RECEPTOR POSITIVE, HER2 NEGATIVE-ADVANCED BREAST CANCER

- In combination with exemestane for postmenopausal patients (ECOG PS ≤2) with documented hormone receptor positive, HER2 negative-advanced breast cancer after recurrence or progression following a non-steroidal aromatase inhibitor (NSAI).

Note:

- It may be clinically reasonable to use the combination in patients with treated and stable brain metastasis.

METASTATIC PANCREATIC NEUROENDOCRINE TUMORS (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.

EVOLOCUMAB *(Repatha 140mg/mL Prefilled Syringe and 120mg/mL Automated Mini Doser)*

- For the treatment of heterozygous familial hypercholesterolemia (HeFH) in adult patients who require additional lowering of low-density lipoprotein cholesterol (LDL-C) if the following criteria are met:
    - Definite or probable diagnosis of HeFH using the Simon Broome or Dutch Lipid Network criteria or genetic testing; and
    - Patient is unable to reach LDL-C target (less than 2.0 mmol/L or at least a 50% reduction in LDL-C from untreated baseline) despite confirmed adherence to at least 3 months of continuous treatment with:
        - high-dose statin (e.g., atorvastatin 80 mg, rosuvastatin 40 mg) in combination with ezetimibe; or
        - ezetimibe alone if high dose statin is not possible due to rhabdomyolysis, contraindication or intolerance
- **Initial renewal criteria:**
    - A reduction in LDL-C of at least 40% from baseline or has reached a target LDL-C less than 2.0 mmol/L.
- **Subsequent renewal criteria:**
    - The patient continues to maintain a reduction in LDL- C of at least 40% from baseline or has reached a target LDL-C less than 2.0 mmol/L.

Clinical Notes:

- LDL-C levels must be provided.
- Intolerance to high dose statin will be considered if patient has developed documented, myopathy or abnormal biomarkers (i.e. creatinine kinase greater than 5 times the upper limit of normal) after trial of at least two statins and

- for each statin, dose reduction was attempted rather than statin discontinuation, and intolerance was reversible upon statin discontinuation, but reoccurred with statin re-challenge where clinically appropriate; and
- at least one statin was initiated at the lowest daily starting dose; and
- other known causes of intolerance or abnormal biomarkers have been ruled out.

- For patients who cannot take a statin due to an intolerance or contraindication, details must be provided (ie. confirmed rhabdomyolysis, active liver disease, unexplained persistent elevations of serum transaminases exceeding three times the upper limit of normal).
- For patients who cannot take ezetimibe due to an intolerance or contraindication, details must be provided.

Claim Notes:

- Maximum dose approved: 140mg every 2 weeks or 420mg monthly
- Initial approval: 6 months
- Renewal approval: 1 year

FEBUXOSTAT *(Uloric 80mg Tablet and generic brands)*

- For the treatment of symptomatic gout in patients who have documented hypersensitivity to allopurinol.

*FENTANYL *(Fentanyl 12mcg/hr, 25mcg/hr, 50mcg/hr, 75mcg/hr, 100mcg/hr Transdermal System and generic brands)*

- For the treatment of malignant or chronic non-malignant pain in adult patients who were previously receiving continuous opioid administration (i.e., not opioid naive), or who are unable to take oral therapy.

FESOTERODINE FUMARATE *(Toviaz 4mg and 8mg Tablet)*

- See **OAB Medications**

FIDAXOMICIN *(Dificid 200mg Tablet)*

- For the treatment of Clostridium Difficile Infection (CDI) where the patient:
  - has experienced a third or subsequent episode within 6 months of treatment with vancomycin for prior episode(s), with no previous trial of fidaxomicin; OR
  - has experienced treatment failure[1] with oral vancomycin for the current CDI episode; OR
  - has had a documented allergy (immune-mediated reaction) to oral vancomycin; OR
  - has experienced a severe adverse reaction or intolerance[2] to oral vancomycin treatment that resulted in the discontinuation of vancomycin therapy.
- **Re-treatment criteria:**
  - Re-treatment with fidaxomicin will only be considered for an early relapse occurring within 30 days of the completion of the most recent fidaxomicin course.
  - Relapse/recurrence occurring beyond 30 days after the completion of the most recent fidaxomicin course will require a trial with vancomycin, unless there is a documented allergy, severe adverse reaction or intolerance to prior oral vancomycin use.

Clinical Notes:

1. Treatment failure is defined as 7 days of vancomycin therapy without acceptable clinical improvement.
2. Details of severe adverse reaction or intolerance must be provided and should be clinically related to oral administration of vancomycin.

Claim Note:

- Requests will be approved for 200mg twice a day for 10 days.

FINGOLIMOD *(Gilenya 0.5mg Capsule)*

- For the treatment of patients with relapsing remitting multiple sclerosis (RRMS) who meet **all** of the following criteria:
    - have failed to respond to a full and adequate course[1] of at least one disease modifying therapy (DMT) publicly insured in Nova Scotia as an initial therapy, or has contraindications/intolerance[2] to at least two initial therapies;
    - one or more clinically disabling relapses in the previous year;
    - significant increase in T2 lesion load compared with that from a previous MRI scan (i.e. 3 or more new lesions) or at least one gadolinium-enhancing lesion;
    - requested and followed by a neurologist experienced in the management of RRMS;
    - recent expanded disability status scale (EDSS) score of 5.5 or less (i.e. patients must be able to ambulate at least 100 meters without assistance).
- Dosage: 0.5mg daily
- Approval period: 1 year
- **Exclusions:**
    - not funded in combination with other disease modifying therapies;
    - not funded in patients with an EDSS>5.5;
    - not funded in patients who have had a heart attack or stroke in the last six months of funding request, patients with a history of sick sinus syndrome, atrioventricular block, significant QT prolongations, bradycardia, ischemic heart disease, or congestive heart failure;
    - not funded in patients <18 years of age;
    - not funded due to needle phobia or preference for oral therapy over injection in patients without clinical contraindications to interferon or glatiramer therapy.

Note:

- Skin reactions at the site of injection do not qualify as contraindications to interferon or glatiramer therapy.

Renewal:

- EDSS score ≤ 5.5 (i.e. patients must be able to ambulate at least 100 meters without assistance). 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
- Patients must be stable or have experienced no more than 1 disabling attack/relapse in the past year.

Of Note:

1. Failure to respond to full and adequate courses: defined as a trial of at least 6 months of interferon or glatiramer therapy AND experienced at least one disabling relapse (attack) while on interferon or glatiramer therapy
2. Intolerance is defined as: documented serious adverse effects or contraindications that are incompatible with further use of that

class of drug

*FLUCONAZOLE *(Diflucan POS 10mg/mL)*

- For the treatment of oropharyngeal candidiasis when nystatin has failed, or for systemic infections when oral tablets are not an option.

*FLUDARABINE *(Fludara 10mg Tablet)*

- For the treatment of chronic lymphocytic leukemia (CLL), in patients with an ECOG performance status of 0-2, when:
    - the patient has failed to respond or relapsed during or after previous therapy with an alkylating agent, and
    - intravenous administration is not desirable.

FLUOROQUINOLONES, OPHTHALMIC *(Ciprofloxacin, Ofloxacin)*

- For the treatment of eye infections upon the order of an ophthalmologist, ophthalmology resident, prescribing optometrist or other prescriber who has a specialty in ophthalmology. **[Criteria Code 01]**

*FLUOROQUINOLONES, ORAL *(Ciprofloxacin, Norfloxacin)*

- For the treatment of patients intolerant or allergic (hypersensitivity reaction) to all other effective oral agents. **[Criteria Code 01]**
- For the treatment of aerobic, gram-negative infections which are resistant to other suitable oral agents. **[Criteria Code 02]**
- For the oral treatment of multi-resistant, aerobic, gram-negative infections traditionally requiring parenteral therapy (e.g., osteomyelitis, complicated urinary tract infections, bacterial pneumonia in cystic fibrosis, prostatitis) for which other oral agents are not effective or available. **[Criteria Code 03]**
- For infections due to Pseudomonas aeruginosa (ciprofloxacin is the preferred agent). **[Criteria Code 04]**
- For the treatment of necrotizing (malignant) otitis externa. **[Criteria Code 05]**
- For the prevention of endophthalmitis in patients who have had cataract surgery involving an unplanned vitrectomy (ciprofloxacin). **[Criteria Code 06]**

*FLUOROQUINOLONES, RESPIRATORY *(Levofloxacin, Moxifloxacin)*

- for the completion of therapy instituted in the hospital setting for the treatment of nosocomial pneumonia, community acquired pneumonia (CAP) or acute exacerbation of chronic bronchitis (AECB). **[Criteria Code 01]**
- for the treatment of severe pneumonia in nursing home patients. **[Criteria Code 02]**
- for the treatment[1] of CAP in patients with comorbidity[2] upon radiographic confirmation of pneumonia, or who have failed first line therapies (macrolide, doxycycline, amoxicillin-clavulanate). **[Criteria Code 03]**
- 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. **[Criteria Code 04]**

1. If treated with an antibiotic within the past 3 months choose an antibiotic from a different class.
2. Comorbidity includes chronic lung disease, malignancy, diabetes, liver failure, renal failure, 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 FEV1 < 50% predicted or FEV1 50% - 65% and one of the following: ≥4 exacerbations per year, ischemic heart disease, chronic oral steroid use or antibiotic use in past 3 months

FLUOXETINE *(Prozac 20mg/5mL Syr and generic brands)*

- For use in patients for whom oral capsules are not an option.

NOTE: Exception status drugs for Drug Assistance for Cancer Patients are indicated by an asterisk (*).

FLUTICASONE FUROATE AND VILANTEROL (AS TRIFENATATE) *(Breo Ellipta 100mcg/25mg and 200mcg/25mg Powder for Inhalation)*

- See **Long-Acting Beta$_2$-Agonists/Inhaled Corticosteroids**

FORMOTEROL *(Foradil 12ug Capsule For Inhalation, Oxeze 6mcg/Dose, 12mcg/Dose Turbuhaler, Zenhale 50/5mcg, 100/5mcg, 200/5mcg Inh)*

- See **Long-Acting Beta$_2$-Agonists**

FORMOTEROL, IN COMBINATION *(Symbicort 100/6mcg, 200/6mcg Turbuhaler)*

- See **Long-Acting Beta$_2$-Agonists/Inhaled Corticosteroids**

FOSFOMYCIN TROMETHAMINE *(Monurol 3g/sachet and generic brands)*

- For the treatment of uncomplicated urinary tract infections in adult female patients where:
    - the infecting organism is resistant to other oral agents **[Criteria Code 01]**; OR
    - other less costly treatments are not tolerated. **[Criteria Code 02]**

*GABAPENTIN *(Neurontin 100mg, 300mg, 400mg, 600mg and 800mg Capsule and Tablet and generic brands)*

- For the treatment of neuropathic pain (e.g. diabetic neuropathy, postherpetic neuropathy) in patients who have failed a trial of a tricyclic antidepressant (e.g. amitriptyline, desipramine, imipramine, nortriptyline).

GALANTAMINE *(Reminyl ER 8mg, 16mg, 24mg Capsule and generic brands)*

- See **Cholinesterase Inhibitors (ChEI)**

GLATIRAMER ACETATE *(Copaxone 20mg/mL Syringe Injection)*

Prescribed by a neurologist with experience in the treatment of multiple sclerosis for patients who meet the following criteria:

Treatment initiation:

- Diagnosis of Multiple Sclerosis with a relapsing course*:
    - Includes relapsing-remitting MS and secondary progressive MS with clear superimposed relapses;
    - Does not include primary progressive MS, progressive- relapsing or secondary progressive MS without relapses;

      and
    - Disability judged to be equivalent to Expanded Disability Status Score (EDSS) of 5.5 or less (exceptions are permitted in special cases).

Renewal:

- EDSS not greater than 6.0 for at least 12 months in the absence of relapses.
- Patients must be assessed for compliance and for any therapy related side effects that are intolerable.

Exclusions:

- Concurrent illness likely to alter compliance or substantially reduce life expectancy

* Relapsing course is defined as evidence of one relapse in the past 18 months or two relapses in the past 3 years.

GLECAPREVIR/ PIBRENTASVIR *(Maviret 100mg/40mg 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 or 6 ▪ Treatment-naïve	▪ 8 weeks (12 weeks with cirrhosis)
Genotypes 1, 2, 4, 5 or 6 ▪ Treatment-experienced with regimens containing peginterferon/ribavirin (PR) and/or sofosbuvir (SOF)	▪ 8 weeks (12 weeks with cirrhosis)
Genotype 1 ▪ NS5A inhibitor treatment-naïve and treatment-experienced with regimens containing: ▪ Boceprevir/PR; or ▪ Simeprevir (SMV)/SOF; or ▪ SMV/PR; or ▪ Telaprevir/PR	▪ 12 weeks
Genotype 1 ▪ NS3/4A inhibitor treatment-naïve and treatment-experienced with regimens containing: ▪ Daclatasvir (DCV)/SOF; or ▪ DCV/PR; or ▪ Ledipasvir/SOF	▪ 16 weeks
Genotype 3 ▪ Treatment-experienced with regimens containing PR and/or SOF	▪ 16 weeks

- The following information is also required:
  - Lab-confirmed hepatitis C genotype 1, 2, 3, 4, 5 or 6
  - Quantitative HCV RNA value within the last 6 months
  - Fibrosis stage

Clinical Note:

- Acceptable methods for the measurement of fibrosis score include Fibrotest, liver biopsy, transient elastography (FibroScan®), serum biomarker panels (such as AST-to-Platelet Ratio Index or Fibrosis-4 score) either alone or in combination.

Claim Notes:

- Must be prescribed by a hepatologist, gastroenterologist, or infectious disease specialist (or other physician experienced in treating a patient with hepatitis C infection).
- Claims will be limited to a 28-day supply.

NOTE: Exception status drugs for Drug Assistance for Cancer Patients are indicated by an asterisk (*).

- Claims that exceed the maximum claim amount of $9,999.99 must be divided and submitted as separate transactions using the DIN first and then the following PINs:
    - 00904394
    - 00904395

GLYCEROL PHENYLBUTYRATE *(Ravicti 1.1g/mL Oral Liquid)*

- For the chronic management of patients with urea cycle disorders (UCDs).

Clinical Note:

- Diagnosis must be confirmed by blood, enzymatic, biochemical or genetic testing.

Claim Notes:

- Must be prescribed by, or in consultation with, a prescriber experienced in the treatment of UCDs.
- Claims that exceed the maximum claim amount of $9,999.99 must be divided and submitted as separate transactions using the DIN first and then the following PINs:
    - 00904360
    - 00904361

GLYCOPYRRONIUM BROMIDE *(Seebri 50mcg Capsule for Inhalation)*

- For the treatment of moderate to severe chronic obstructive pulmonary disease (COPD) as defined by spirometry. OR
- For the treatment of COPD in patients with an inadequate response to short acting bronchodilators.
- Combination therapy with a long- acting beta-$_2$ agonist /inhaled corticosteroid (LABA/ICS) and a long acting anticholinergic (LAAC) inhaler will be considered in patients with: moderate to severe COPD, as defined by spirometry, a history of COPD exacerbation(s) and an inadequate response to LABA/ICS or LAAC.

Clinical Notes:

1. Moderate to severe COPD is defined by spirometry as a post bronchodilator 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.

Notes:

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

GOLIMUMAB *(Simponi 50mg/0.5ml and 100mg/1mL Autoinjector and Prefilled Syringe)*

- See **Anti-Tumor Necrosis Factor (TNF) Agents**

*GRANISETRON *(Kytril 1mg Tablet and generic brands)*

- See **Serotonin (5-HT$_3$) Antagonists**

Note:

- Recommended dose is 2mg orally 1 hour pre-chemotherapy *or* 1mg 1 hour pre-chemotherapy and 1mg 12 hours post-chemotherapy.

GRASS POLLEN ALLERGEN EXTRACT *(Oralair 100 and 300 Unit IR S/L Tablet)*

- For the seasonal treatment of grass pollen allergic rhinitis in patients that have not adequately responded to, or tolerated, conventional pharmacotherapy.

Notes:

- Treatment with 5-GPAE must be prescribed and initiated by physicians with adequate training and experience in the treatment of respiratory allergic diseases.
- Treatment should be initiated four (4) months before onset of pollen season and should only be continued until the end of the season.
- Treatment should not be taken for more than three (3) consecutive years.

HYDROXYZINE *(10mg, 25mg, 50mg Capsule, generic brands and Atarax Syrup)*

- For chronic urticaria, defined as the presence of hives or lesions for longer than six weeks, which has responded to treatment with hydroxyzine

*IBRUTINIB *(Imbruvica 140mg Capsule)*

FIRST LINE CHRONIC LYMPHOCYTIC LEUKEMIA/ SMALL LYMPHOCYTIC LYMPHOMA

- As a single agent treatment option for patients with previously untreated chronic lymphocytic leukemia (CLL)/ small lymphocytic lymphoma (SLL) for whom fludarabine –based treatment is considered inappropriate due to high risk of relapse or refractory disease based on prognostic biomarkers. Treatment should be discontinued upon disease progression or unacceptable toxicity.

Clinical Notes:

- High risk for relapse or refractory disease includes 17p deletion, TP53 mutation, 11q deletion and unmutated IGHV.
- Sequential use of ibrutinib and idelalisib will not be funded, except as a bridge to transplant. Exceptions may be considered in the case of intolerance without disease progression.

RELAPSED/REFRACTORY CHRONIC LYMPHOCYTIC LEUKEMIA OR SMALL LYMPHOCYTIC LYMPHOMA

- As a treatment option for patients with relapsed and/or refractory chronic lymphocytic leukemia (CLL) or 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, including :
    - Patients who received prior fludarabine-based treatment and had a progression free interval of less than three years
    - Patients who received prior fludarabine-based treatment and had a progression free interval of greater than three years, but are now considered unfit for fludarabine-based retreatment due to age ≥ 70, or age ≥ 65 and the presence of comorbidities (Cumulative Illness Rating Scale [CIRS] ≥ 6 or creatinine clearance <70ml/min)
    - Patients who did not receive prior fludarabine-based treatment because they were considered unfit, and who relapsed after at least two cycles of alkylator-based therapy, regardless of the progression free interval after that therapy

RELAPSED/REFRACTORY MANTLE CELL LYMPHOMA

- As a single agent treatment option for patients with relapsed or refractory mantle cell lymphoma who have received at least one prior therapy. Patients should have a good performance status. Treatment should be discontinued upon disease progression or unacceptable toxicity.

ICATIBANT *(Firazyr 30mg/30mL Prefilled Syringe)*

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

Notes:

- Limited to a single dose for self-administration per attack
- Be prescribed by physicians with experience in the treatment of HAE

Claim Note:

- Maximum of two doses on hand at any time.

*IDELALISIB *(Zydelig 100mg and 150mg Tablet)*

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

*IMATINIB *(Gleevec 100mg, 400mg Tablet and generic brands)*

- As a single agent for adult patients with a histological diagnosis of localized primary Gastrointestinal Stromal Tumors (GIST) (KIT (CD-117)-positive) following surgical complete resection and at a high risk of recurrence
    - risk of recurrence is dependent on location, size and mitotic rate. Specific parameters for considering adjuvant therapy after resection of GIST along the gastrointestinal tract may include but are not limited to:
        - gastric: any tumor >3cm where the mitotic rate is >5/50 high powered fields (HPFs). Adjuvant treatment could be considered where the mitotic rate is <5HPFs and tumor >10cm;
        - duodenal, small bowel, peritoneal, colorectal: any tumor where the mitotic rate is >5HPFs; any

tumor >5cm in size;
        - coverage duration: 36 months.
- For the treatment of chronic myelogenous leukemia (CML), as a single agent, in patients who have documented evidence of Philadelphia chromosome positive CML, with an ECOG performance status of 0-2 and who:
    - are in blast crisis, accelerated phase, or chronic phase; OR
    - as a secondary treatment in patients who demonstrate a hematologic relapse or cytogenetic progression after interferon-alpha (INF-a) therapy;
    - coverage duration: 1 year.
- Requests for other indications will be reviewed on a case by case basis.
- Written request of an oncologist required.

*IMIQUIMOD *(Aldara P 5% Cream and generic brands)*

- 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 the treatment of biopsy-confirmed primary superficial basal cell carcinoma:
    - with a tumor diameter of ≤ 2cm; AND
    - located on the trunk, neck or extremities (excluding hands and feet); AND
    - where surgery or eradication 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

Note:

- Surgical management should be considered first-line for superficial basal cell carcinoma in most patients, especially for isolated lesions.

INCOBOTULINUMTOXIN-A *(Xeomin 50U/Vial and 100U/Vial)*

- For the treatment of blepharospasm or cervical dystonia (spasmodic torticollis).

INDACATEROL *(Onbrez 75mcg Micronized Powder for Inhalation)*

- See **Long-Acting Beta$_2$-Agonists**

INDACATEROL AND GLYCOPYRRONIUM *(Ultibro Breezhaler 110mcg/50mcg Capsule for Inhalation)*

- 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).

Note:

- Moderate to severe COPD is defined by spirometry (post-bronchodilator) FEV1 < 60% predicted and FEV1/FVC ratio of < 0.70. Spirometry reports from any point in time will be accepted.
- If spirometry cannot be obtained, reasons must be clearly explained and other evidence regarding COPD severity must be provided for consideration (i.e. Medical Research Council (MRC) Dyspnea Scale score of at least Grade

3). MRC Grade 3 is described as: walks slower than people of same age on the level because of shortness of breath (SOB) from COPD or has to stop for breath when walking at own pace on the level.

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

INFLIXIMAB *(Inflectra, Remicade and Renflexis 100mg Powder For Injection)*

- See **Anti-Tumor Necrosis Factor (TNF) Agents**

INSULIN LISPRO *(Humalog Insulin, Cartridges and Kwikpen)*

- Regular benefit for children 18 years and younger, under Community Services, Family Pharmacare and Diabetes Assistance Programs
- For the management of Type I and Type II diabetes mellitus in patients 19 years of age and older, who are:
    - undergoing intensive therapy, i.e., administering three or more injections of insulin per day including basal insulin, and
    - testing blood glucose levels 4-6 times per day

INSULIN DETEMIR *(Levemir 100iu/mL Penfill and FlexTouch Prefilled Pen)*
INSULIN GLARGINE *(Lantus 100iu/mL Vial, Cartridge, and Solostar Prefilled Pen)*

- For the treatment of patients who have been diagnosed with Type 1 or Type 2 diabetes requiring insulin and have previously taken NPH and/or premix insulin daily at optimal dosing

    AND

    - have experienced unexplained nocturnal hypoglycemia at least once a month despite optimal management

      OR

    - have documented severe or continuing systemic or local allergic reaction to existing insulin(s)

***IPRATROPIUM BROMIDE** *(Atrovent 125mcg/mL and 250mcg/mL Inhaled Solutions and generic brands)*

- See **Wet Nebulization Solutions**

***IPRATROPIUM BROMIDE, IN COMBINATION** *(Combivent Inhaled Solution and generic brands)*

- See **Wet Nebulization Solutions**

INTERFERON BETA-1A *(Avonex PS 30mcg/0.5mL Injection and Rebif 22mcg Multidose Cartridges, 22mcg/0.5mL Injection, 44mcg Mulitdose Cartridges and 44mcg/0.5mL Injection)*
INTERFERON BETA-1B *(Betaseron 0.3mg/Vial Injection and Extavia 0.3mg/vial Injection)*

Prescribed by a neurologist with experience in the treatment of multiple sclerosis for patients who meet the following criteria:

Treatment initiation:

- Diagnosis of multiple sclerosis with a relapsing course*.
    - Includes relapsing-remitting MS and secondary progressive MS with clear superimposed relapses;
    - Does not include primary progressive MS, progressive- relapsing or secondary progressive MS without relapses;

      and

    - Disability judged to be equivalent to Expanded Disability Status Score (EDSS) of 5.5 or less.

NOTE: Exception status drugs for Drug Assistance for Cancer Patients are indicated by an asterisk (*).

Renewal:

- EDSS not greater than 6.0 for at least 12 months in the absence of relapses.
- Patients must be assessed for compliance and for any therapy related side effects that are intolerable.

Exclusions:

- Concurrent illness likely to alter compliance or substantially reduce life expectancy.
- Planned pregnancy, pregnancy or breast-feeding.
- Active and severe depression.

* Relapsing course is defined as evidence of one relapse in the past 18 months or two relapses in the past 3 years.

*ITRACONAZOLE *(Sporanox 100mg Capsule and generic brands)*

- For the treatment of severe systemic fungal infections.
- For the treatment of severe or resistant fungal infections in immunocompromised patients.
- For the treatment of severe onychomycosis caused by dermatophyte fungi as diagnosed by a dermatologist, attending physician or prescriber with a specialty in dermatology.

IVABRADINE HYDROCHLORIDE *(Lancora 5mg and 7.5mg Tablet)*

- For the treatment of adult patients with New York Heart Association (NYHA) classes II or III stable chronic heart failure to reduce the incidence of cardiovascular death and hospitalization, administered in combination with standard chronic heart failure therapies, who meet all of the following criteria:
    - reduced left ventricular ejection fraction (LVEF) (<35%)
    - sinus rhythm with a resting heart rate ≥77 beats per minute (bpm)
    - at least one hospitalization due to heart failure in the past year
    - NYHA class II to III symptoms despite at least four weeks of optimal treatment of the following:
        - a stable dose of an angiotensin converting enzyme inhibitor (ACEI) or an angiotensin II receptor blocker (ARB); and
        - a stable dose of a beta blocker; and
        - an aldosterone antagonist

Clinical Notes:

- 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.
- For patients who have not received four weeks of therapy with an ACEI/ARB, beta blocker or aldosterone antagonist due to an intolerance or contraindication, details must be provided.

Claim Note:

- Patients should be under the care of a specialist experienced in the treatment of heart failure for patient selection, titration, follow-up and monitoring.

IVACAFTOR *(Kalydeco 150mg 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:
            - the patient's sweat chloride level fell below 60 mmol/litre;
              OR
            - 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:
            - the patient's sweat chloride level is 30% lower than the level reported in a previous test;
              OR
            - 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 ivacaftor, these parameters may be used to evaluate the effect of ivacaftor 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.

IXEKIZUMAB *(Taltz 80mg/mL Autoinjector and Prefilled Syringe)*

- See **Anti-Tumor Necrosis Factor (TNF) Agents**

LACOSAMIDE *(Vimpat 50mg, 100mg, 150mg, 200mg Tablet and generic brands)*

- As adjunctive treatment for patients with refractory partial-onset seizures who meet all of the following criteria:
    - are under the care of a 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.

*LACTULOSE *(667mg/mL Oral Liquid, generic brands)*

- For portal systemic encephalopathy.
- For pneumatosis cystoides intestinalis.

LAMIVUDINE *(Heptovir 100mg Tablet and generic brands)*

- For the treatment of hepatitis B, upon written request of a specialist.
- Therapy is approved for one year, with reassessment required at that time.

NOTE: Exception status drugs for Drug Assistance for Cancer Patients are indicated by an asterisk (*).

*LANSOPRAZOLE *(Prevacid FasTab 15mg, 30mg Tablet)*

- For patients who require the use of a proton pump inhibitor and require administration through a feeding tube.

*LANSOPRAZOLE *(Prevacid 15mg, 30mg Capsule and generic brands)*

- See **Proton Pump Inhibitors**

*LAPATINIB *(Tykerb 250mg Tablet)*

- in combination with capecitabine as a treatment option in patients with human epidermal growth factor receptor 2 (HER2) positive advanced or Metastic Breast Cancer (MBC) with trastuzumab refractory disease (previously treated with trastuzumab alone or in combination with chemotherapy such as taxane and/or vinorelbine) who have an ECOG performance status of 0 to 2 and choose to receive systemic chemotherapy. Patients with previous exposure to capecitabine are not considered eligible.

LEDIPASVIR AND 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:
    - Must be 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;
    - Quantitative HCV RNA value within the last 6 months;
    - Fibrosis stage must be provided.

Clinical Notes:

NOTE: Exception status drugs for Drug Assistance for Cancer Patients are indicated by an asterisk (*).

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 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.

Claim Notes:

- Claims that exceed the maximum claim amount of $9,999.99 must be divided and submitted as separate transactions using the following PINs:
    - 00904032
    - 00904033
- Claims will be limited to a 28-day supply.

*LENALIDOMIDE *(Revlimid 2.5mg, 5mg, 10mg, 15mg, 20mg, 25mg Capsule)*

MYELODYSPLASTIC SYNDROME (MDS)

- As a single agent in adult myelodysplastic syndrome (MDS) patients with transfusion dependent anemia due to low or intermediate-1 risk MDS associated with a deletion 5q cytogenetic abnormality with or without additional cytogenic abnormalities.

MULTIPLE MYELOMA (MM-AOPT)

- In combination with dexamethasone in adult patients with progressive myeloma (MM) after at least one previous treatment, not resistant to dexamethasone, documented measurable disease and ECOG performance status of 0-2.

NEWLY DIAGNOSED MULTIPLE MYELOMA POST-AUTOLOGOUS STEM CELL TRANSPLANT (NDMM POST-ASCT)

- For the maintenance treatment of patients with newly diagnosed multiple myeloma, following autologous stem-cell transplantation (ASCT):
    - in patients with stable disease or better, with no evidence of disease progression;
    - treat until progression or development of unacceptable toxicity requiring discontinuation of lenalidomide;
    - initial dose 10 mg lenalidomide PO daily; AND
    - dose adjustments (5-15 mg) may be necessary based on individual patient characteristics/responses.

MULTIPLE MYELOMA NOT ELIGIBLE FOR AUTOLOGOUS STEM CELL TRANSPLANT (MM-TNE)

- As a first-line treatment option for newly diagnosed patients with multiple myeloma who are not eligible for autologous stem cell transplantation. Treatment should be in combination with dexamethasone for patients with ECOG performance status 0-2, and until disease progression.

Note:

- Celgene will ensure that the Product will be prescribed and dispensed only by physicians and pharmacists, respectively, who are registered with and agree in writing to adhere to the guidelines of the Company's RevAid® Program, details of which Program are available at https://revaid.ca/revaid.

NOTE: Exception status drugs for Drug Assistance for Cancer Patients are indicated by an asterisk (*).

*LENVATINIB *(Lenvima 10mg, 14mg, 20mg, 24mg Compliance Pack)*

- For the 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.

LEVOCARNITINE *(Carnitor 100mg/mL Oral Liquid and 330mg Tablet)*

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

LEVODOPA AND CARBIDOPA AND ENTACAPONE *(Stalevo 50mg, 75mg, 100mg, 125mg, 150mg Tablet)*

- For the treatment of Parkinson's disease as adjunctive therapy in patients who:
    - are not well controlled and are experiencing significant "wearing off" symptoms despite optimal therapy with levodopa/carbidopa;
    - were not well controlled and experienced significant "wearing off" symptoms despite optimal therapy with levodopa/carbidopa and are currently using levodopa/carbidopa and entacapone separately.

*LEVOFLOXACIN *(Levaquin 250mg, 500mg Tablet and generic brands)*

- See **Fluoroquinolones, Respiratory**

LINEZOLID *(Zyvoxam 600mg Tablet)*

- Written request from an infectious disease specialist or prescriber with a specialty in infectious diseases.
- For the treatment of proven vancomycin-resistant enterococci (VRE) infections.
- For the treatment of proven methicillin-resistant staphylococcus aureus or epidermidis (MRSA/MRSE) infections in those patients who are unresponsive to, or intolerant of vancomycin.

LINAGLIPTIN *(Trajenta 5mg Tablet)*

- For the treatment of Type II diabetes for patients with:
    - inadequate glycemic control on metformin and a sulfonylurea; and
    - for whom insulin is not an option.

LINAGLIPTIN/METFORMIN *(Jentadueto 2.5mg/500mg, 2.5mg/850mg and 2.5mg/1000mg Tablet)*

- For the treatment of Type II diabetes for patients:
    - who are already stabilized on therapy with metformin, a sulfonylurea and linagliptin to replace the individual components of linagliptin and metformin; and
    - for whom insulin is not an option.

LISDEXAMFETAMINE *(Vyvanse 10mg, 20mg, 30mg, 40mg, 50mg, and 60mg Capsule)*

- For the treatment of attention deficit hyperactivity disorder (ADHD) in patients who:
    - demonstrate significant and problematic disruptive behaviour or who have problems with inattention that interfere with learning; and
    - have been tried on methylphenidate (immediate release or long-acting formulation) or dexamphetamine with unsatisfactory results.

Notes:

- Requests will be considered from prescribers with expertise in ADHD.
- The maximum dose reimbursed is 60mg daily.

LONG-ACTING BETA$_2$-AGONISTS *(Formoterol, Indacaterol, Salmeterol)*
LONG-ACTING BETA$_2$-AGONISTS/INHALED CORTICOSTEROIDS *(Formoterol, In Combination; Salmeterol, In Combination)*

ASTHMA

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

Products and Strengths Approved:

Advair	• 50/100mcg, 50/250mcg and 50/500mcg Diskus • HFA 25/125 mcg/dose • HFA 25/250 mcg/dose Inhaler
Breo Ellipta	• 100mcg/25mg and 200mcg/25mg dry powder for inhalation
Foradil	• 12ug Capsule For Inhalation
Oxeze	• 6mcg/Dose, 12mcg/Dose Turbuhaler
Serevent	• 50mcg/dose Diskhaler • 50mcg/dose Diskus
Symbicort	• 100/6mcg Turbuhaler • 200/6mcg Turbuhaler
Zenhale	• 5/100mcg and 5/200mcg

CHRONIC OBSTRUCTIVE PULMONARY DISEASE

- For the treatment of moderate to severe chronic obstructive pulmonary disease (COPD) as defined by spirometry; OR
- For the treatment of COPD in patients with an inadequate response to short acting bronchodilators.
- Combination therapy with a long- acting beta-$_2$ agonist /inhaled corticosteroid (LABA/ICS) and a long acting anticholinergic (LAAC) inhaler will be considered in patients with: moderate to severe COPD, as defined by spirometry, a history of COPD exacerbation(s) and an inadequate response to LABA/ICS or LAAC.

Clinical Notes:

1. Moderate to severe COPD is defined by spirometry as a post bronchodilator FEV1 < 60% predicted and FEV1/FVC ratio of < 0.70. Spirometry reports from any point in time will be accepted.

   If spirometry cannot be obtained, reasons must be clearly explained and other evidence of COPD severity provided, i.e., Medical Research Council (MRC) Dyspnea Scale Score of at least Grade 3.

NOTE: Exception status drugs for Drug Assistance for Cancer Patients are indicated by an asterisk (*).

MRC Grade 3 is described as: walks slower than people of same age on the level because of shortness of breath from COPD or has to stop for breath when walking at own pace on the level.

2. Inadequate response to short acting bronchodilators is defined as persistent symptoms, i.e., MRC of at least Grade 3, after at least 2 months of short acting bronchodilator at the following doses*:
    - 8 puffs per day of short acting beta-$_2$ agonist; or
    - 12 puffs per day of ipratropium; or
    - 6 puffs per day of ipratropium plus salbutamol combination inhaler.

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

Note:

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

Products and Strengths Approved:

Advair	• 50/100mcg, 50/250mcg and 50/500mcg Diskus • HFA 25/125 mcg/dose • HFA 25/250 mcg/dose Inhaler
Breo Ellipta	• 100mcg/25mg dry powder for inhalation
Foradil	• 12ug Capsule For Inhalation
Onbrez	• 75mcg Micronized powder for inhalation
Serevent	• 50mcg/dose Diskhaler • 50mcg/dose Diskus
Symbicort	• 100/6mcg and 200/6mcg Turbuhaler

LORATADINE *(Claritin 10mg Tablet and generic brands)*

- For chronic urticaria, defined as the presence of hives or lesions for longer than six weeks, which has responded to treatment with loratadine.

LURASIDONE *(Latuda 20mg, 40mg, 60mg, 80mg, 120mg Tablet)*

- For the treatment of schizophrenia and related psychotic disorders (not dementia related) in patients with a history of failure, intolerance, or contraindication to at least one less expensive antipsychotic agent.

MAGNESIUM GLUCOHEPTONATE *(5mg/mL Solution and generic brands)*

- For the treatment of hypomagnesemia.

MEPOLIZUMAB *(Nucala 100mg/mL Powder for Injection)*

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

Initial Discontinuation Criteria:

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

Subsequent Discontinuation Criteria:

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

Clinical Notes:

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

Claim Notes:

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

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*METHADONE *(Metadol 1mg, 5mg, 10mg, 25mg Tablet)*

- For the management of severe chronic or malignant pain as an alternative to other opiates.
- Written request of a physician authorized to prescribe methadone.

Clinical Note:

- In the case of comorbid opioid use disorder (past or current), methadone oral liquid would normally be prescribed as per treatment standards. If methadone tablets are requested in this context, a specialist consult may be required.

METHYLPHENIDATE *(Biphentin 10mg, 15mg, 20mg 30mg, 40mg, 50mg, 60mg and 80mg Capsule)*
METHYLPHENIDATE ER *(Concerta 18mg, 27mg, 36mg, and 54mg Tablet and generic brands)*

- For patients diagnosed with attention deficit hyperactivity disorder (ADHD) who require 12-hour continuous coverage due to academic and/or psychosocial needs, and who meet the following:
    - patients who demonstrate significant and problematic disruptive behaviour or who have problems with inattention that interfere with learning; AND
    - have been tried on immediate release or slow release methylphenidate with unsatisfactory results.

Note:

- Requests will be considered from prescribers with expertise in ADHD.

*MIDAZOLAM *(1mg/mL, 5mg/mL Injection and generic brands)*

- For adjunctive therapy of pain management in palliative care patients outside the hospital setting. **[Criteria Code 01]**

MIDOSTAURIN *(Rydapt 25mg Capsule)*

- For the treatment of adult patients with newly diagnosed FMS-like tyrosine kinase 3 (FLT3)-mutated acute myeloid leukemia when used in combination with standard cytarabine and daunorubicin (7+3) induction and cytarabine consolidation chemotherapy. Patients should be deemed fit to receive standard induction and consolidation chemotherapy.

Clinical Notes:

- Midostaurin is not funded as maintenance therapy.
- Midostaurin may be used in combination with other 7+3 induction regimens (i.e. cytarabine and idarubicin)

Claim Note:

- Claims for Rydapt 25mg capsule that exceed the maximum claim amount of $9,999.99 must be divided and submitted as separate transactions using the DIN first and then the following PIN:
    - 00904390

MIGALASTAT *(Galafold 123mg Capsule)*

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

Clinical Note:

- Galafold will not be used concomitantly with any ERT.

Claims Note:

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

MIRABEGRON *(Myrbetriq 25mg ER and 50mg ER Tablet)*

- For the treatment of overactive bladder (OAB) with symptoms of urgency, urgency incontinence, and urinary frequency in patients who have an intolerance or insufficient response to an adequate trial of immediate-release oxybutynin, solifenacin or tolterodine.

Note:

- Not to be used in combination with other pharmacological treatments for OAB.

MODAFINIL *(Alertec 100mg Tablet and generic brands)*

- for the treatment of narcolepsy confirmed by sleep study

*MOXIFLOXACIN *(Avelox 400mg Tablet and generic brands)*

- See **Fluoroquinolones, Respiratory**

NALTREXONE *(Revia 50mg Tablet and generic brands)*

- For the treatment of alcohol dependence, as an adjunct to a comprehensive psychotherapeutic or psychological alcoholism counseling program to support abstinence, and reduce the risk of relapse.
- Eligibility is initially restricted to a three month period with reassessment at that time for further coverage.

NARATRIPTAN *(Amerge 1mg, 2.5mg Tablet and generic brands)*

- See **Selective $5HT_1$ - Receptor Agonists**

NATALIZUMAB *(Tysabri 300mg/15mL Vial)*

- **Initial Request:**
  - For the treatment of Relapsing-Remitting Multiple Sclerosis (RRMS) who meet all the following criteria:
    - The patient's physician is a neurologist experienced in the management of relapsing-remitting multiple sclerosis (RRMS); AND
    - The patient;
      - has a current EDSS less than or equal to 5.0; AND
      - has failed to respond to a full and adequate course[1] (at least six months) of at least ONE disease modifying therapy OR has contraindications/intolerance to at least TWO disease modifying therapies; AND
      - has had ONE of the following types of relapses in the past year:
        - the occurrence of one relapse with partial recovery during the past year AND has at least ONE gadolinium-enhancing lesion on brain MRI, OR significant increase in T2 lesion load compared to a previous MRI; OR
        - the occurrence of two or more relapses with partial recovery during the past year; OR
        - the occurrence of two or more relapses with complete recovery during the past year AND has at least ONE gadolinium-enhancing lesion on brain MRI, OR significant increase in T2 lesion load compared to a previous MRI.
  - approval period: 1 year.
- **Requirements for Initial Requests:**
  - the patient's physician provides documentation setting out the details of the patient's most recent neurological examination within ninety (90) days of the submitted request. This must include a description of any recent attacks, the dates, and the neurological findings.
  - MRI reports do NOT need to be submitted with the initial request.
- **Renewal:**
  - Date and details of the most recent neurological examination and EDSS scores must be provided (exam must have occurred within the last 90 days); AND
  - Patients must be stable or have experienced no more than 1 disabling attack/relapse in the past year; AND
  - Recent Expanded Disability Status Scale (EDSS) score less than or equal to 5.0.

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

*NETUPITANT/PALONOSETRON *(Akynzeo 300mg/0.5mg Capsule)*

- In combination with dexamethasone for the prevention of acute and delayed nausea and vomiting in patients receiving:
    - highly emetogenic chemotherapy, OR
    - moderately emetogenic chemotherapy who have had inadequate symptom control using a 5-HT3 antagonist and dexamethasone in a previous cycle.

Clinical Notes:

- Highly emetogenic chemotherapy (HEC) may include, but is not limited to: cisplatin regimens, anthracycline and cyclophosphamide combination regimens, and regimens containing carmustine, mechlorethamine, streptozocin, dacarbazine and cyclophosphamide ≥ 1500mg/m^2.
- Patients who receive carboplatin-based regimens with AUC ≥ 4 are also eligible to receive netupitant/palonosetron in combination with dexamethasone for primary prevention of acute and delayed nausea and vomiting.

*NILOTINIB *(Tasigna 150mg & 200mg Capsule)*

- **First Line:**
    - As a **single first line agent** for the treatment of adults with chronic phase CML.
- **Second Line:**
    - As a **single second line agent** for the treatment of adults with chronic or accelerated phase CML with resistance or intolerance to prior therapy.
- These **second line** criteria include:
    - Patients with CML in chronic phase who are intolerant to oral tyrosine kinase inhibitors (TKIs) (i.e. imatinib or dasatinib or both);
    - Patients with CML in chronic phase who are resistant to imatinib;
    - Patients with CML that have progressed to accelerated phase while on imatinib therapy.
- In any one patient, only two of the TKIs will be funded within these criteria during their lifetime.
- If a patient develops grade 3 or 4 toxicity to one of the TKIs used within 3 months of initiating therapy, access to a third agent will be funded.
- Sequential use of nilotinib and dasatinib is not permitted except in the circumstance described above (i.e. grade 3 or 4 toxicity).

NINTEDANIB *(Ofev 100mg and 150mg Capsule)*

- **Initial approval criteria:**
    - Adult patients who have a diagnosis of mild to moderate idiopathic pulmonary fibrosis (IPF)[1] confirmed by a respirologist and a high-resolution CT scan within the previous 24 months;
    - All other causes of restrictive lung disease (e.g. collagen vascular disorder or hypersensitivity pneumonitis) should be excluded;
    - Patient is under the care of a physician with experience in IPF;
    - Initial approval period: 7 months (allow 4 weeks for repeat pulmonary function tests).
- **Initial renewal criteria:**
    - Patients must NOT demonstrate progression of disease defined as an absolute decline in percent

predicted FVC of ≥10% from initiation of therapy until renewal (initial 6 month treatment period). If a patient has experienced progression as defined above, then the results should be validated with a confirmatory pulmonary function test conducted 4 weeks later.

- Approval period: 6 months.

- **Second and Subsequent renewal criteria (at 12 months after initiation and thereafter):**
  - Patients must NOT demonstrate progression of disease defined as an absolute decline in percent predicted FVC of ≥10% within any 12 month period. If a patient has experienced progression as defined above, then the results should be validated with a confirmatory pulmonary function test conducted 4 weeks later.
  - Approval period: 12 months.
- **Exclusion Criteria:**
  - Combination use of Ofev (nintedanib) and Esbriet (pirfenidone) will not be funded.

1. Mild-moderate IPF is defined as: a forced vital capacity (FVC) ≥ 50% of predicted.

Note:

- Patients who have experienced intolerance or failure to Ofev (nintedanib) or Esbriet (pirfenidone) will be considered for the alternate agent provided that the patient continues to meet the above coverage criteria.

NITISINONE *(Cycle-Nitisinone 2mg, 5mg and 10mg Tablet and Orfadin 2mg, 5mg, 10mg, 20mg Capsule)*

- For the treatment of adult and pediatric patients with hereditary tyrosinemia type 1 (HT-1) in combination with dietary restriction of tyrosine and phenylalanine.

Clinical Note:

- For use in patients with an established diagnosis of HT-1.

Claim Notes:

- Must be prescribed by a physician experienced in the diagnosis and management of HT-1.
- Claims for nitisinone 10mg tablet/capsule and 20mg capsule that exceed the maximum claim amount of $9,999.99 must be divided and submitted as separate transactions using the DIN first and then the following PINs:
  - Nitisinone 10mg Tab
    - 00904442
    - 00904443
    - 00904444
  - Orfadin 10mg Cap
    - 00904434
    - 00904435
    - 00904436
  - Orfadin 20mg Cap
    - 00904437
    - 00904438
    - 00904439

NOTE: Exception status drugs for Drug Assistance for Cancer Patients are indicated by an asterisk (*).

*NORFLOXACIN *(400mg Tablet and generic brands)*

- See **Fluoroquinolones, Oral**

NUSINERSEN *(Spinraza 12mg/5mL Vial)*

- For patients diagnosed with 5q Spinal Muscular Atrophy (SMA) under the care of a specialist with experience in the diagnosis and management of SMA, if the following clinical criteria are met:
    - Genetic documentation of 5q SMA homozygous gene deletion, homozygous mutation, or compound heterozygote, AND
    - Patients who:
        - are pre-symptomatic with two or three copies of SMN2, OR
        - have had disease duration of less than six months, two copies of SMN2, and symptom onset after the first week after birth and on or before seven months of age, OR
        - are under the age of 18 with symptom onset after six months of age,

          AND
    - Patient is not currently requiring permanent invasive ventilation*, AND
    - A baseline assessment using an age-appropriate scale (the Hammersmith Infant Neurological Examination [HINE] Section 2, Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders [CHOP INTEND], or Hammersmith Functional Motor Scale-Expanded [HFMSE]) must be completed prior to initiation of nusinersen treatment.

      Other patients with SMA type 2 or 3 who are over the age of 18 may be considered on a case by case basis.
- For continued coverage, the patient must meet the following criteria:
    - There is demonstrated achievement or maintenance of motor milestone function (as assessed using age-appropriate scales: the [HINE] Section 2), CHOP INTEND, or HFMSE) since treatment initiation in patients who were pre-symptomatic at the time of treatment initiation; OR
    - There is demonstrated maintenance of motor milestone function (as assessed using age-appropriate scales: the HINE Section 2, CHOP INTEND, or HFMSE) since treatment initiation in patients who were symptomatic at the time of treatment initiation;

      AND
    - Patient does not require permanent invasive ventilation*.
- Treatment should be discontinued if, prior to the fifth dose or every subsequent dose of nusinersen, the above renewal criteria are not met.

* Permanent invasive ventilation is defined as the use of tracheostomy and a ventilator due to progression of SMA that is not due to an identifiable and reversible cause.

Claim Note:

- Claims for Spinraza 12mg/5mg vials that exceed the maximum claim amount of $9,999.99 must be divided and submitted as separate transactions using the DIN first and then the following PINs:
    - 00904366
    - 00904367
    - 00904368
    - 00904369

NOTE: Exception status drugs for Drug Assistance for Cancer Patients are indicated by an asterisk (*).

- 00904370
- 00904371
- 00904372
- 00904373
- 00904374
- 00904375
- 00904376
- 00904377

OAB MEDICATIONS *(Darifenacin, Fesoterodine Fumarate and Trospium)*

- For the treatment of overactive bladder (OAB) with symptoms of urgency, urgency incontinence, and urinary frequency in patients who have an intolerance or insufficient response to an adequate trial of immediate-release oxybutynin, solifenacin or tolterodine.

OBETICHOLIC ACID *(Ocaliva 5mg and 10mg Tablet)*

Initiation Criteria:

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

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

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

Renewal Criteria:

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

Claim Note:

- Duration of approval: 12 months

NOTE: Exception status drugs for Drug Assistance for Cancer Patients are indicated by an asterisk (*).

OCRIPLASMIN *(Jetrea 2.5mg/mL Injection)*

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

OFLOXACIN, OPHTHALMIC *(Ocuflox 0.3% Ophthalmic Solution and generic brands)*

- See **Fluoroquinolones, Ophthalmic**

*OLAPARIB *(Lynparza 50mg Capsule and 100mg and 150mg Tablet)*

- As monotherapy maintenance treatment for patients with platinum-sensitive, relapsed, BRCA-mutated (germline or somatic), high grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who have completed at least two previous lines of platinum-based chemotherapy and are in radiologic response (complete or partial) to their most recent platinum-based chemotherapy regimen as per the SOLO-2 trial.
- Patients must have received at least four cycles of their most recent platinum-based chemotherapy before starting treatment with olaparib.

Clinical Notes:

- Maintenance therapy with olaparib should begin within eight weeks of the last dose of platinum-based chemotherapy.
- Platinum-sensitive disease is defined as disease progression occurring at least six months after completion of platinum-based chemotherapy.
- Patients should have a good performance status.
- Treatment should continue until unacceptable toxicity or disease progression.
- Patients who are unable to tolerate platinum-based chemotherapy (due to allergic reaction) and otherwise meet criteria, will be assessed on a case by case basis to determine eligibility for treatment with olaparib.

NOTE: Exception status drugs for Drug Assistance for Cancer Patients are indicated by an asterisk (*).

OMALIZUMAB *(Xolair 150mg Powder for Injection)*

- For the treatment of adults and adolescents (12 years of age or older) with moderate to severe chronic idiopathic urticaria (CIU) who remain symptomatic (presence of hives and/or associated itching) despite optimum management with available oral therapies.

Criteria Notes:

- Prescribed by a specialist (allergist, immunologist, dermatologist, etc.) or other authorized prescriber with knowledge of CIU treatment.
- Initial approval period of 24 weeks at a maximum dose of 300mg every 4 weeks.
- Treatment cessation could be considered for patients who experience complete symptom control for at least 12 consecutive weeks at the end of a 24 week treatment period.
- Continued coverage will be authorized if the patient has achieved:
    - complete symptom control for less than 12 consecutive weeks; or
    - partial response to treatment, defined as at least a ≥ 9.5 point reduction in baseline urticaria activity score over 7 days (UAS7)

***OMEPRAZOLE** *(Losec 10mg, 20mg Capsule/Tablet and generic brands)*

- See **Proton Pump Inhibitors**

Note:

- Omeprazole is available as a full benefit if the dose does not exceed the standard dose of 20mg per day (maximum of 425 tablets/capsules per year). If the dosage is greater than 20mg per day then the criteria for coverage must be met.

ONABOTULINUMTOXIN-A *(Botox 50iu/vial and 100iu/vial Injection)*

- For the treatment of the following Health Canada approved indications:
    - focal spasticity following stroke in adults;
    - equinus foot deformity in cerebral palsy patients 2 years of age and older;
    - cervical dystonia;
    - blepharospasm, hemifacial spasm (VII nerve disorder) or strabismus in patients 12 years of age and older.

ONABOTULINUMTOXIN-A *(Botox 200iu/vial Injection)*

- For the treatment of urinary incontinence due to neurogenic detrusor overactivity resulting from neurogenic bladder associated with multiple sclerosis (MS) or subcervical spinal cord injury (SCI) in patients who have failed to respond to behavioural modification and anticholinergics and/or are intolerant to anticholinergics.
- Subsequent treatments are provided at intervals no less than every 36 weeks.

***ONDANSETRON** *(Zofran 4mg, 8mg Tablet, 4mg/5mL Oral Liquid, ODT Tablet and generic brands)*

- See **Serotonin (5-HT$_3$) Antagonists**

Note:

- Only requests for the oral dosage forms are eligible for consideration. Although the dose may vary, usually a

single oral 8mg dose pre-chemotherapy is sufficient to control symptoms. As well, some patients may require additional therapy up to 48 hours after the last dose of chemotherapy or last radiation treatment. Benefit beyond 48 hours has not been established and is therefore, not insured.

*OSELTAMIVIR *(Tamiflu 30mg, 45mg, 75mg Capsule, 12mg/mL Oral Suspension and generic brands)*

- For the treatment of long-term care 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 the prophylaxis of influenza A or B in long-term care residents where the facility has an outbreak.
- A protocol has been developed by Public Health for the treatment of patients in long-term care facilities. The facility must contact the Medical Officer of Health or local Public Health Office, who will notify the Pharmacare office (or dispensing pharmacy after office hours) if coverage is required.

*OSIMERTINIB *(Tagrisso 40mg and 80mg Tablet)*

- For the treatment of patients with locally advanced or metastatic epidermal growth factor receptor (EGFR) T790M mutation-positive non-small cell lung cancer (NSCLC) who have progressed on EGFR tyrosine kinase inhibitor (TKI) therapy, or as initial therapy in patients with a de novo EGFR T790M mutation.

Clinical Note

- Treatment may be continued until there is evidence of disease progression or the development of unacceptable toxicity.

OXCARBAZEPINE *(Trileptal 60mg/mL Oral Liquid and 150mg, 300mg, 600mg Tablet and generic brands)*

- For the treatment of epileptic seizures in patients who have had an inadequate response to or are intolerant of at least three other formulary agents (prior or current use) including carbamazepine.

OXYBUTYNIN XL *(Ditropan XL 5mg and 10mg Tablet)*

- For the treatment of over-active bladder (not stress incontinence) for patients who cannot tolerate immediate release oxybutynin after an adequate trial (e.g. 3 months).
- A three month trial will be approved initially with assessment of the effectiveness of this therapy required if further coverage is considered.

*PALBOCICLIB *(Ibrance 75mg, 100mg and 125mg Capsule)*

- In combination with an aromatase inhibitor (AI) (i.e. letrozole, anastrozole or exemestane) for the treatment of post-menopausal women with estrogen receptor (ER) positive, human epidermal growth factor receptor 2 (HER 2) negative advanced breast cancer who have not received any prior treatment for metastatic disease. Treatment should continue until unacceptable toxicity or disease progression. Patients should have a good performance status and not be resistant to prior (neo) adjuvant aromatase inhibitor therapy (i.e: have the potential to benefit from first-line endocrine based therapy), without active or uncontrolled metastases to the central nervous system.

Clinical Note:

- Patients will be eligible for either palbociclib plus an aromatase inhibitor in the first line setting or everolimus plus exemestane as a subsequent line of therapy, but not both therapies.

NOTE: Exception status drugs for Drug Assistance for Cancer Patients are indicated by an asterisk (*).

PALIPERIDONE *(Invega Sustenna 50mg/0.5mL, 75mg/0.75mL, 100mg/mL and 150mg/1.5mL Injection Kit)*

- For the maintenance treatment of schizophrenia and related psychotic disorders (not dementia related) in patients who are not adherent to an oral antipsychotic; OR
- Who are currently receiving a long-acting injectable antipsychotic and require an alternative long acting injectable antipsychotic.

PALIPERIDONE *(Invega Trinza 175mg/0.875mL, 263mg/1.315mL, 350mg/1.75mL and 525 mg/2.625mL Injection)*

- For the maintenance treatment of schizophrenia and related psychotic disorders (not dementia related) in patients who have been stabilized on therapy with injectable paliperidone for at least four months.

***PANTOPRAZOLE MAGNESIUM** *(Tecta 40mg Tablet and generic brands)*

- See **Proton Pump Inhibitors**

***PANTOPRAZOLE SODIUM** *(Pantoloc 20mg, 40mg EC Tablet and generic brands)*

- See **Proton Pump Inhibitors**

***PAZOPANIB** *(Votrient 200mg Tablet)*

- As a single agent first-line treatment option for patients with documented evidence of histologically confirmed advanced or metastatic clear cell renal cell carcinoma (RCC) who have an ECOG PS of 0 or 1. In any one patient, all the following conditions must be met:
    - pazopanib may be a first line option;
    - pazopanib may not be used after another VEGF tyrosine kinase inhibitor as sequential therapy;
    - In the event of significant toxicity, a switch to another VEGF tyrosine kinase inhibitor may be allowed.

PERAMPANEL *(Fycompa 2mg, 4mg, 6mg, 8mg, 10mg and 12mg Tablet)*

- As an adjunctive therapy in the management of partial-onset seizures, in adult patients with epilepsy who are not satisfactorily controlled with conventional therapy who meet all of the following criteria:
    - are under the care of a physician experienced in the treatment of epilepsy;
    - are currently receiving two or more antiepileptic drugs; and
    - in whom all other antiepileptic drugs are ineffective or not appropriate.

***PILOCARPINE, ORAL** *(Salagen 5mg Tablet)*

- For oncology patients only.
- For the treatment of the symptoms of xerostomia due to salivary gland hypofunction caused by radiotherapy for cancer of the head and neck.

NOTE: Exception status drugs for Drug Assistance for Cancer Patients are indicated by an asterisk (*).

PIOGLITAZONE *(Actos 15mg, 30mg, 45mg Tablet and generic brands)*

- For treatment of Type II diabetes in patients who have:
  - inadequate glycemic control on optimal doses of sulfonylurea and metformin; or
  - demonstrated intolerance or contraindication to metformin and are on optimal doses of sulfonylurea; or
  - demonstrated intolerance or contraindication to sulfonylurea and are on optimal does of metformin.
- Patients must have a recent A1C of < 10% unless insulin therapy is inappropriate for the patient. Duration of initial approval will be 6 months; further coverage will require demonstrated evidence of efficacy (a reduction of A1C of 0.7 observed to continue coverage).

PIRFENIDONE *(Esbriet 267mg Capsule, 267mg Tablet and 801mg Tablet)*

- **Initial approval criteria:**
  - Adult patients who have a diagnosis of mild to moderate idiopathic pulmonary fibrosis (IPF)[1] confirmed by a respirologist and a high-resolution CT scan within the previous 24 months;
  - All other causes of restrictive lung disease (e.g. collagen vascular disorder or hypersensitivity pneumonitis) should be excluded;
  - Patient is under the case of a physician with experience in IPF;
  - Initial approval period: 7 months (allow 4 weeks for repeat pulmonary function tests).
- **Initial renewal criteria:**
  - Patients must NOT demonstrate progression of disease defined as an absolute decline in percent predicted FVC of ≥10% from initiation of therapy until renewal (initial 6 month treatment period). If a patient has experienced progression as defined above, then the results should be validated with a confirmatory pulmonary function test conducted 4 weeks later;
  - Approval period: 6 months
- **Second and Subsequent renewal criteria (at 12 months after initiation and thereafter):**
  - Patients must NOT demonstrate progression of disease defined as an absolute decline in percent predicted FVC of ≥10% within any 12 month period. If a patient has experienced progression as defined above, then the results should be validated with a confirmatory pulmonary function test conducted 4 weeks later;
  - Approval period: 12 months
- **Exclusion Criteria:**
  - Combination use of Esbriet (pirfenidone) and Ofev (nintedanib) will not be funded.

1. Mild-moderate IPF is defined as: a forced vital capacity (FVC) ≥ 50% of predicted.

NOTE: Exception status drugs for Drug Assistance for Cancer Patients are indicated by an asterisk (*).

*PLERIXAFOR *(Mozobil 24mg/1.2mL (20mg/mL) Single Use Vial)*

- For use in combination with filgrastim to mobilize hematopoietic stem cells for subsequent autologous transplantation in patients with Non-Hodgkin's lymphoma (NHL) or multiple myeloma (MM) if one of the following criteria are met:
    - a PBCD34+ count of < 10cells/uL after 4 days of filgrastim; OR
    - less than 50% of the target CD34 yield is achieved on the 1st day of apheresis (after being mobilized with filgrastim alone or following chemotherapy); OR
    - if a patient has failed a previous stem cell mobilization with filgrastim alone or following chemotherapy.

Note:

- Reimbursement is limited to a maximum of 4 doses (0.24mg/kg given daily) for a single mobilization attempt and to prescriptions written by an oncologist or hematologist.

*POMALIDOMIDE *(Pomalyst 1mg, 2mg, 3mg, and 4mg Capsule)*

- For patients with relapsed and/or refractory multiple myeloma who have previously failed at least two treatments, including both bortezomib and lenalidomide and demonstrated disease progression on the last treatment.
- Pomalidomide may be an option in rare instances where bortezomib is not tolerated or contraindicated but in all cases, patients should have failed lenalidomide.

Note:

- Pomalidomide must be prescribed and dispensed only by physicians and pharmacists who are registered with and agree in writing to adhere to the guidelines of the Company's RevAid® Program. Details are available at https://revaid.ca/revaid.

*PONATINIB *(Iclusig 15mg Tablet)*

- For the treatment of patients with chronic phase, accelerated phase or blast phase chronic myeloid leukemia (CML) or Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) for whom other tyrosine kinase inhibitor (TKI) therapy is not appropriate, including CML or Ph+ ALL that is T315i mutation positive or where there is resistance or intolerance to prior TKI therapy. Funding should be for ECOG performance status 0-2. Treatment should continue until unacceptable toxicity or disease progression.

PRASUGREL HYDROCHLORIDE *(Effient 10mg Tablet)*

- In combination with ASA for patients with:
    - ST-elevated myocardial infarction (STEMI) undergoing primary percutaneous coronary intervention (PCI) who have not received antiplatelet therapy prior to arrival in the catheterization lab;
    - treatment must be initiated in hospital;
    - approval period 12 months (up to 3 months for patients with bare metal stents).

Notes:

- **[Criteria Code 30]** may be used for the initial 30 day coverage period, however a written request submitted to the Pharmacare office is required to allow coverage for the remaining duration of treatment.
- As per the product monograph, prasugrel is contraindicated in patients with a known history of transient ischemic attack or stroke; those with active pathological bleeding such as gastrointestinal bleeding or intracranial hemorrhage; and those with severe hepatic impairment (Child-Pugh Class C).
- As per the product monograph, prasugrel is not recommended in patients ≥ 75 years of age because of the increase risk of fatal and intracranial bleeding; or those with body weight < 60kg because of increased risk of major bleeding due to an increase in exposure to the active metabolite of prasugrel.

*PREGABALIN *(Lyrica 25mg, 50mg, 75mg, 150mg, 225mg, 300mg Capsule and generic brands)*

- For the treatment of neuropathic pain (e.g. diabetic neuropathy, postherpetic neuropathy) in patients who have failed a trial of a tricyclic antidepressant (e.g. amitriptyline, desipramine, imipramine, nortriptyline).

*PROTON PUMP INHIBITORS (PPIs)

OMEPRAZOLE

- Standard dose: full benefit at usual daily dose (e.g. 20mg per day). Maximum 425 tabs/caps per year.
- Double dose: requires special authorization and must have failed standard daily doses of all full benefit PPI's omeprazole, rabeprazole and pantoprazole sodium. Coverage duration: 8 week trial, followed by up to one year of coverage. Use beyond the 8 week trial will be considered if step down to standard dose is not successful.

PANTOPRAZOLE SODIUM

- Standard dose: full benefit at usual daily dose (e.g. 40mg per day). Maximum 425 tabs/caps per year.
- Double dose: requires special authorization and must have failed standard daily doses of all full benefit PPI's omeprazole, rabeprazole and pantoprazole sodium. Coverage duration: 8 week trial, followed by up to one year of coverage. Use beyond the 8 week trial will be considered if step down to standard dose is not successful

PANTOPRAZOLE MAGNESIUM AND LANSOPRAZOLE

- Standard dose: failure of a trial of all open benefit PPIs (omeprazole, rabeprazole and pantoprazole sodium). Maximum 425 tabs/caps per year.
- Double dose: failure of standard dose of requested agent and double doses of rabeprazole. Coverage duration: 8 week trial, followed by up to one year of coverage. Use beyond an 8 week trial will be considered if step down to standard dose is not successful.

*QUINAGOLIDE *(Norprolac 0.025mg, 0.05mg, 0.075mg, 0.15mg Tablet)*

- For the treatment of hyperprolactinemia (idiopathic or originating from a prolactin secreting micro or macro-adenoma of the pituitary) after failure of bromocriptine (as determined by prolactin levels) or if bromocriptine is not

tolerated.

RALOXIFENE *(Evista 60mg Tablet and generic brands)*

- For the treatment of postmenopausal osteoporosis associated with documented fragility fracture when bisphosphonates are not tolerated or are contraindicated.
- For the treatment of postmenopausal osteoporosis without documented fractures when patient is at high 10 year fracture risk (using fracture risk tables) and bisphosphonates are not tolerated or are contraindicated.
- Other requests reviewed on a case by case basis.

*REGORAFENIB *(Stivarga 40mg Tablet)*

GASTROINTESTINAL STROMAL TUMORS (GIST)

- For patients with metastatic and/or unresectable gastrointestinal stromal tumors (GIST) who have had disease progression on, or intolerance to, imatinib and sunitinib; AND has ECOG ≤ 1.

HEPATOCELLULAR CARCINOMA (HCC)

- For the treatment of patients with unresectable hepatocellular carcinoma (HCC) who have experienced disease progression on sorafenib and meet all of the following criteria:
    - ECOG performance status of 0 or 1.
    - Child-Pugh class status of A.
    - Tolerated sorafenib at a dose of at least 400mg per day for at least 20 days of the last 28-day cycle.

Clinical Note

- Treatment should continue until disease progression or unacceptable toxicity.

*RIBOCICLIB *(Kisqali 200mg Tablet)*

- In combination with an aromatase inhibitor (AI) (i.e. letrozole, anastrozole or exemestane) for the treatment of post-menopausal women with estrogen receptor (ER) positive, human epidermal growth factor receptor 2 (HER 2) negative advanced breast cancer who have not received any prior treatment for metastatic disease.

Clinical Notes

- Treatment should continue until unacceptable toxicity or disease progression.
- Patients should have a good performance status and not be resistant to prior (neo) adjuvant aromatase inhibitor therapy (i.e. have the potential to benefit from first-line endocrine based therapy), without active or uncontrolled metastases to the central nervous system.

RIFAXIMIN *(Zaxine 550mg Tablet)*

- For reducing the risk of overt hepatic encephalopathy (HE) recurrence if the following clinical criteria are met:
    - patients are unable to achieve adequate control of HE recurrence with lactulose alone;
    - used in combination with a maximal tolerated dose of lactulose.

NOTE: Exception status drugs for Drug Assistance for Cancer Patients are indicated by an asterisk (*).

RILUZOLE *(Rilutek 50mg Tablet and generic brands)*

- 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;
    - ALS symptoms for less than five years;
    - FVC >60% predicted upon initiation of therapy;
    - no tracheostomy for invasive ventilation.
- Coverage to be reviewed every six months.
- Coverage cannot be renewed once the patient has a tracheostomy for the purpose of invasive ventilation or mechanical ventilation.

RIOCIGUAT *(Adempas 0.5mg, 1.0mg, 1.5mg, 2.0mg, 2.5mg Tablet)*

- For the treatment of inoperable chronic thromboembolic pulmonary hypertension (CTEPH, World Health Organization [WHO] Group 4) or persistent or recurrent CTEPH after surgical treatment in adult patients (≥18 years of age) with WHO Functional Class (FC) II or III pulmonary hypertension (PH).
- Adempas® should be prescribed by a clinician with experience in the diagnosis and treatment of CTEPH.

RISEDRONATE *(Actonel 30mg Tablet and generic brands)*

- Paget's disease of bone (2 month limit, one re-treatment course may be considered).
- Other requests reviewed on a case by case basis.

RISPERIDONE *(Risperdal Consta 12.5mg/2mL 25mg/2mL, 37.5mg/2mL, 50mg/2mL Injection)*

- For the maintenance treatment of schizophrenia and related psychotic disorders (not dementia related) in patients who are not adherent to an oral antipsychotic; OR
- Who are currently receiving a long-acting injectable antipsychotic and require an alternative long acting injectable antipsychotic.

RITUXIMAB *(Rituxan 10mg/mL Injection)*

- 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.
- Cannot be used concomitantly with anti-TNF agents.
- Written request from a rheumatologist or prescriber with a specialty in rheumatology.
- 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.
- For the induction of remission in patients with severely active granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA) who have severe intolerance or other contraindication to cyclophosphamide, or who have failed an adequate trial of cyclophosphamide.

RIVAROXABAN *(Xarelto 10mg Tablet)*

- For the prophylaxis of venous thromboembolism following total knee replacement surgery for up to 14 days, as an alternative to low molecular weight heparins. **[Criteria Code 14]**
- For the prophylaxis of venous thromboembolism following total hip replacement surgery for up to 35 days, as an alternative to low molecular weight heparins. **[Criteria Code 35]**

NOTE: Exception status drugs for Drug Assistance for Cancer Patients are indicated by an asterisk (*).

RIVAROXABAN *(Xarelto 15mg and 20mg Tablet)*

DEEP VEIN THROMBOSIS/PULMONARY EMBOLISM

- **Inclusion Criteria:**
  - For the treatment of deep vein thrombosis (DVT) or pulmonary embolism (PE).
  - Approval Period: Up to six (6) months.
  - **[Criteria Code 42]** will be used to allow the 15mg strength to pay (max 42 tablets), which will allow patients to start therapy while awaiting ESD approval for the six months of therapy.

Notes:

- The recommended dose of rivaroxaban for patients initiating DVT or PE treatment is 15mg twice daily for 3 weeks, followed by 20mg once daily.
- Drug plan coverage for rivaroxaban is an alternative to heparin/warfarin for up to six 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 rivaroxaban product monograph).

NON-VALVULAR ATRIAL FIBRILLATION

- **Inclusion Criteria:**
  - At-risk[1] patients with non-valvular atrial fibrillation (AF) who require rivaroxaban for the prevention of stroke and systemic embolism AND in whom:
    - Anticoagulation is inadequate[2] following a reasonable trial[3] on warfarin; OR
    - Anticoagulation with warfarin is contraindicated or not possible due to inability to regularly monitor via International Normalized Ratio (INR) testing (i.e. no access to INR testing services at a laboratory, clinic, pharmacy, and at home).
- **Exclusion Criteria:**
  - Patients with impaired renal function[4] (creatinine clearance or estimated glomerular filtration rate < 30 mL/min) OR ≥ 75 years of age and without documented stable renal function[5] OR hemodynamically significant rheumatic valvular heart disease[6], especially mitral stenosis; OR prosthetic heart valves.

* Please Note: Patients starting rivaroxaban should have ready access to appropriate medical services to manage a major bleeding event.

1. At-risk patients with non-valvular 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. A reasonable trial on warfarin is defined as at least two months of therapy.
4. 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 Xarelto® (rivaroxaban) Product Monograph).
5. Documented stable renal function is defined as creatinine clearance or estimated glomerular filtration rate of 30-49 mL/min for 15mg once daily dosing or ≥ 50 mL/min for 20mg once daily dosing that is maintained for at least 3 months.
6. There is currently no data to support that rivaroxaban provides adequate anticoagulation in patients with rheumatic valvular disease or those with prosthetic heart valves, so rivaroxaban is not recommended in these populations.

RIVASTIGMINE *(Exelon 2mg/mL Oral Liquid and 1.5mg, 3mg, 4.5mg, 6mg Capsule and generic brands)*

- See **Cholinesterase Inhibitors (ChEI)**

ROTIGOTINE *(Neupro 2mg/24hr, 4mg/24hr, 6mg/24hr, 8mg/24hr Patch)*

- For adjunctive therapy to levodopa for the treatment of patients with advanced stage Parkinson's disease (APD).

RUFINAMIDE *(Banzel 100mg, 200mg and 400mg Tablet)*

- For the adjunctive treatment of seizures associated with Lennox-Gastaut syndrome for patients 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.

*RUXOLITINIB *(Jakavi 5mg, 10mg, 15mg and 20mg Tablet)*

MYELOFIBROSIS

- As a single agent in patients with intermediate or high risk symptomatic myelofibrosis (using the Dynamic International Prognostic Scoring System (DIPSS) Plus or symptomatic splenomegaly) with an ECOG performance status (PS) ≤ 3 as **first line therapy or refractory to other treatments.** Ongoing monitoring and follow up of therapy will be required.

POLYCYTHEMIA VERA

- For the treatment of patients with polycythemia vera who have demonstrated resistance or intolerance to hydroxyurea (HU).

Renewal Criteria:

- Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.

Clinical Notes:

1. Patients must have a good performance status.
2. Treatment should be discontinued upon disease progression or unacceptable toxicity.
3. Resistance is considered if, after at least 3 months of HU therapy at the maximum tolerated dose, patients experience at least one of the following:
    - Need for phlebotomy to maintain hematocrit (HCT) < 45%
    - Uncontrolled myeloproliferation (i.e., platelet count > 400 x 10^9/L and white blood cell count > 10 x 10^9/L)
    - Failure to reduce massive splenomegaly by greater than 50%, as measured by palpation
4. Intolerance to HU is considered if patients experience at least one of the following:
    - Absolute neutrophil count < 1.0 x 10^9/L, platelet count < 100 x 10^9/L or hemoglobin < 100g/L at the lowest dose of HU required to achieve a response (a response to HU is defined as HCT < 45% without phlebotomy, and/or all of the following: platelet count < 400 x 10^9/L, white blood cell count < 10 x 10^9/L, and nonpalpable spleen).

NOTE: Exception status drugs for Drug Assistance for Cancer Patients are indicated by an asterisk (*).

- Presence of leg ulcers or other unacceptable HU-related non-hematological toxicities (defined as grade 3 or 4 or, more than one week of grade 2) such as mucocutaneous manifestations, gastrointestinal symptoms, pneumonitis, or fever.
- Toxicity requiring permanent discontinuation of HU, interruption of HU until toxicity resolved, or hospitalization due to HU toxicity.

Claim Notes:

- Initial approval period: 6 months
- Renewal approval period: 1 year

*SACCHARATED IRON OXIDE *(Venofer 20mg/mL Injection)*

- 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.

Notes:

- Given the safety concerns associated with IV iron, it is expected that the patients will be carefully screened and will have tried various oral iron options before being eligible for IV iron.
- Details regarding oral iron tried, length of therapy, and outcome must be provided.

SACUBITRIL/VALSARTAN *(Entresto 24.3mg/25.7mg, 48.6mg/51.4mg, 97.2mg/102.8mg Tablet)*

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

Clinical Note:

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

*SALBUTAMOL *(0.5mg/mL, 1mg/mL, 2mg/mL Unit Dose Inhaled Solution and 5mg/mL Inhaled Solution)*

- See **Wet Nebulization Solutions**

*SALBUTAMOL, IN COMBINATION *(Combivent Inhaled Solution and generic brands)*

- See **Wet Nebulization Solutions**

SALMETEROL *(Serevent 50mcg/dose Diskhaler and 50mcg/dose Diskus)*

- See **Long-Acting Beta$_2$-Agonists**

SALMETEROL IN COMBINATION *(Advair 50/100mcg, 50/250mcg, 50/500mcg Diskus and HFA 25/125 mcg/dose, HFA 25/250 mcg/dose Inhaler)*

- See **Long-Acting Beta$_2$-Agonists/Inhaled Corticosteroids**

SAXAGLIPTIN *(Onglyza 2.5mg and 5mg Tablet)*

- For the treatment of Type II diabetes for patients with:
  - inadequate glycemic control on metformin and a sulfonylurea; and
  - for whom insulin is not an option.

SAXAGLIPTIN AND METFORMIN *(Komboglyze 2.5mg/500mg, 2.5mg/850mg, 2.5mg/1000mg Tablet)*

- For the treatment of Type II diabetes for 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.

SECUKINUMAB *(Cosentyx 300mg dose kits (two subcutaneous injections of 150mg/1mL))*

ANKYLOSING SPONDYLITIS

- For the treatment of patients with moderate to severe ankylosing spondylitis (e.g. Bath AS Disease Activity Index (BASDAI) score ≥ 4 on 10 point scale) who:
  - Have axial symptoms and who have failed to respond to the sequential use of at least 2 NSAIDs at the optimum dose for a minimum period of 3 months or in whom NSAIDs are contraindicated, or
  - Have peripheral symptoms and who have failed to respond, or have contraindications to, the sequential use of at least 2 NSAIDs at the optimum dose for a minimum period of 3 months and have had an inadequate response to an optimal dose or maximal tolerated dose of a DMARD.
- Requests for renewal must include information demonstrating the beneficial effects of the treatment, specifically:
  - A decrease of at least 2 points on the BASDAI scale, compared with the pre-treatment score, or
  - Patient and expert opinion of an adequate clinical response as indicated by a significant functional improvement (measured by outcomes such as HAQ or “ability to return to work”).

Clinical Note:

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

Claim Notes:

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

NOTE: Exception status drugs for Drug Assistance for Cancer Patients are indicated by an asterisk (*).

- Initial Approval: 6 months.
- Renewal Approval: 1 year.

PSORIASIS

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

PSORIATIC ARTHRITIS

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

Clinical Notes:

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

Claim Notes:

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

NOTE: Exception status drugs for Drug Assistance for Cancer Patients are indicated by an asterisk (*).

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

SELECTIVE $5HT_1$ - RECEPTOR AGONISTS *(Almotriptan Tablet, Naratriptan Tablet, Sumatriptan Nasal Spray)*

SUMATRIPTAN 50MG & 100MG TABLET, NARATRIPTAN TABLET

- For the treatment of migraine[1] headache when:
    - migraines are moderate[2] in severity and other therapies (e.g. NSAIDs, acetaminophen, DHE spray) are not effective; or
    - migraine attacks are severe[2] or ultra severe[2].

ALMOTRIPTAN TABLET, ZOLMITRIPTAN NASAL SPRAY, SUMATRIPTAN NASAL SPRAY

- For the treatment of migraine[1] headache of moderate[2] intensity when:
    - Other therapies (e.g. NSAIDs, acetaminophen, DHE spray) are not effective AND patients have not responded to oral sumatriptan, zolmitriptan, rizatriptan and naratriptan.
    - For the treatment of migraine[1] headache of severe[2] or ultra severe[2] intensity when patients have not responded to oral sumatriptan, zolmitriptan, rizatriptan, and/or naratriptan.

SUMATRIPTAN 6MG/SYRINGE INJECTION

- For the treatment of migraine[1] headache of moderate[2] intensity when:
    - other therapies (e.g. NSAIDs, acetaminophen, DHE spray) are not effective AND oral and nasal triptans are not appropriate.
    - for the treatment of migraine[1] headache of severe[2] or ultra severe[2] intensity when oral and nasal triptans are not appropriate.

Note:

- Coverage limited to 18 doses/3 months[3]
- patients with >3 migraines/month on average despite prophylactic therapy may be considered for up to a maximum of 12 doses/30 day

1. As diagnosed based on current Canadian guidelines.
2. Definitions: Moderate – pain is distracting causing need to slow down and limit activities;
   Severe – pain affects ability to concentrate and very difficult to continue with daily activities;
   Ultra severe – unable to speak or think clearly; not able to function; likely lying down or sleeping.
3. Reimbursement will be available for a maximum quantity of 18 triptan doses per quarter (e.g., Jan to Mar) regardless of the agent(s) used within the 90 day period.

SELEXIPAG *(Uptravi 200mcg, 400mcg, 600mcg, 800mcg, 1000mcg, 1200mcg, 1400mcg, 1600mcg Tablet)*

- For the long-term treatment of idiopathic pulmonary arterial hypertension (PAH), heritable HPAH, 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 criteria are met:
    - Inadequate control with a first- and second-line PAH therapy.
    - Must be prescribed by a clinician with experience in the diagnosis and treatment of PAH.

Claim Note:

- Combination therapy with prostacyclin or prostacyclin analogs will not be reimbursed.

NOTE: Exception status drugs for Drug Assistance for Cancer Patients are indicated by an asterisk (*).

*SEROTONIN (5-HT$_3$) ANTAGONISTS *(Granisetron, Ondansetron)*

- For the treatment of emesis in patients who are:
    - receiving moderately or severely emetogenic chemotherapy **[Criteria Code 01]** or
    - receiving intravenous chemotherapy or radiotherapy and who have not experienced adequate control with other available antiemetics **[Criteria Code 02]** or
    - receiving intravenous chemotherapy or radiotherapy and who are experiencing intolerable side effects to other antiemetics, including steroids and anti-dopaminergic agents **[Criteria Code 03]**

Note:

- Use of criteria codes is limited to appropriate doses pre and post chemotherapy or radiation. Criteria codes must not be used for claims related to other causes of nausea and vomiting or for long term, daily management of nausea and vomiting.

SEVELAMER *(Renagel 800mg Tablet)*

- For the treatment of hyperphosphatemia (>1.8 mmol/L) in patients with end-stage renal disease (eGFR < 15 mL/min) who have:
    - Inadequate control of phosphate levels on a calcium based phosphate binder, or
    - Hypercalcemia (corrected for albumin), or
    - Calciphylaxis (calcific arteriolopathy)

Claim Notes:

- Must be prescribed by a nephrologist or other prescriber within the Provincial Dialysis Program.
- Initial Approval: 6 months.
- Renewal Approval: 1 year. Confirmation of improvement of phosphate levels is required (lab values must be provided).

SILDENAFIL *(Revatio 20mg Tablet and generic brands)*

- Written request from a pulmonary arterial hypertension (PAH) specialist only
- Diagnosis of PAH should be confirmed by right heart catheterization
- Dose of sildenafil will be limited to 20mg tid

IPAH (FUNCTIONAL CLASS III)

- For the treatment of patients with World Health Organization (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.

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.

SITAGLIPTIN *(Januvia 25mg, 50mg, 100mg Tablet)*

- For the treatment of Type II diabetes for patients with:
    - inadequate glycemic control on metformin and a sulfonylurea; and
    - for whom insulin is not an option.

SITAGLIPTIN AND METFORMIN *(Janumet 50/500mg, 50/850mg, 50/1000mg and 50/1000 XR Tablet)*

- For the treatment of Type II diabetes for patients:
    - who are already stabilized on therapy with metformin, a sulfonylurea and sitagliptin to replace the individual components of sitagliptin and metformin;
      AND
    - for whom insulin is not an option.

SMOKING CESSATION THERAPIES *(bupropion and varenicline)*

- A maximum of 12 weeks standard therapy (168 tablets) will be reimbursed annually without a special authorization request.
- Additional reimbursement (e.g. for a second course of therapy) will require a special authorization request with details regarding readiness to quit, success with previous therapy, enrolment in cessation programs and any other pertinent information.

SODIUM BICARBONATE *(500mg generic brands)*

- For patients with chronic kidney disease with a serum bicarbonate (CO_2) <22 mmol/L.

SODIUM FERRIC GLUCONATE *(Ferrlecit 12.5mg/ml Injection)*

- 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.

Notes:

- Given the safety concerns associated with IV iron, it is expected that the patients will be carefully screened and will have tried various oral iron options before being eligible for IV iron.
- Details regarding oral iron tried, length of therapy, and outcome must be provided.

SODIUM PHENYLBUTYRATE *(Pheburane 483mg/g Oral Granules)*

- For the treatment of patients with urea cycle disorders (UCDs).

Clinical Note:

- Diagnosis must be confirmed by blood, enzymatic, biochemical or genetic testing.

Claim Note:

- Must be prescribed by, or in consultation with, a physician experienced in the treatment of UCDs.

SOFOSBUVIR *(Sovaldi 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 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 RBV

- **Patients must also meet all of 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)
    - Lab-confirmed hepatitis C genotype 2 and 3
    - Quantitative HCV RNA value within the last 6 months
    - Fibrosis stage must be provided

Clinical Notes:

1. Treatment-experienced is defined as a patient who has been previously treated with a peginterferon/ribavirin regimen and 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 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.

Claim Notes:

- Claims that exceed the maximum claim amount of $9,999.99 must be divided and submitted as separate transactions using the DIN first and then the following PINs:
    - 00904041
    - 00904042
- Claims will be limited to a 28-day supply.

SOFOSBUVIR AND VELPATASVIR *(Epclusa 400mg/100mg 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 also meet all of 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)
  - 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 must be provided

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 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.

Claim Notes:

- Claims that exceed the maximum claim amount of $9,999.99 must be divided and submitted as separate transactions using the DIN first and then the following PINs:
  - 00904233
  - 00904234
- Claims will be limited to a 28-day supply.

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	
▪ With compensated cirrhosis ▪ With no cirrhosis	▪ 12 weeks

- **Patients must also meet all of 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)
  - 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 must be provided

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 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.

Claim Notes:

- Claims that exceed the maximum claim amount of $9,999.99 must be divided and submitted as separate transactions using the DIN first and then the following PINs:
  - 00904312
  - 00904313
- Claims will be limited to a 28-day supply.

SOMATROPIN *(Humatrope, Genotropin GoQuick and MiniQuick, Nutropin, Nutropin AQ, Nutropin AQ NuSpin, Saizen Injection and Cartridge)*

- For treatment of growth hormone deficiency in patients with Turner Syndrome, upon the request of an endocrinologist or prescriber with a specialty in endocrinology

Note:

- The larger 8.8mg/vial format can be approved when suitable for dosing requirements, if it does not result in drug wastage.

*SORAFENIB *(Nexavar 200mg Tablet)*

- As a single agent first line systemic therapy option in adult patients with a diagnosis of hepatocellular carcinoma (HCC) with Child-Pugh Class A liver dysfunction (mild hepatic impairment) with ECOG performance status 0-1; and who have either progression of disease, or who are not candidates for curative intent treatments (transplantation, hepatic resection), or other well established palliative interventions (ablation, transcatheter arterial chemo-embolization (TACE), internal radiation)

NOTE: Exception status drugs for Drug Assistance for Cancer Patients are indicated by an asterisk (*).

- As a single agent for second line treatment of patients with documented evidence of histologically confirmed advanced or metastatic clear cell renal cell carcinoma, considered to be intermediate or low risk (according to Memorial Sloan-Kettering (MSKCC) prognostic score), have an ECOG performance status of 0 or 1 and progressed after prior cytokine therapy (or intolerance) within the previous 8 months. In any one patient all of the following conditions must be met:
    - sorafenib may be a second line option only after cytokine therapy
    - sorafenib may not be used after another tyrosine kinase inhibitor (i.e., sunitinib) as sequential therapy
    - In the event of severe toxicity within the first 8 weeks of therapy, a switch to another tyrosine kinase inhibitor (i.e., sunitinib) may be allowed
- Coverage approved for 5 months with reassessment

STIRIPENTOL *(Diacomit 250mg and 500mg Capsule, 250mg and 500mg Powder for Suspension)*

- 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.

SUMATRIPTAN *(Imitrex 50mg, 100mg Tablet and generic brands)*

- See **Selective $5HT_1$ - Receptor Agonists**

SUMATRIPTAN *(Imitrex 6mg/Syringe Injection and generic brands)*

- See **Selective $5HT_1$ - Receptor Agonists**

***SUNITINIB** *(Sutent 12.5mg, 25mg, 50mg Capsule)*

- As a single agent first line treatment in patients with documented evidence of histologically confirmed advanced or metastatic clear cell renal cell carcinoma who have an ECOG performance status of 0 or 1. In any one patient all of the following conditions must be met:
    - sunitinib may be a first line option
    - sunitinib may not be used after another tyrosine kinase inhibitor (i.e., sorafenib, or pazopanib) as sequential therapy
    - in the event of significant toxicity, a switch to another tyrosine kinase inhibitor (i.e., sorafenib or pazopanib) may be allowed
- As a single agent for the treatment of advanced gastrointestinal stromal tumor (GIST) patients after failure of imatinib due to intolerance or resistance
- Coverage approved for 9 months with reassessment
- 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

TACROLIMUS *(Protopic 0.03%, 0.1% Ointment)*

- For children greater than 2 years of age with refractory atopic dermatitis. Coverage will be renewed yearly
- 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)

NOTE: Exception status drugs for Drug Assistance for Cancer Patients are indicated by an asterisk (*).

TAZAROTENE *(Tazorac 0.05%, 0.1% Gel)*

- For use in psoriasis therapy when conventional therapies have been ineffective or inappropriate

TEDUGLUTIDE *(Revestive 5mg Powder for Injection)*

- For the ongoing treatment of adult patients with Short Bowel Syndrome (SBS) who have all of the following:
    - SBS as a result of major intestinal resection (e.g., volvulus, vascular disease, cancer, Crohn's disease, injury)
    - dependency on parenteral nutrition (PN) for a least 12 months
    - prior to initiating teduglutide, PN required at least three times weekly to meet caloric, fluid and electrolyte needs, due to ongoing malabsorption and stable PN frequency and volume for at least one month

Renewal Criteria:

- Has maintained at least a 20% reduction in PN volume from baseline at 12 months.

Clinical Note:

- PN is defined as the parenteral delivery of lipids, protein and/or carbohydrates to address caloric needs, and intravenous fluids which addresses fluid and electrolyte needs of patients.

Claim Notes:

- Must be prescribed by a gastroenterologist or an internal medicine specialist with a specialty in gastroenterology.
- Approval period: 1 year.
- Claims for Revestive 5mg powder for injection that exceed the maximum claim amount of $9,999.99 must be divided and submitted as separate transactions using the DIN first and then the following PINs:
    - 00904402
    - 00904403
    - 00904422

*TEMOZOLOMIDE *(Temodal 5mg, 20mg, 100mg, 200mg Capsule and generic brands)*

- In combination with radiotherapy (concomitant therapy) and as adjuvant therapy (post radiation for 6 cycles) for newly diagnosed high grade glioma patients with a good performance status (PS) (Karnofsky ≥ 60) and who choose to receive first line systemic chemotherapy
- Use as a single agent may be considered for patients with recurrent high grade glioma and a good PS (Karnofsky ≥ 60) who have not previously been treated with first line combination (temozolomide and radiation) therapy
- Use as a single agent may be considered for patients with high grade glioma who have recurrent disease occurring during their initial adjuvant therapy. Other systemic treatment options such as etoposide, nitrosourea based therapy or a clinical trial should be considered for patients who recur immediately following temozolomide therapy. Rechallenge with temozolomide could be considered for patients with a temozolomide free interval of six months

TENOFOVIR DISOPROXIL *(Viread 300mg Tablet and generic brand)*

- For the treatment of chronic hepatitis B infection in patients with:
    - documented cirrhosis on radiologic or histologic grounds AND
    - a HBV DNA concentration above 2000iu/mL

TERBINAFINE *(Lamisil 250mg Tablet and generic brands)*

- For the treatment of severe onychomycosis caused by dermatophyte fungi. (Suggested treatment periods: 6 weeks for fingernails and 12 weeks for toenails. Longer periods of time will be considered on a case by case basis)
- For the treatment of dermatophyte infection unresponsive to other treatments or unlikely to respond to other treatments due to the site or severity of the infection

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.

***TESTOSTERONE, TOPICAL** *(Androderm Patch, Androgel Gel Packet & generic brands, and Testim Gel)*

- For the treatment of congenital and acquired primary or secondary hypogonadism in males with a specific diagnosis of:
    - Primary: cryptorchidism, Klinefelter's, orchidectomy, and other established causes; OR
    - Secondary: pituitary-hypothalamic injury due to tumors, trauma, radiation; AND
    - For those with one of the above diagnoses, the deficiency must be clearly demonstrated by clinical features and confirmed by two separate biochemical tests.

Note:

- Maximum dose approved is 5g per day or a 5mg patch per day.
- This will be adjudicated by limiting the quantity payable each quarter (e.g. Jan-Mar) to:
    - 120 Androderm Patches (2.5mg or 5mg Patch);
    - 300g of Androgel 2.5g gel (packet);
    - 600g of Androgel 5g gel (packet); or
    - 600g of Testim Gel.

Please be reminded that topical gels are to be billed per gram (not per packet).

*THYROTROPIN *(Thyrogen 0.9mg/mL Injection)*

- To monitor for recurrence and metastatic disease, in patients who have documented evidence of thyroid cancer and who have undergone appropriate surgical and/or medical management. This includes:
    - primary use in patients with inability to raise an endogenous TSH level (≥25 mu/L) with thyroid hormone withdrawal;
    - primary use in cases of documented morbidity in patients for whom severe hypothyroidism could be life-threatening;
    - secondary use in patients with previous thyroid hormone withdrawal resulting in a documented life-threatening event.
- As a single agent for the preparation of radioiodine remnant ablation in patients with papillary or follicular thyroid cancer who have undergone thyroidectomy as treatment for thyroid cancer
    - thyrotropin is a reasonable alternate to thyroid hormone withdrawal in patients who are unable to tolerate the prolonged hypothyroid state or who cannot achieve satisfactory elevation of endogenous TSH;
    - thyrotropin may be used in new patients or patients with previously incomplete remnant ablation or who have a recurrence of thyroid cancer and require therapeutic remnant ablation.

TICLOPIDINE *(Ticlid 250mg Tablet and generic brands)*

- For the secondary prevention of ischemic stroke or transient ischemic attack (TIA) in patients with a documented severe allergy to ASA or who experience a recurrent thrombotic event (stroke, symptoms of TIA) while taking ASA. **[Criteria Code 01]**
- For the prevention of thrombosis in patients post intracoronary stent implantation for a period of up to 30 days following insertion. **[Criteria Code 02]**
- Other requests on a case by case basis.

TICAGRELOR *(Brilinta 90mg Tablet)*

- To be taken in combination with ASA 75 mg -150mg daily[1] 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[2,3]
    - STEMI patients undergoing primary percutaneous coronary intervention (PCI).

  NSTEMI or UA[2,3]
    - 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[4].
- Coverage duration: 12 months.

NOTE: Exception status drugs for Drug Assistance for Cancer Patients are indicated by an asterisk (*).

Note:

- **[Criteria Code 30]** may be used for the initial 30 day coverage period, however a written request submitted to the Pharmacare office is required to allow coverage for the remaining duration of treatment.

1. Co-administration of ticagrelor with high maintenance dose ASA (>150 mg daily) is not recommended.
2. 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.
3. Ticagrelor is contraindicated in patients with active pathological bleeding, in those with a history of intracranial hemorrhage and moderate to severe hepatic impairment.
4. 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.

TIOTROPIUM BROMIDE *(Spiriva 18mcg Cap for Inhalation)*
TIOTROPIUM BROMIDE MONOHYDRATE *(Spiriva Respimat 2.5µg/actuation Inhaled Solution)*

- For the treatment of moderate to severe chronic obstructive pulmonary disease (COPD) as defined by spirometry;

  OR
- For the treatment of COPD in patients with an inadequate response to short acting bronchodilators.
- Combination therapy with a long- acting beta-$_2$ agonist /inhaled corticosteroid (LABA/ICS) and a long acting anticholinergic (LAAC) inhaler will be considered in patients with: moderate to severe COPD, as defined by spirometry, a history of COPD exacerbation(s) and an inadequate response to LABA/ICS or LAAC.

Clinical Notes:

1. Moderate to severe COPD is defined by spirometry as a post bronchodilator FEV1 < 60% predicted and FEV1/FVC ratio of < 0.70. Spirometry reports from any point in time will be accepted.

   If spirometry cannot be obtained, reasons must be clearly explained and other evidence of COPD severity provided, i.e., Medical Research Council (MRC) Dyspnea Scale Score of at least Grade 3.

   MRC Grade 3 is described as: walks slower than people of same age on the level because of shortness of breath from COPD or has to stop for breath when walking at own pace on the level.
2. Inadequate response to short acting bronchodilators is defined as persistent symptoms, i.e., MRC of at least Grade 3, after at least 2 months of short acting bronchodilator at the following doses*:
   - 8 puffs per day of short acting beta-$_2$ agonist or
   - 12 puffs per day of ipratropium or
   - 6 puffs per day of ipratropium plus salbutamol combination inhaler

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

Notes:

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

TIOTROPIUM BROMIDE MONOHYDRATE/OLODATEROL HYDROCHLORIDE *(Inspiolto Respimat 2.5mcg/2.5mc g Inhaled Solution)*

- For the treatment of moderate to severe chronic obstructive pulmonary disease (COPD), as defined by spirometry, in patients with an inadequate response to a long-acting beta-$_2$ agonist (LABA) or long-acting anticholinergic (LAAC).

Notes:

- Moderate to severe COPD is defined by spirometry (post-bronchodilator) FEV1 < 60% predicted and FEV1/FVC ratio of < 0.70. Spirometry reports from any point in time will be accepted. If spirometry cannot be obtained, reasons must be clearly explained and other evidence regarding COPD severity must be provided for consideration (i.e. Medical Research Council (MRC) Dyspnea Scale score of at least Grade 3). MRC Grade 3 is described as: walks slower than people of same age on the level because of shortness of breath (SOB) from COPD or has to stop for breath when walking at own pace on the level.
- Inadequate response is defined as persistent symptoms after at least 2 months of long-acting beta-agonist (LABA) or long-acting anticholinergic therapy (LAAC).

TOCILIZUMAB *(Actemra 80mg/4mL, 200mg/10mL, 400mg/20mL Injection, 162mg/0.9mL SC Injection and Autoinjector)*

GIANT CELL ARTERITIS (GCA) (ACTEMRA 162MG/0.9ML SC INJECTION AND AUTOINJECTOR)

- For the treatment of Giant Cell Arteritis (GCA) in adult patients who are receiving prednisone at initiation of therapy, or with relapse.

Notes:

- Patients should be under the care of a physician with the experience of diagnosis and management of GCA.
- Duration of therapy with tocilizumab should be limited to 52 weeks per treatment course.
- Discontinuation of tocilizumab should be considered at 12 weeks if there is no response to therapy.

POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (PJIA) (ACTEMRA 80MG/4ML, 200MG/10ML, 400MG/20ML INJECTION)

- For the treatment of children (age 2-17) with moderately to severely active polyarticular juvenile idiopathic arthritis (pJIA) who have had inadequate response to one or more disease-modifying antirheumatic drugs (DMARDs).

Notes:

- Must be prescribed by, or in consultation with, a rheumatologist who is familiar with the use of biologic DMARDs in children.
- Intravenous infusion: Approvals will be for 10mg/kg for patients <30kg or 8mg/kg for patients ≥ 30kg, to a maximum of 800mg, administered every four weeks.
- Initial approval period: 16 weeks.
- Renewal Approval: 1 year. Confirmation of continued response is required.

RHEUMATOID ARTHRITIS (RA) (ACTEMRA 80MG/4ML, 200MG/10ML, 400MG/20ML INJECTION AND 162MG/0.9ML SC INJECTION)

- For the treatment of severely active rheumatoid arthritis, in combination with methotrexate or other disease-modifying antirheumatic drugs (DMARDs), in adult patients who are refractory or intolerant to:

- methotrexate (oral or parenteral) at a dose of ≥ 20 mg weekly (≥15mg if patient is ≥65 years of age), or use in combination with another DMARD, for a minimum of 12 weeks

  AND

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

Clinical Notes:

- For patients who do not demonstrate a clinical response to oral methotrexate, or who experience gastrointestinal intolerance, a trial of parenteral methotrexate must be considered.
- Optimal treatment response to DMARDs may take up to 24 weeks, however coverage of a biologic therapy can be considered if no improvement is seen after 12 weeks of triple DMARD use.
- If patient factors (e.g. intolerance) prevent the use of triple DMARD therapy, these must be described and dual therapy with DMARDs must be tried.
- Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above.
- Intolerant is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs. The nature of intolerance(s) must be clearly documented.

Claim Notes:

- Must be prescribed by a rheumatologist.
- Combined use of more than one biologic DMARD will not be reimbursed.
- Initial Approval: 6 months.
- Renewal Approval: 1 year. Confirmation of continued response is required.
- **Maximum Dosage Approved:**
  - Tocilizumab: 4mg/kg/dose once every 4 weeks followed by an increase to 8 mg/kg/dose based on clinical response

SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS (SJIA) (ACTEMRA 80MG/4ML, 200MG/10ML, 400MG/20ML INJECTION)

- For the treatment of active systemic juvenile idiopathic arthritis (sJIA) in patients two years of age and 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
- Written request of a pediatric rheumatologist
- Initial coverage for 16 weeks at dose of 12 mg/kg for those < 30kg or 8 mg/kg for those ≥ 30 kg to a maximum of 800mg, administered by IV every 2 weeks
- Continued coverage beyond 16 weeks dependent on a positive patient response as determined by a pediatric rheumatology specialist
- Yearly coverage dependent on a continued positive patient response as determined by a pediatric rheumatology specialist

TOFACITINIB *(Xeljanz 5mg Tablet)*

RHEUMATOID ARTHRITIS

- For the treatment of severely active rheumatoid arthritis, in combination with methotrexate or other disease-modifying antirheumatic drugs (DMARDs), in adult patients who are refractory or intolerant to:
  - methotrexate (oral or parenteral) at a dose of ≥ 20mg weekly (≥15mg if patient is ≥ 65 years of age) for a

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

- initial use of triple DMARD therapy with methotrexate in combination with at least two other DMARDs such as hydroxychloroquine and sulfasalazine, for a minimum of 24 weeks.

Notes:

- For patients who do not demonstrate a clinical response to oral methotrexate, or who experience gastrointestinal intolerance, a trial of parenteral methotrexate must be considered.
- Optimal treatment response may take up to 24 weeks; however coverage of tofacitinib can be considered if no improvement is seen after 12 weeks of triple DMARD use.
- If the patient is intolerant to triple DMARD therapy, then dual therapy with DMARDs (methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) must be considered.
- Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above.
- Intolerant is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs. The nature of intolerance(s) must be clearly documented.
- Must be prescribed by a rheumatologist.
- Combined use with biologic DMARD will not be reimbursed.

TOPIRAMATE *(Topamax 25mg Sprinkle Capsule)*

- For patients who require topiramate, cannot take the tablet form, and require sprinkle capsules for proper administration.

TRAMETINIB *(Mekinist 0.5mg and 2mg Tablet)*

- See **Dabrafenib (Tafinlar 50mg and 75mg Capsule) and Trametinib (Mekinist 0.5mg and 2mg Tablet)**

TRETINOIN *(Vitamin A Acid Topical Preparations)*

- Regular benefit for beneficiaries 30 years and under
- For treatment of actinic keratosis in beneficiaries over the age of 30

TROSPIUM *(Trosec 20mg Tablet and generic brands)*

- See **OAB Medications**

TRYPTOPHAN *(Tryptan 500mg Capsule and 500mg, 750mg, 1g Tablet and generic brands)*

- As an adjunct for the treatment of depression in the management of patients suffering from bipolar affective disorders

ULIPRISTAL ACETATE *(Fibristal 5mg 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; and
  - the patient is under the care of a physician experienced in the management of gynecological conditions such as uterine fibroids

UMECLIDINIUM (AS BROMIDE) *(Incruse Ellipta 62.5mcg Dry Powder for Oral Inhalation)*

- For the treatment of moderate to severe chronic obstructive pulmonary disease (COPD) as defined by spirometry;

  OR
- For the treatment of COPD in patients with an inadequate response to short acting bronchodilators.
- Combination therapy with a long-acting beta-$_2$ agonist /inhaled corticosteroid (LABA/ICS) and a long acting anticholinergic (LAAC) inhaler will be considered in patients with: moderate to severe COPD, as defined by spirometry, a history of COPD exacerbation(s) and an inadequate response to LABA/ICS or LAAC.

Clinical Notes:

1. Moderate to severe COPD is defined by spirometry as a post bronchodilator FEV1 < 60% predicted and FEV1/FVC ratio of < 0.70. Spirometry reports from any point in time will be accepted. If spirometry cannot be obtained, reasons must be clearly explained and other evidence of COPD severity provided, i.e., Medical Research Council (MRC) Dyspnea Scale Score of at least Grade 3. MRC Grade 3 is described as: walks slower than people of same age on the level because of shortness of breath from COPD or has to stop for breath when walking at own pace on the level.
2. Inadequate response to short acting bronchodilators is defined as persistent symptoms, i.e., MRC of at least Grade 3, after at least 2 months of short acting bronchodilator at the following doses*:
    - 8 puffs per day of short acting beta-$_2$ agonist or
    - 12 puffs per day of ipratropium or
    - 6 puffs per day of ipratropium plus salbutamol combination inhaler

* Inadequate response to LABA/ICS or LAAC is defined as persistent symptoms after at least 2 months of therapy.

3. COPD exacerbation is defined as an increase in symptoms requiring treatment with antibiotics and/or systemic (oral or intravenous) corticosteroids.

Notes:

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

UMECLIDINIUM (AS BROMIDE) AND VILANTEROL (AS TRIFENATATE) *(Anoro Ellipta 62.5mcg/25mcg Powder for Oral Inhalation)*

- For the treatment of moderate to severe chronic obstructive pulmonary disease (COPD), as defined by spirometry, in patients with an inadequate response to a long-acting beta-$_2$ agonist (LABA) or long-acting anticholinergic (LAAC).

Notes:

- Moderate to severe COPD is defined by spirometry (post-bronchodilator) FEV1 < 60% predicted and FEV1/FVC ratio of < 0.70. Spirometry reports from any point in time will be accepted.

  If spirometry cannot be obtained, reasons must be clearly explained and other evidence regarding COPD severity must be provided for consideration (i.e. Medical Research Council (MRC) Dyspnea Scale score of at least Grade 3). MRC Grade 3 is described as: walks slower than people of same age on the level because of shortness of breath (SOB) from COPD or has to stop for breath when walking at own pace on the level.

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

URSODIOL *(Urso 250mg, DS 500mg Tablet and generic brands)*

- For dissolution of radiolucent, noncalcified gallstones of less than 20mm size for patients who cannot undergo a cholecystectomy
- For management of cholestatic liver disease such as primary biliary cirrhosis

USTEKINUMAB *(Stelara 45mg/0.5mL Injection)*

- For patients with severe, debilitating chronic plaque psoriasis (PsO) who meet all of the following criteria:
    - Body Surface Area (BSA) involvement of >10% and/or significant involvement of the face, hands, feet or genitals
    - failure to respond to, contraindication to or intolerant of methotrexate and cyclosporine
    - failure to respond to, intolerant of or unable to access phototherapy
- Written request of a dermatologist or prescriber with a specialty in dermatology
- Continued coverage is dependent on evidence of improvement, specifically:
    - ≥ 75% reduction in the Psoriasis Area and Severity Index (PASI) score, *or*
    - ≥ 50% reduction in PASI with a ≥ 5 point improvement in DLQI (Dermatology Life Quality Index), *or*
    - significant reduction in BSA involved, with consideration of important regions such as the face, hands, feet or genitals
- Concurrent use of biologics not approved.
- Initial approval for a maximum of 16 weeks.
- Dosage restricted to 45mg at 0, 4 and 16 weeks, response must be assessed prior to fourth dose.
- Maintenance dosing every 12 weeks.

VALGANCICLOVIR *(Valcyte 50mg/mL Powder for Oral Solution)*

- For the treatment of cytomegalovirus (CMV) retinitis in HIV-positive patients, upon the request of an infectious disease specialist or prescriber with a specialty in infectious disease
- For the prevention of CMV disease post solid organ transplantation in patients at high-risk (D+ / R-) (i.e., donor positive/recipient negative). Coverage will be for a maximum of 90 days
- For the treatment of patients with CMV infection who have received a solid organ transplant.

Note:

- Requests for oral suspension will be considered for patients when oral tablets are not an option.

VARENICLINE *(Champix 0.5mg and 1mg Tablet, 0.5mg/1mg combopack and generic brands)*

- See **Smoking Cessation Therapies**

NOTE: Exception status drugs for Drug Assistance for Cancer Patients are indicated by an asterisk (*).

VEDOLIZUMAB *(Entyvio 300mg Vial)*

CROHN'S DISEASE

- For patients with moderate to severely active Crohn's disease and are:
    - refractory or have contraindications to an adequate course of 5-aminosalicylic acid and corticosteroids and other immunosuppressive therapy.

Claim Notes:

- Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology.
- Initial reimbursement is restricted to induction doses of 300mg at Weeks 0, 2 and 6.
- Clinical response to be assessed prior to the administration of the fourth dose.

ULCERATIVE COLITIS

- For the treatment of adult patients with moderately to severely active ulcerative colitis who have a partial Mayo score > 4, and a rectal bleeding subscore ≥ 2 and are:
    - refractory or intolerant to conventional therapy (i.e. 5-ASA for a minimum of 4 weeks, and prednisone ≥ 40mg daily for two weeks or IV equivalent for one week); or
    - corticosteroid dependent (i.e. cannot be tapered from corticosteroids without disease recurrence; or have relapsed within three months of stopping corticosteroids; or require two or more courses of corticosteroids within one year.)
- Renewal requests must include information demonstrating the beneficial effects of the treatment, specifically:
    - a decrease in the partial Mayo score ≥ 2 from baseline, and
    - a decrease in the rectal bleeding subscore ≥1.

Clinical Notes:

- Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above.
- Intolerant is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs. The nature of intolerance(s) must be clearly documented.
- Patients with severe disease do not require a trial of 5-ASA

Claim Notes:

- Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology.
- Combined use of more than one biologic DMARD will not be reimbursed.
- Initial Approval: 16 weeks.
- Renewal Approval: 1 year.

*VEMURAFENIB *(Zelboraf 240mg Tablet)*

- As a first line, single agent for the treatment of BRAF V600 mutation positive unresectable or metastatic melanoma in patients with an ECOG performance status (PS) of ≤ 1
- For BRAF V600 mutation positive patients who have progressed after first line treatment prior to vemurafenib availability, funding of vemurafenib as a second line agent may be considered

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*VENETOCLAX *(Venclexta 10mg, 50mg, 100mg Tablets and Starter Kit)*

- As a **single agent treatment option** for patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) who have received at least one prior therapy, **and** who have failed a B-cell receptor inhibitor (BCRi). Treatment should be continued until disease progression or unacceptable toxicity.

Clinical Note:

- Patients who have intolerance or a contraindication to a B-cell receptor inhibitor (BCRi) will be eligible for treatment with venetoclax. Intolerance to BCRi would be determined by the clinician.

VERTEPORFIN *(Visudyne 15mg/Vial Injection)*

- For the treatment of wet age-related macular degeneration (AMD) as prescribed by an authorized ophthalmologist **[Criteria Code 01]**

VIGABATRIN *(Sabril 0.5g Sachet and 500mg Tablet)*

- For the treatment of epilepsy in those patients who respond inadequately to alternative treatment combinations, or in whom other drug combinations have not been tolerated, and in whom the potential benefits conferred by its use outweigh the risk of ophthalmologic abnormalities.
- For the management of infantile spasms.

*VISMODEGIB *(Erivedge 150mg Capsule)*

- As a single agent for the treatment of measurable metastatic BCC, OR
- For the treatment of locally advanced BCC (including basal cell nevus syndrome i.e. Gorlin syndrome who are 18 years of age and older) in patients who are inappropriate for surgery and radiotherapy based on a discussion/evaluation with other members of the multi-disciplinary team.
- Patient has ECOG ≤ 2

*VITAMIN B_{12}, INJECTION

- See **Cyanocobalamin, Injection**

*VITAMIN B_{12}, ORAL

- See **Cyanocobalamin, Oral**

VORICONAZOLE *(Vfend 50mg, 200mg Tablet and generic brands)*

- For the management of invasive aspergillosis
- For the treatment of culture proven invasive candidiasis with documented resistance to fluconazole

Claim Notes:

- Must be prescribed by a hematologist or specialist in infectious diseases or medical microbiology.
- Initial requests will be approved for a maximum of 3 months.

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*WET NEBULIZATION SOLUTIONS *(Budesonide, Cromoglycate Sodium, Fenoterol, Ipratropium Bromide, Salbutamol)*

- For adult patients with a vital capacity of 900mL or less
- For adult patients with a respiratory rate greater than 25 breaths/minute
- For patients who have demonstrated they cannot follow instructions, cannot hold the spacer device or cannot hold the device long enough to actuate it
- Other requests reviewed on a case by case basis

*ZANAMIVIR *(Relenza 5mg Powder For Inhalation)*

- For the treatment of long-term care residents with clinically suspected or lab confirmed influenza A or B, when there is documented resistance to oseltamivir or when 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 the prophylaxis of influenza A or B in long term care residents where the facility has an outbreak, when there is documented resistance to oseltamivir or when oseltamivir is contraindicated.
- A protocol has been developed by Public Health for the treatment of patients in long-term care facilities. The facility must contact the Medical Officer of Health or local Public Health Office, who will notify the Pharmacare office (or dispensing pharmacy after office hours) if coverage is required.

ZIPRASIDONE *(Zeldox 20mg, 40mg, 60mg, 80mg Capsule and generic brands)*

- For the treatment of schizophrenia and related psychotic disorders (not dementia related) in patients with a history of failure, intolerance, or contraindication to at least one less expensive antipsychotic agent

*ZOLEDRONIC ACID *(Aclasta 5mg/100mL Injection and generic brands)*

- For the treatment of Paget's disease
- For women with postmenopausal osteoporosis for whom oral bisphosphonates are contraindicated due to abnormalities of the esophagus (e.g. esophageal stricture or achalasia) and have at least two of the following:
    - age > 75 years;
    - a prior fragility fracture;
    - a bone mineral density (BMD) T-score ≤-2.5.

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