# 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 online 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 moderately to 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 cofmbination 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 (*).**

## *ABEMACICLIB *(Verzenio 50mg, 100mg and 150mg Tablet)*

- In combination with endocrine therapy (ET) for the adjuvant treatment of adult patients with hormone receptor (HR)–positive, human epidermal growth factor receptor 2 (HER2)–negative, node-positive early breast cancer at high risk of disease recurrence based on clinicopathological features.

**Clinical Notes:**

- Patient should have a good performance status.
- Treatment should continue until disease progression, unacceptable toxicity, or completion of 2 years of adjuvant therapy. ET may be continued after abemaciclib is completed.
- Patients are not eligible if they have inflammatory breast cancer, or prior treatment with a CDK4/6 inhibitor.
- Retreatment with a CDK4/6 inhibitor may be reasonable in the metastatic setting if disease recurrence occurs greater than or equal to 6 months after completion of adjuvant abemaciclib.
- Sequencing with olaparib is not funded. Only one of abemaciclib or olaparib will be funded in the adjuvant setting when eligible.

## 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.

## ABROCITINIB *(Cibinqo 50mg, 100mg and 200mg Tablet)*

- For the treatment of moderate to severe atopic dermatitis (AD) in patients 12 years of age and older who meet all the following criteria:
    - Patients must have had an adequate trial (with a documented refractory disease, including the relief of pruritis), or were intolerant (with documented intolerance), or are ineligible for each of the following therapies:
        - Maximally tolerated medical topical therapies for AD combined with phototherapy (where available), and
        - Maximally tolerated medical topical therapies for AD combined with at least 1 of the 4 systemic immunomodulators (methotrexate, cyclosporine, mycophenolate mofetil, or azathioprine)
    - Baseline Physician Global Assessment score of 3 or greater and Eczema Area and Severity Index (EASI) of 7.1 or greater.

**Renewal Criteria:**

- Requests for renewal must provide proof of beneficial clinical effect defined as a 75% or greater improvement from baseline in the EASI score (EASI-75) six months after treatment initiation.
- Proof of maintenance of EASI-75 response from baseline must be provided for subsequent authorizations.

**Clinical Note:**

- Not to be used in combination with phototherapy or any immunomodulatory agents (including biologics or other janus kinase inhibitor treatment) for moderate to severe AD.Treatment should continue until disease progression or unacceptable toxicity.

**Claim Notes:**

- The patient must be under the care of a dermatologist, allergist, clinical immunologist, or pediatrician who has expertise in the management of moderate to severe AD.

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

- Approvals will be for a maximum of 200 mg once daily.
- Initial Approval: 6 months.
- Renewal Approval: 1 year.

## *ACALABRUTINIB *(Calquence 100mg Capsule & Tablet)*

### PREVIOUSLY UNTREATED CHRONIC LYMPHOCYTIC LEUKEMIA (CLL)/SMALL LYMPHOCYTIC LYMPHOMA (SLL)

- As a single agent treatment option for adult patients with previously untreated chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) for whom a fludarabine-based regimen is considered inappropriate due to high risk of relapse or refractory disease based on prognostic biomarkers.

**Clinical Notes:**

- High risk for relapse or refractory disease includes 17p deletion, TP53 mutation, 11q deletion and unmutated IGHV.
- Patients should have a good performance status.
- Treatment should be continued until disease progression or unacceptable toxicity.

**Claim Notes:**

- Requests will not be considered for patients who experience disease progression on a Bruton's tyrosine kinase (BTK) inhibitor or idelalisib.
- Requests will be considered for patients who are not suitable candidates for intravenous therapy.
- Venetoclax with or without rituximab is funded as a subsequent line of therapy in patients who have experienced disease progression during first-line acalabrutinib treatment, provided all other funding eligibility criteria are met.

### RELAPSED/REFRACTORY CHRONIC LYMPHOCYTIC LEUKEMIA (CLL)/ SMALL LYMPHOCYTIC LYMPHOMA (SLL)

- As a single agent treatment option for adult patients with relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) who have received at least one prior therapy.

**Clinical Notes:**

- Patients should have a good performance status.
- Treatment should be continued until disease progression or unacceptable toxicity.

**Claim Note:**

- Requests will not be considered for patients who experience disease progression on a Bruton's tyrosine kinase (BTK) inhibitor or idelalisib.

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

- See **Long-Acting Beta$_2$-Agonists/Long-Acting Muscarinic Antagonists**

## ADALIMUMAB *(Abrilada; Amgevita; Hadlima; Hulio; Hyrimoz; Idacio; Simlandi; Yuflyma)*
*(Please see formulary for specific strength/route(s) covered for each product)*

### 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[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 2 weeks each, 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 2 weeks each 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").

**Claim Notes:**

- Initial period 6 months.
- Renewal Approval: Long term.
- Maximum dose of 40mg every two weeks.
- Concurrent use of biologics not approved.

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.

### CROHN'S DISEASE

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

**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 to treatments. The nature of intolerance(s) must be clearly documented.

**Claim Notes:**

- Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology.
- Combined use with other biologic drugs or janus kinase (JAK) inhibitors will not be reimbursed.
- 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.
- Initial Approval: 6 months.
- Renewal Approval: Long term.

### HIDRADENITIS SUPPURATIVA

- For the treatment of 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: 6 months.
- Renewal Approval: Long term.

**POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS**

- For the treatment of polyarticular juvenile idiopathic arthritis (pJIA) with the following criteria:
    - For patients 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.

**Claim Notes:**

- Initial Approval: 6 months.
- Renewal Approval: Long term.

**PLAQUE PSORIASIS**

- For the treatment of patients with chronic moderate to severe plaque psoriasis who meet all of the following:
    - Psoriasis Area Severity Index (PASI) greater than 10 and Dermatology Life Quality Index (DLQI) greater than 10, OR major involvement of visible areas, scalp, genitals, or nails;
    - Refractory, intolerant to or unable to access phototherapy;
    - Refractory, intolerant to or have contraindications to methotrexate (oral or parenteral) at a dose of greater than or equal to 20 mg weekly (greater than or equal to 15 mg if patient is 65 years of age or older) for a minimum of 12 weeks **OR** cyclosporine (6 weeks treatment).
- For continued coverage, patients must meet the following criteria:
    - Greater than or equal to 75% reduction in PASI score, **OR**
    - Greater than or equal to 50% reduction in PASI and greater than or equal to 5 points in the DLQI **OR**
    - Significant reduction in BSA involved, with consideration of specific regions such as face, hands, feet or genital region and situations such as itch and recalcitrant plaques.

**Clinical Notes:**

- For patients who do not demonstrate a clinical response to oral methotrexate, or who experience gastrointestinal intolerance, a trial of parenteral methotrexate may be considered if clinically appropriate.
- 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.

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

**Claim Notes:**

- Must be prescribed by a dermatologist or prescriber with a specialty in dermatology.
- Combined use of more than one biologic will not be reimbursed.
- Maximum dosage for ongoing coverage is 40mg every two weeks.
- Initial Approval: 6 months.
- Renewal Approval: Long term.

**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.
- Concurrent use of biologics not approved.
- Maximum dose of 40mg every two weeks
- Initial Approval: 6 months.
- Renewal Approval: Long term.

**RHEUMATOID ARTHRITIS**

- For the treatment of moderately to 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.
- Concurrent use of biologics not approved.
- Maximum dose 40mg every two weeks with no dose escalation permitted.
- Initial Approval: 6 months.
- Renewal Approval: Long term.

**ULCERATIVE COLITIS**

- For the treatment of patients with moderately to severely active ulcerative colitis who have a partial Mayo score > 4, and a rectal bleeding subscore ≥ 2 and are:
    - 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.
- Concurrent use of biologics not approved.
- Maximum dose 40mg every two weeks with no dose escalation permitted.
- Initial Approval: 6 months.
- Renewal Approval: Long term.

**UVEITIS**

- For the treatment of patients with non-infectious uveitis who are refractory, intolerant or havecontraindications to conventional therapy.

**Claim Notes:**

- Must be prescribed by, or in consultation with an ophthalmologist.
- Concurrent use of biologics not approved.
- Approvals will be for a maximum of 80 mg followed by 40mg in one week, then 40 mg every two weeks thereafter.
- Initial Approval: 6 months.
- Renewal Approval: Long term.

## ADAPALENE/BENZOYL PEROXIDE/CLINDAMYCIN *(Cabtreo 0.15%/3.1%/1.2% Gel)*

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

## ADEFOVIR DIPIVOXIL *(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 and generic brands)*

- 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.

## AFLIBERCEPT *(Eylea 2mg/0.05mL Vial)*

### ACTIVE (WET) AGE-RELATED MACULAR DEGENERATION

- For the treatment of patients with neovascular (wet) age-related macular degeneration (AMD) who meet all of the following criteria:
    - Best Corrected Visual Acuity (BCVA) is greater than 6/96
    - The lesion size is ≤ 12 disc areas in greatest linear dimension
    - There is evidence of recent (<3 months) presumed disease progression [blood vessel growth, as indicated by fluorescein angiography, optical coherence tomography (OCT), or recent visual acuity changes]
    - There is active disease activity and no permanent structural damage to the central fovea (as defined in the Royal College of Ophthalmologists guidelines)

**Renewal Criteria:**

- Patient must meet all of the following criteria:
    - Evidence of continued disease activity
    - Maintaining adequate response to therapy
    - Absolute BCVA maintained above 6/120
    - Reductions in BCVA of < 6 lines compared to either baseline and/or best recorded level since baseline

**Claim Notes:**

- Must be prescribed and administered by a retina specialist or an ophthalmologist with experience in administering intravitreal injections.

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

- Will not be insured in combination with other anti-VEGF drugs for ophthalmic use.
- Approvals will be for a maximum of 1 vial per eye every 30 days.
- Approval period: 1 year. Confirmation of continued response is required.

**DIABETIC MACULAR EDEMA**

- For the treatment of patients with diabetic macular edema (DME) who meet the following criteria:
    - Clinically significant center-involving macular edema
    - Best Corrected Visual Acuity (BCVA) is greater than 6/120

**Renewal Criteria:**

- Patient must meet all of the following criteria:
    - Evidence of continued disease activity
    - Maintaining adequate response to therapy
    - Absolute BCVA maintained above 6/120
    - Reductions in BCVA of < 6 lines compared to either baseline and/or best recorded level since baseline.

**Claim Notes:**

- Must be prescribed and administered by a retina specialist or an ophthalmologist with experience in administering intravitreal injections.
- Will not be insured in combination with other anti-VEGF drugs for ophthalmic use.
- Approvals will be for a maximum of 1 vial per eye every 30 days.
- Approval period: 1 year. Confirmation of continued response is required.

**RETINAL VEIN OCCLUSION**

- For the treatment of patients with clinically significant center-involving macular edema secondary to non-ischemic branch retinal vein occlusion (BRVO), or central retinal vein occlusion (CRVO) who meet the following criteria:
    - Best Corrected Visual Acuity (BCVA) is greater than 6/120

**Renewal Criteria:**

- Patient must meet all of the following criteria:
    - Evidence of continued disease activity
    - Maintaining adequate response to therapy
    - Absolute BCVA maintained above 6/120
    - Reductions in BCVA of <6 lines compared to either baseline and/or best recorded level since baseline

**Claim Notes:**

- Must be prescribed and administered by a retina specialist or an ophthalmologist with experience in administering intravitreal injections.
- Will not be insured in combination with other anti-VEGF drugs for ophthalmic use.
- Approvals will be for a maximum of 1 vial per eye every 30 days.
- Approval period: 1 year. Confirmation of continued response is required.

## AFLIBERCEPT *(Eylea HD 8mg/0.07mL Vial)*

### ACTIVE WET AGE-RELATED MACULAR DEGENERATION

- For the treatment of adult patients with neovascular (wet) Age-Related Macular Degeneration (nAMD) who meet all of the following criteria:
    - treatment **naive** to anti-VEGF drugs for nAMD
    - Best Corrected Visual Acuity (BCVA) is greater than 6/96
    - The lesion size is ≤ 12 disc areas in greatest linear dimension
    - There is evidence of recent (<3 months) presumed disease progression [blood vessel growth, as indicated by fluorescein angiography, optical coherence tomography (OCT), or recent visual acuity changes]
    - There is active disease activity and no permanent structural damage to the central fovea (as defined in the Royal College of Ophthalmologists guidelines)

**Renewal Criteria:**

- Patients must meet all of the following criteria:
    - Able to be maintained on a 12-week or greater interval between injections
    - Evidence of continued disease activity.
    - Maintaining adequate response to therapy.
    - Absolute BCVA maintained above 6/120.
    - Reductions in BCVA of < 6 lines compared to either baseline and/or best recorded level since baseline.

**Claim Notes:**

- Must be prescribed and administered by a retina specialist or an ophthalmologist with experience in administering intravitreal injections.
- Will not be insured in combination with other anti-VEGF drugs for ophthalmic use.
- Approvals will be for 1 vial per eye every 30 days for the first 3 doses, followed by 1 vial per eye every 12 to 16 weeks.
- Approval period: 1 year. Confirmation of continued response is required.

### DIABETIC MACULAR EDEMA

- For the treatment of adult patients with diabetic macular edema who meet all of the following criteria:
    - Clinically significant center-involving macular edema
    - Best Corrected Visual Acuity (BCVA) is greater than 6/120

**Renewal Criteria:**

- Patients must meet all of the following criteria:
    - Able to be maintained on a 12-week or greater interval between injections.
    - Evidence of continued disease activity.
    - Maintaining adequate response to therapy.
    - Absolute BCVA maintained above 6/120.
    - Reductions in BCVA of < 6 lines compared to either baseline and/or best recorded level since baseline.

**Claim Notes:**

- Must be prescribed and administered by a retina specialist or an ophthalmologist with experience in administering intravitreal injections.

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

- Will not be insured in combination with other anti-VEGF drugs for ophthalmic use.
- Approvals will be for 1 vial per eye every 30 days for the first 3 doses, followed by 1 vial per eye every 12 to 16 weeks.
- Approval period: 1 year. Confirmation of continued response is required.

## *ALECTINIB *(Alecensaro 150mg Capsule)*

### LOCALLY ADVANCED OR METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC)

- 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)

### EARLY-STAGE NON-SMALL CELL LUNG CANCER

- For the adjuvant treatment of adult patients with resected ALK-positive non-small cell lung cancer (NSCLC) tumors that are ≥ 4cm and/or are locoregional lymph node positive with no distant spread of disease.

**Clinical Notes:**

- Treatment should continue until disease recurrence, unacceptable toxicity, or to a maximum of two years.
- Patients will be eligible for ALK inhibitors in the advanced setting if disease recurrence occurs at least 6 months after the last dose of adjuvant alectinib.
- Patients should have a good performance status.

## 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 Note:**

- A maximum of two years of therapy (i.e. two treatment courses; 8 vials) will be reimbursed.

## 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 75mg/mL, 150mg/mL and 300mg/2mL 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
- Initial Approval: 6 months
- Renewal Approval: 1 year

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

## 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 *(6.25mg)*

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

## ALTEPLASE *(Cathflo 2mg Vial)*

- For the treatment of home hemodialysis central venous catheter occlusion.

**Clinical Note:**

- Not intended for regularly scheduled use.

## 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.

## AMIFAMPRIDINE *(Firdapse 10mg Tablet)*

- For the treatment of patients with Lambert-Eaton myasthenic syndrome (LEMS) who are 18 years of age and older.

**Renewal Criteria:**

- Patients should be assessed for a response to treatment within 3 months of initiating amifampridine.
- A response to treatment is defined as an improvement of at least 30% on the 3TUG test.

**Claims Notes:**

- The patient should be under the care of a neurologist with expertise in managing LEMS.
- Initial Approval: 6 months
- Renewal Approval: Long term

## AMIFAMPRIDINE *(Ruzurgi 10mg Tablet)*

- For the treatment of patients with Lambert-Eaton myasthenic syndrome (LEMS) who are 6 years of age and older.

**Renewal Criteria:**

- Patients should be assessed for a response to treatment within 3 months of initiating amifampridine.
- A response to treatment is defined as an improvement of at least 30% on the 3TUG test.

**Claims Notes:**

- The patient should be under the care of a neurologist with expertise in managing LEMS.
- Initial Approval: 6 months
- Renewal Approval: Long term

## ANAGRELIDE *(0.5mg Capsule)*

**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.

## ANIFROLUMAB *(Saphnelo 150mg/mL IV Injection)*

- For the treatment of adult patients with active, autoantibody positive, systemic lupus erythematosus (SLE), in addition to standard therapy, who meet all the following criteria:
    - Moderate to severe SLE, defined as Systemic Lupus Erythematosus Disease Activity Index 2000 (SLEDAI-2K) score of at least 6; AND
    - Unable to control their disease while using an oral corticosteroid (OCS) dose of at least 10mg/day of prednisone or equivalent.

**Exclusion Criteria:**

- Severe or unstable neuropsychiatric SLE
- Active severe SLE nephritis

**Initial Renewal Criteria:**

- OCS dose decreased to ≤ 7.5mg/day of prednisone or equivalent, or OCS dose decreased by at least 50% from baseline; AND
- Reduction in disease activity measured by:
- Reducing the SLEDAI-2K score to 5 or less; OR
- British Isles Lupus Activity Group (BILAG) improvement in organ systems and no new worsening.

**Subsequent Renewal Criteria:**

- The initial response achieved after the first 12 months of therapy has been maintained.

**Clinical Notes:**

- SLEDAI-2K and BILAG scores must be provided.

**Claim Notes:**

- Approval: 12 months.

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

- Patient should be under the care of a physician with expertise in the diagnosis and management of SLE.
- Not to be used in combination with other biologic treatments.

## *APALUTAMIDE *(Erleada 60mg and 240mg Tablet)*

### NON-METASTATIC CASTRATION-RESISTANT PROSTATE CANCER (NMCRPC)

- In combination with androgen deprivation therapy (ADT) for the treatment of patients with non-metastatic castration-resistant prostate cancer (nmCRPC) who have no detectable distant metastases (M0) by either CT, MRI or technetium-99m bone scan and who are at high risk of developing metastases[1].

[1]High risk of developing metastases is defined as a prostate-specific antigen (PSA) doubling time of ≤ 10 months during continuous ADT.

**Clinical Notes:**

- Patients should have a good performance status and no risk factors for seizures.
- Treatment should continue until radiographic disease progression or unacceptable toxicity.
- Castration-resistance must be demonstrated during continuous ADT and is defined as 3 PSA rises at least one week apart, with the last PSA greater than 2 ng/mL.
- Castrate levels of testosterone must be maintained.
- Patients with N1 disease, pelvic lymph nodes less than 2cm in short axis located below the common iliac vessels, are eligible for apalutamide.
- Apalutamide will not be funded for patients who experience disease progression on enzalutamide or darolutamide.

### METASTATIC CASTRATION-SENSITIVE PROSTATE CANCER (MCSPC)

- In combination with androgen deprivation therapy (ADT) for the treatment of patients with metastatic castration-sensitive prostate cancer (mCSPC).

**Clinical Notes:**

- Patients should have a good performance status and no risk factors for seizures.
- Treatment should continue until disease progression or unacceptable toxicity.
- Patients should have had no prior ADT in the metastatic setting, or are within 6 months of initiating ADT in the metastatic setting with no disease progression.
- Patients will be eligible if they received ADT in the non-metastatic setting as long as at least a one year interval has passed since completion.
- Apalutamide will not be funded for patients who experience disease progression on enzalutamide or darolutamide.

## *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, **[Criteria Code 01]** OR
    - moderately emetogenic chemotherapy who have had inadequate symptom control using a 5-HT3 antagonist and dexamethasone in a previous cycle. **[Criteria Code 02]**

**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 Maintena 300mg and 400mg Prolonged Release Injectable Suspension)*

- For the treatment of patients who are:
    - not adherent to an oral antipsychotic, OR
    - currently receiving a long-acting injectable antipsychotic and require an alternative long-acting injectable antipsychotic.

**Claim Note:**

- Requests will not be considered for the treatment of psychotic symptoms related to dementia.

## ARTIFICIAL TEARS, PRESERVATIVE FREE *(Celluvisc, Refresh, Refresh Plus, Refresh Tears and 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.

## *ASCIMINIB *(Scemblix 20mg and 40mg Tablet)*

### PHILADELPHIA CHROMOSOME-POSITIVE CHRONIC MYELOID LEUKEMIA (PH+ CML)

- For the treatment of adult patients with Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in the chronic phase who meet the following criteria:
    - Treatment failure on or intolerance to a minimum of two prior tyrosine kinase inhibitor (TKI) therapies.
    - No evidence of a T315I or V299L mutation.

**Clinical Notes:**

- Patients should have a good performance status.
- Not for use in the acute phase or blast phase.

## ASFOTASE ALFA *(Strensiq 18mg/0.45mL, 28mg/0.7mL, 40mg/1mL and 80mg/0.8mL Single Use Vial)*

- For the treatment of patients with perinatal, infantile, or juvenile-onset hypophosphatasia (HPP).

**Clinical Note:**

- Eligibility for the treatment of HPP is determined by the Canadian HPP Clinical Expert Committee. Please contact the Nova Scotia Pharmacare Programs via fax at 1-888-594-4440 for the request form.

**Claim Notes:**

- Must be prescribed by a metabolic specialist with expertise in the diagnosis and management of HPP.

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

## 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.

## ATOGEPANT *(Qulipta 10mg, 30mg and 60mg Tablet)*

**Initiation:**

- For the treatment of patients with episodic[1] or chronic migraine[2], who have experienced an inadequate response, intolerance, or contraindication to at least two oral prophylactic migraine medications of different classes.

**Renewal:**

- Proof of beneficial clinical effect, defined as a reduction of at least 50% in the average number of migraine days per month at the time of first renewal compared with baseline.
- For subsequent renewals, proof that the initial 50% reduction in the average number of migraine days per month has been maintained.

**Clinical Notes:**

- Baseline number of headache and migraine days per month must be provided at the time of initial request.
- [1]Episodic migraine: migraine headaches on at least 4 days per month and less than 15 headache days per month for more than 3 months.
- [2]Chronic migraine: headaches for at least 15 days per month for more than 3 months of which at least eight days per month are with migraine.

**Claim Notes:**

- Initial Approval: 6 months
- Renewal Approval: 1 year
- Must be prescribed by a physician who has experience in the management of migraine headaches.

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

For the treatment of patients with advanced (not amenable to curative surgery or radiation therapy) or metastatic renal cell carcinoma when used as:

- First-line therapy in combination with pembrolizumab
- Second-line monotherapy following disease progression on:
    - vascular endothelial growth factor receptor (VEGFR) tyrosine kinase inhibitor (TKI) (i.e., sunitinib or pazopanib); or
    - pembrolizumab in combination with lenvatinib or nivolumab in combination with cabozantinib
- Third-line monotherapy following disease progression on:
    - first-line nivolumab in combination with ipilimumab and second-line VEGFR TKI (i.e., sunitinib or pazopanib)

**Clinical Notes:**

- Patients should have a good performance status.
- Treatment should continue until disease progression or unacceptable toxicity.

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

- Patients treated with immunotherapy in the adjuvant setting will be eligible for pembrolizumab in combination with axitinib provided that there has been a 6-month interval between the completion of immunotherapy and metastatic disease.
- Requests for axitinib will not be considered for patients who experience disease progression on cabozantinib monotherapy, nivolumab monotherapy, or everolimus.

## *AZACITIDINE *(Onureg 200mg and 300mg Tab)*

### ACUTE MYELOID LEUKEMIA

- As maintenance therapy for adult patients with acute myeloid leukemia (AML) who meet all of the following criteria:
    - Intermediate or poor risk
    - Complete remission (CR) or complete remission with incomplete blood count recovery (CRi) following induction therapy, with or without consolidation treatment.
    - Not eligible for hematopoietic stem cell transplantation (HSCT)

**Clinical Notes:**

- Newly diagnosed includes patients with AML secondary to prior myelodysplastic syndrome (MDS) or chronic myelomonocytic leukemia (CMML).
- Last dose of chemotherapy should be within 4 months of starting azacitidine maintenance.
- Treatment should be discontinued upon disease relapse (i.e., appearance of greater than 5% blasts in the bone marrow or peripheral blood), unacceptable toxicity, or if patient becomes eligible for allogeneic bone marrow or stem cell transplant during the treatment period.

## *AZITHROMYCIN *(Azithromycin 600mg Tablet)*

- 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]**

## BELIMUMAB *(Benlysta 120mg/5mL and 400mg/20mL Vial, 200mg/mL Autoinjector)*

### ACTIVE LUPUS NEPHRITIS

- For the treatment of active lupus nephritis (LN) as adjunctive therapy in patients who meet all the following criteria:
    - Diagnosed LN with any of the following:
    - class III with or without class V;
    - class IV with or without class V;
    - class V (i.e., pure class V).
- Must have started standard induction therapy within the previous 60 days.
- Must not have any of the following:
    - previously failed both cyclophosphamide and mycophenolate mofetil (or other forms of mycophenolate) induction therapies;

- an estimated glomerular filtration rate (eGFR) < 30mL/min/1.73m$^2$.

**Initial Renewal Criteria:**

- Must provide proof of beneficial clinical effect, defined as all of the following:
  - reduction in glucocorticoids to ≤ 7.5mg/day after 12 months of therapy
  - an estimated eGFR that is no more than 20% below the value before the renal flare (preflare value) or ≥ 60mL/min/1.73m2 after 12 months of therapy.
- Must provide proof of improvement in proteinuria, defined as either:
  - proteinuria no greater than 0.7g/24 hours after 12 months of therapy if baseline proteinuria is < 3.5g/24 hours
  - proteinuria no greater than 0.7g/24 hours after 18 to 24 months of therapy if baseline proteinuria is in the nephrotic range (i.e., > 3.5g/24 hours).

**Subsequent Renewal Criteria:**

- Must provide proof that the initial response achieved after the first 12 months of therapy has been maintained.

**Discontinuation Criteria:**

- Patient has any of the following:
  - Does not meet all of the renewal criteria; OR
  - An eGFR decrease to less than 30mL/min/1.73m$^2$; OR
  - The addition of other immunosuppressant agents (other than as part of the induction and maintenance regimens), corticosteroid use outside of the limits, anti-tumour necrosis factor therapy, or other biologics.

**Claim Notes:**

- The patient must be under the care of a rheumatologist or a nephrologist experienced in the management of LN.
- Intravenous infusion: Approvals will be for a maximum of 10mg/kg every two weeks for three doses, and every 4 weeks thereafter.
- Subcutaneous injection: Approvals will be for a maximum of 400mg once weekly for four doses, then 200mg once weekly thereafter.
- Approvals: 12 months.

## **BELZUTIFAN** *(Welireg 40mg Tablet)*

- For the treatment of adult patients with von Hippel-Lindau (vHL) disease who require therapy for associated nonmetastatic renal cell carcinoma, central nervous system hemangioblastomas, or nonmetastatic pancreatic neuroendocrine tumours, not requiring immediate surgery.

**Clinical Notes:**

- Patients should have a good performance status.
- Treatment should continue until disease progression or unacceptable toxicity.

## BENRALIZUMAB *(Fasenra 30mg/mL Prefilled Syringe and Autoinjector)*

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

**Initial Discontinuation Criteria:**

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

**Subsequent Discontinuation Criteria:**

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

**Clinical Notes:**

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

**Claim Notes:**

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

## *BENZYDAMINE HCL *(0.15% Oral Rinse)*

- For oncology patients only. **[Criteria Code 01]**

## BEROTRALSTAT HYDROCHLORIDE *(Orladeyo 150mg Capsule)*

- For the routine prevention of attacks of type I or II hereditary angioedema (HAE) in patients 12 years of age and older who have experienced at least three HAE attacks within any four-week period and required the use of an acute injectable treatment.

**Discontinuation Criteria:**

- No reduction in the number of HAE attacks for which acute injectable treatment was received during the first three months of treatment with berotralstat compared to the number of attacks observed before initiating treatment with berotralstat;

  **OR**

- Increase in the number of HAE attacks for which acute injectable treatment was received compared to the number of attacks before initiating treatment with berotralstat.

**Clinical Note:**

- The pre-treatment attack rate must be provided. For those patients who are already receiving long-term prophylactic treatment for HAE and intend to transition to berotralstat, pre-treatment attack rate prior to long-term prophylactic treatment must be provided.

**Claim Notes:**

- Must be prescribed by a physician experienced in the diagnosis and treatment of HAE.
- Combination use of Orladeyo (berotralstat) with other long-term prophylactic treatment of HAE (e.g., a C1 esterase inhibitor or lanadelumab) will not be funded.
- Initial Approval: 3 months.
- Renewal Approval: 6 months.

## BIMEKIZUMAB *(Bimzelx 160mg/mL and 320mg/2mL Prefilled Syringe, 160mg/mL and 320mg/2mL Autoinjector)*

### ANKYLOSING SPONDYLITIS (160MG/ML PREFILLED SYRINGE AND AUTOINJECTOR)

- 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 2 weeks each, 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 2 weeks each and have had an inadequate response to an optimal dose or maximal tolerated dose of a DMARD.
- Requests for renewal must include information showing the beneficial effects of the treatment, specifically:
  - A decrease of at least 2 points on the BASDAI scale, compared with the pre-treatment score; *OR*
  - Patient and expert opinion of an adequate clinical response as indicated by a significant functional improvement (measured by outcomes such as HAQ or "ability to return to work")

**Clinical Note:**

- Patients with recurrent uveitis (2 or more episodes within 12 months) as a complication of 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 160mg by subcutaneous injection every 4 weeks.
- Initial period: 6 months
- Renewal approval: 1 year.

### PLAQUE PSORIASIS (160MG/ML AND 320MG/2ML PREFILLED SYRINGE, 160MG/ML AND 320MG/2ML AUTOINJECTOR)

- For the treatment of patients with chronic moderate to severe plaque psoriasis who meet all of the following:
    - Psoriasis Area Severity Index (PASI) greater than 10 and Dermatology Life Quality Index (DLQI) greater than 10, OR major involvement of visible areas, scalp, genitals, or nails;
    - Refractory, intolerant to or unable to access phototherapy;
    - Refractory, intolerant to or have contraindications to methotrexate (oral or parenteral) at a dose of greater than or equal to 20 mg weekly (greater than or equal to 15 mg if patient is 65 years of age or older) for a minimum of 12 weeks **OR** cyclosporine (6 weeks treatment).
- For continued coverage, patients must meet the following criteria:
    - Greater than or equal to 75% reduction in PASI score, **OR**
    - Greater than or equal to 50% reduction in PASI and greater than or equal to 5 points in the DLQI **OR**
    - Significant reduction in BSA involved, with consideration of specific regions such as face, hands, feet or genital region and situations such as itch and recalcitrant plaques.

**Clinical Notes:**

- For patients who do not demonstrate a clinical response to oral methotrexate, or who experience gastrointestinal intolerance, a trial of parenteral methotrexate may be considered if clinically appropriate.
- 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 dermatologist or prescriber with a specialty in dermatology.
- Approvals will be for 320mg by subcutaneous injection at weeks 0, 4, 8, 12, and 16, followed by maintenance dosing of 320mg every 8 weeks. Maintenance dosing every 4 weeks may be considered for patients >120kg.
- Combined use of more than one biologic will not be reimbursed.
- Initial Approval: 6 months.
- Renewal Approval: 1 year.

### PSORIATIC ARTHRITIS (160MG/ML PREFILLED SYRINGE AND AUTOINJECTOR)

- 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;

- 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 160mg by subcutaneous injection every 4 weeks.
- Initial Approval: 6 months.
- Renewal Approval: 1 year.

## *BINIMETINIB *(Mektovi 15mg Capsule)*

**METASTATIC MELANOMA**

- In combination with encorafenib for the treatment of patients with BRAF V600 mutation-positive unresectable or metastatic melanoma.

**Clinical Notes:**

- Patients should have a good performance status.
- If brain metastases are present, patients should be asymptomatic or have stable symptoms.
- Treatment should be discontinued upon disease progression or unacceptable toxicity.

**Claim Notes:**

- Binimetinib will not be reimbursed in patients who have progressed on BRAF targeted therapy.
- Requests will be considered for patients who received adjuvant BRAF targeted therapy if disease progression occurred at least 6 months following completion of therapy.

## 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.

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

- For the treatment of adult patients with chronic, accelerated, or blast phase Philadelphia chromosome positive (Ph +) chronic myelogenous leukemia (CML) who have resistance or intolerance to prior tyrosine kinase inhibitor (TKI) therapy.

## *BRIGATINIB *(Alunbrig 30mg, 90mg, 180mg Tablet and Initiation Pack)*

### LOCALLY ADVANCED OR METASTATIC NON-SMALL CELL LUNG CANCER

- For the first line treatment of patients with locally advanced or metastatic anaplastic lymphoma kinase (ALK) positive non-small cell lung cancer (NSCLC).

**Clinical Notes:**

- Patients should have a good performance status and treatment should be continued until disease progression or unacceptable toxicity.
- Patients are not eligible for subsequent ALK inhibitor therapy following disease progression on brigatinib.
- Patients may be switched to an alternate ALK inhibitor in the case of intolerance without disease progression.

## BRIVARACETAM *(Brivlera 10mg, 25mg, 50mg, 75mg, 100mg Tablet and generic brands)*

- 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 Note:**

- The patient must be under the care of a physician experienced in the treatment of epilepsy.

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

- For the treatment of patients with chronic moderate to severe plaque psoriasis who meet all of the following:
    - Psoriasis Area Severity Index (PASI) greater than 10 and Dermatology Life Quality Index (DLQI) greater than 10, OR major involvement of visible areas, scalp, genitals, or nails;
    - Refractory, intolerant to or unable to access phototherapy;
    - Refractory, intolerant to or have contraindications to methotrexate (oral or parenteral) at a dose of greater than or equal to 20 mg weekly (greater than or equal to 15 mg if patient is 65 years of age or older) for a minimum of 12 weeks **OR** cyclosporine (6 weeks treatment).
- For continued coverage, patients must meet the following criteria:
    - Greater than or equal to 75% reduction in PASI score, **OR**
    - Greater than or equal to 50% reduction in PASI and greater than or equal to 5 points in the DLQI **OR**
    - Significant reduction in BSA involved, with consideration of specific regions such as face, hands, feet or genital region and situations such as itch and recalcitrant plaques.

**Clinical Notes:**

- For patients who do not demonstrate a clinical response to oral methotrexate, or who experience gastrointestinal intolerance, a trial of parenteral methotrexate may be considered if clinically appropriate.
- 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 dermatologist or prescriber with a specialty in dermatology.
- Approvals will be for 210mg at week 0, 1, 2, followed by 210mg every two weeks.
- Combined use of more than one biologic will not be reimbursed.
- Initial Approval: 6 months.
- Renewal Approval: 1 year.

## *BUDESONIDE *(Pulmicort Nebuamps 0.125mg/mL, 0.25mg/mL, 0.5mg/mL Suspension and generic brands)*

- See **Wet Nebulization Solutions**

**SINONASAL IRRIGATION**

- For patients who require budesonide for sinonasal irrigation when it is prescribed by, or in consultation with, a specialist (e.g., ENT, allergists, immunologists).

**Claim Notes:**

- Initial Approval: 1 year.
- Renewal Approval: Long term

## BUDESONIDE/GLYCOPYRRONIUM/FORMOTEROL FUMERATE DIHYDRATE *(Breztri Aerosphere 160mcg/7.2mcg/5mcg Inhaler)*

- See **Long-Acting Muscarinic Antagonists/Long-Acting Beta2-Agonists/Inhaled Corticosteroids**

## BUPROPION *(Zyban 150mg Tablet)*

- See **Smoking Cessation Therapies**

## BUROSUMAB *(Crysvita 10mg/mL, 20mg/mL and 30mg/mL Vial)*

**Initiation Criteria:**

- For the treatment of patients with X-linked hypophosphatemia (XLH) who meet all the following criteria:
    - Initiated in a pediatric patient who is at least one year of age and in whom epiphyseal closure has not yet occurred
    - Fasting hypophosphatemia
    - Normal renal function (defined as a serum creatinine below the age-adjusted upper limit of normal)
    - Radiographic evidence of rickets with a rickets severity score (RSS) of two or greater
    - Confirmed phosphate-regulating endopeptidase homolog, X-linked (PHEX) gene variant in either the patient or in a directly related family member with appropriate X-linked inheritance

**Discontinuation Criteria:**

- In pediatric patients under 18 years of age in whom epiphyseal closure has not yet occurred and who met the

initiation criteria, treatment should be discontinued if:

  - there is no demonstrated improvement in the 12-month RSS total score from baseline RSS total score; or
  - the patient's RSS total score achieved after the first 12 months of therapy has not been maintained subsequently.

- In adolescent patients who are 13 to 17 years of age in whom epiphyseal closure has occurred and who met the initiation criteria and initiated treatment as a pediatric patient, treatment should be discontinued if any of the following occur:
  - Hyperparathyroidism; or
  - Nephrocalcinosis; or
  - Evidence of fracture or pseudo-fracture based on radiographic assessment.
- In adult patients who met the initiation criteria and initiated treatment as a pediatric patient, treatment should be discontinued if any of the following occur:
  - Hyperparathyroidism; or
  - Nephrocalcinosis; or
  - Evidence of fracture or pseudo-fracture based on radiographic assessment.

**Claim Notes:**

- Requests will not be considered for treatment-naïve adults.
- Must be prescribed by a physician working in a multidisciplinary team of health care providers who are experienced in the diagnosis and management of XLH.
- Approvals for children (1-17 years of age) will be up to a maximum of 90mg every 2 weeks.
- Approvals for adults (18 years of age and older) will be up to a maximum of 90mg every 4 weeks.
- Approval period: 1 year.

## 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.

## CABOTEGRAVIR *(Apretude 30mg Tablet and 600mg/3mL Vial)*

- For individuals aged 12 years and older, weighing at least 35 kg, who are considered at risk of acquiring HIV-1 infection as defined by clinical guidelines, for use as pre-exposure prophylaxis (PrEP) to reduce the risk of acquiring HIV-1 infection.

**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 for clinical use where there is no or negligible risk of transmissible HIV-1.

**Claim Notes:**

- Oral tablets are approved for short term use as lead-in therapy or as bridge therapy in the event of a missed injection.

## *CABOZANTINIB *(Cabometyx 20mg, 40mg and 60mg Tablet)*

### ADVANCED OR METASTATIC RENAL CELL CARCINOMA (RCC)

For the treatment of patients with advanced (not amenable to curative surgery or radiation therapy) or metastatic renal cell carcinoma when used as:

- First-line therapy in combination with nivolumab
- Second-line monotherapy following disease progression on:
    - vascular endothelial growth factor receptor (VEGFR) tyrosine kinase inhibitor (TKI) (i.e., sunitinib or pazopanib); or
    - pembrolizumab in combination with either axitinib or lenvatinib
- Third-line monotherapy following disease progression on:
    - first-line VEGFR TKI (i.e., sunitinib or pazopanib) and second-line nivolumab monotherapy; or
    - first-line nivolumab in combination with ipilimumab and second-line VEGFR TKI (i.e., sunitinib or pazopanib)

**Clinical Notes:**

- Patients should have a good performance status.
- Treatment should continue until disease progression or unacceptable toxicity.
- No active CNS metastases (eligible if treated/stable).
- Patients treated with immunotherapy in the adjuvant setting will be eligible for nivolumab in combination with cabozantinib provided that there has been a 6-month interval between the completion of immunotherapy and metastatic disease.
- Sequential use of axitinib (as monotherapy) and cabozantinib is not permitted except in the case of intolerance or contraindication.

### LOCALLY ADVANCED OR METASTATIC DIFFERENTIATED THYROID CARCINOMA (DTC)

- For the treatment of adult patients with locally advanced or metastatic differentiated thyroid carcinoma (DTC) who have progressed on at least one prior line of vascular endothelial growth factor receptor (VEGFR)-targeted tyrosine kinase inhibitor (TKI) therapy.

**Clinical Notes:**

- Patients should have a good performance status.
- Patients should be refractory to radioactive iodine therapy (RAI-R) or not eligible for radioactive iodine therapy.
- Treatment should continue until disease progression or unacceptable toxicity.
- Patients will be eligible for funding if intolerant to the prior line of VEGFR-targeted TKI therapy.
- Cabozantinib may be used in the third line setting for RET fusion positive patients after progression on or intolerance to selpercatinib.

### UNRESECTABLE OR METASTATIC HEPATOCELLULAR CARCINOMA (HCC)

- For the treatment of patients with unresectable or metastatic hepatocellular carcinoma (HCC) in the second line setting who have experienced disease progression on sorafenib or lenvatinib and meet all the following criteria:
    - Child-Pugh class status of A
    - Good performance status

**Clinical Notes:**

- Treatment should continue until disease progression or unacceptable toxicity.
- Patients who are unable to tolerate regorafinib may be switched to cabozantinib if there is no disease progression and provided all other funding criteria are met.
- Patients with disease progression on regorafenib are not eligible for reimbursement of cabozantinib.
- Patients with disease progression on atezolizumab in combination with bevacizumab or durvalumab in combination with tremelimumab are not eligible for reimbursement of cabozantinib.

## 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 generic brands 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)*

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

## CANNABIDIOL *(Epidiolex 100mg/mL Oral Solution)*

For the adjunctive treatment of patients aged 2 years or older with confirmed diagnosis of seizures associated the following:

**Lennox-Gastaut Syndrome**

- Experienced treatment failure on at least 2 antiepileptic drugs
- Currently taking 1 or more antiepileptic drugs at stable doses for at least 4 weeks before initiation
- At least 2 drop seizures per week over a 28-day period before initiation of cannabidiol

**Dravet Syndrome**

- Not adequately controlled with 2 or more antiepileptic drugs at the time of initiation
- At least 4 convulsive seizures per month

**Tuberous Sclerosis Complex**

- Currently taking 1 or more antiepileptic drugs at stable doses for at least 4 weeks before initiation
- Experienced treatment failure despite previously or currently receiving treatment with at least 2 antiepileptic drugs
- At least 8 seizures per 28 days before initiation of cannabidiol

Renewal requests for the treatment of seizures associated with Lennox-Gastaut syndrome, Dravet syndrome, or tuberous sclerosis complex diagnosis must provide proof of beneficial clinical effect, without severe toxicity or treatment intolerance.

**Claim Notes:**

- Cannabidiol should be prescribed by a physician with expertise in the diagnosis and management of patients with Lennox-Gastaut syndrome, Dravet syndrome, or tuberous sclerosis complex.
- Cannabidiol should not be reimbursed in patients concurrently using cannabis or other cannabinoid-based medications.
- Cannabidiol should not be reimbursed in patients with tuberous sclerosis complex concurrently using mTOR inhibitors.
- Initial Approval: 6 months
- Renewal Approval: 12 months

## *CAPIVASERTIB *(Truqap 160mg and 200mg Tablet)*

- In combination with fulvestrant for the treatment of adults with hormone receptor (HR) positive, human epidermal growth factor receptor 2 (HER2) negative locally advanced or metastatic breast cancer with one or more PIK3CA/AKT1/PTEN alterations following progression on at least one endocrine-based regimen in the metastatic setting or recurrence within 12 months of completing adjuvant therapy.

**Clinical Notes:**

- Patient should have a good performance status.
- Treatment should continue until disease progression or unacceptable toxicity.
- Capivasertib is only reimbursed in combination with fulvestrant. Capivasertib must be discontinued if fulvestrant is discontinued.
- Patients are not eligible if they progressed on prior fulvestrant, received more than two lines of hormone therapy, or received more than one line of chemotherapy in the metastatic setting.

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

## CARIPRAZINE *(Vraylar 1.5mg, 3mg, 4.5mg and 6mg Capsule)*

For the treatment of schizophrenia in adults **[Criteria Code 01].**

**Clinical Notes:**

- Cariprazine should not be used in combination with other atypical antipsychotics.
- Cariprazine should not be used in patients with treatment resistant schizophrenia or used as add-on therapy to clozapine.

## *CEFTOLOZANE/TAZOBACTAM *(Zerbaxa 1g/0.5g Vial)*

- For the treatment of patients with multidrug-resistant gram-negative infections, specifically caused by extended spectrum beta lactamase (ESBL)-producing Enterobacteriaceae and multidrug-resistant Pseudomonas aeruginosa when alternative agents are not an option.

**Claim Note:**

- Must be prescribed by, or in consultation with, an infectious disease specialist or medical microbiologist.

## CENOBAMATE *(Xcopri 12.5mg, 25mg, 50mg, 100mg, 150mg and 200mg Tab, 12.5-25mg, 50-100mg, and 150-200mg Tab (starter kit))*

- For the adjunctive treatment of refractory partial-onset seizures (POS) in patients who are currently receiving two or more antiepileptic drugs and 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.

## *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)*

### 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 symptoms1 and who have failed to respond to the sequential use of at least 2 NSAIDs at the optimum dose for a minimum period of 2 weeks each, 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 2 weeks each 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").

**Claim Notes:**

- Initial Approval: 6 months. Loading dose of 400mg at Weeks 0, 2 and 4.
- Renewal Approval: 1 year.
- Maximum maintenance dose of 200mg every 2 weeks or alternatively, 400mg every 4 weeks.
- Concurrent use of biologics not approved.

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.

**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.
- Concurrent use of biologics not approved.
- Approvals will be for a loading dose of 400mg at Weeks 0, 2 and 4 followed by a maximum maintenance dose of 200mg every 2 weeks or alternatively, 400mg every 4 weeks
- Initial Approval: 6 months.
- Renewal Approval: 1 year.

**RHEUMATOID ARTHRITIS**

- For the treatment of moderately to 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.
- Concurrent use of biologics not approved.
- Maximum dose 400mg at weeks 0, 2 and 4 weeks, then 200mg every 2 weeks (or 400mg every 4 weeks) with no dose escalation permitted.
- Initial Approval: 6 months.
- Renewal Approval: 1 year. Confirmation of continued response is required.

## 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.

## CINACALCET *(30mg, 60mg and 90mg Tablet)*

- 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)*

- For the treatment of complicated urinary tract infections (UTI) or acute uncomplicated pyelonephritis when: **[Criteria Code 01]**
  - Alternative agents are ineffective, not tolerated, or contraindicated, OR
  - The patient has a history of infection with resistant gram-negative bacteria.
- For the treatment of uncomplicated UTI when all alternative agents are ineffective, not tolerated, or contraindicated. **[Criteria Code 02]**
- For treatment of bacterial prostatitis. **[Criteria Code 03]**
- For the treatment of gram-negative infections (e.g. osteomyelitis, joint infections, and infections caused by Pseudomonas aeruginosa), which are resistant to other oral agents. **[Criteria Code 04]**
- For the treatment of severe (malignant) otitis externa. **[Criteria Code 05]**
- For the prevention of endophthalmitis in patients who have had cataract surgery with unplanned vitrectomy. **[Criteria Code 06]**
- For chemoprophylaxis of close contacts of a patient with invasive meningococcal disease, as recommended by Public Health guidelines. **[Criteria Code 08]**
- For the treatment of severe bacterial gastroenteritis when alternative agents (e.g. macrolides, sulfamethoxazole/trimethoprim) are ineffective, not tolerated, or contraindicated. **[Criteria Code 09]**
- For the empiric treatment of acute exacerbations of chronic obstructive pulmonary disease (AECOPD) in patients at risk of Pseudomonas infection (e.g. previously isolated Pseudomonas, end stage lung disease, concomitant bronchiectasis, frequent or recent broad spectrum antibiotic use). **[Criteria Code 10]**
- For the treatment of lung infections in patients with cystic fibrosis. **[Criteria Code 11]**
- For the empiric treatment of outpatient febrile neutropenia. **[Criteria Code 13]**

**Clinical Notes:**

- If treated with an antibiotic within the past 3 months choose an antibiotic from a different class.
- Complicated AECOPD defined as patients with COPD (FEV1/FVC < 0.7) experiencing increased sputum purulence, and either increased dyspnea or sputum volume, and one of the following:
  - FEV1 < 50% predicted
  - ≥ 4 exacerbations per year
  - Ischemic heart disease
  - Home oxygen use
  - Chronic oral steroid use

## CIPROFLOXACIN & DEXAMETHASONE, OTIC *(Ciprodex Otic Suspension and generic brands)*

- 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]**

## CLADRIBINE *(Mavenclad 10mg Tablet)*

- For the treatment of adult patients with relapsing-remitting multiple sclerosis (RRMS) who meet all the following criteria:
    - Confirmed diagnosis based on McDonald criteria.
    - Has experienced one or more disabling relapses or new MRI activity in the past year.
    - Ambulatory with or without aid (i.e. has a recent Expanded Disability Status Scale (EDSS) score of less than or equal to 6.5).
    - Refractory or intolerant to at least one disease modifying therapy (e.g., interferon, glatiramer, dimethyl fumarate, teriflunomide, ocrelizumab).

**Clinical Notes:**

- Treatment should be discontinued for patients with an EDSS score of greater than or equal to 7.
- A relapse is defined as the appearance of new or worsening neurological symptoms in the absence of fever or infection, lasting at least 24 hours yet preceded by stability for at least one month and accompanied by new objective neurological findings observed through evaluation by a neurologist.

**Claim Notes:**

- Must be prescribed by a neurologist with experience in the treatment of multiple sclerosis.
- Approvals will be for 1.75mg/kg to a maximum of 200mg per treatment year.
- Approval period: 2 years

## *COBIMETINIB *(Cotellic 20mg Tablet)*

- For the treatment of patients with BRAF V600 mutation-positive unresectable or metastatic melanoma when used in combination with vemurafenib.

**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.
- If brain metastases are present, patients should be asymptomatic or have stable symptoms.
- Treatment should be discontinued upon disease progression or unacceptable toxicity.

**Claim Note:**

- Cobimetinib will not be reimbursed in patients who have progressed on BRAF and/or MEK inhibitor therapy.

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

## *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)*

### ALK-POSITIVE ADVANCED NON-SMALL CELL LUNG CANCER

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

### ROS-1 POSITIVE NON-SMALL CELL LUNG CANCER

- For the first-line treatment of patients with ROS-1 positive non-small cell lung cancer (NSCLC).

**Clinical Notes:**

- Eligible patients should be previously untreated and have a good performance status.
- Treatment may continue until disease progression or unacceptable toxicity.
- Patients with ROS-1 positive NSCLC who are currently receiving first-line chemotherapy or have been previously treated with chemotherapy or immunotherapy will be eligible for treatment with crizotinib.

## *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 and JAMP Vitamin B12 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 1,000mcg 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.

## CYCLOSPORINE *(Verkazia 0.1% Ophthalmic Emulsion)*

- For the treatment of pediatric patients between the age of 4 and 18 years of age with severe vernal keratoconjunctivitis (VKC) who meet the following criteria:
    - Grade 3 (severe) or 4 (very severe) on the Bonini scale, or
    - Grade 4 (marked) or 5 (severe) on the modified Oxford scale.

**Discontinuation Criteria:**

- Treatment should be discontinued if no improvement in signs and symptoms of VKC is observed, or

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

- Treatment should be discontinued if signs and symptoms of VKC have resolved.

**Clinical Notes:**

- Documentation of the severity of signs and symptoms of VKC at treatment initiation and renewal must be provided.
- Patients previously treated with cyclosporine 0.1% but who discontinued treatment upon resolution of VKC signs and symptoms are eligible to reinitiate treatment if signs and symptoms of severe VKC recur and they meet the initiation criteria.

**Claim Notes:**

- The patient must be under the care of a physician experienced in the diagnosis and management of VKC.
- Initial Approval: 6 months.
- Renewal Approval: 1 year

## CYSTEAMINE *(Cystadrops 3.8mg/mL Oph Sol)*

- For the treatment of corneal cystine crystal deposits (CCCDs) in patients 2 years of age and older with cystinosis.

**Clinical Note:**

- Diagnosis of cystinosis confirmed by cystinosin (lysosomal cystine transporter) gene mutation or elevated white blood cell cystine levels. Documentation must be provided.

**Claim Note:**

- Must be prescribed by an ophthalmologist experienced in the treatment of CCCDs.

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

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

**Claim Note:**

- Must be prescribed by, or in consultation with, a prescriber with experience in the diagnosis and management of cystinosis

## *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 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, 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.
- For the adjuvant treatment of patients with stage IIIA (limited to lymph node metastases of > 1 mm) to stage IIID (8th edition of American Joint Committee on Cancer [AJCC] staging system) BRAF-mutated (all BRAF V600

mutations) cutaneous melanoma. Disease must be completely resected including in-transit metastases; however, presence of regional lymph nodes with micrometastases after sentinel lymph node biopsy alone is allowed.

**Clinical Notes:**

- Patients should have a good performance status.
- Treatment with dabrafenib plus trametinib should continue until disease recurrence, unacceptable toxicity, or up to a maximum of 12 months.
- Patients are eligible to receive 12 months of adjuvant treatment with immunotherapy or BRAF targeted therapy. Patients who are unable to tolerate initial adjuvant therapy, within the first 3 months of treatment, may switch to alternate funded treatment, provided criteria are met.
- Patients with mucosal or ocular melanoma are not eligible for treatment with dabrafenib/trametinib.
- Patients who relapse during, or at any time after adjuvant dabrafenib/trametinib therapy, are eligible for treatment with combination immunotherapy (i.e. nivolumab with ipilimumab) in the metastatic setting. Patients who are not candidates for combination immunotherapy are eligible for single agent nivolumab or pembrolizumab immunotherapy in the metastatic setting.
- Re-treatment with BRAF targeted therapy is funded if the treatment-free interval is ≥ 6 months from the completion of adjuvant BRAF therapy.
- For BRAF-positive patients, BRAF-targeted therapy and immunotherapy (including nivolumab plus ipilimumab combination therapy) may be sequenced in either order upon treatment failure, based on clinician assessment.

## DALBAVANCIN HYDROCHLORIDE *(Xydalba 500mg Vial)*

- For the treatment of adult patients with acute bacterial skin and skin structure infections (ABSSSI) who meet all the following criteria:
    - known or suspected methicillin-resistant Staphylococcus aureus (MRSA) ABSSSI; AND
    - high risk of nonadherence to outpatient antibiotic treatment or high risk of nonadherence to prolonged hospitalization.

**Claim Notes:**

- Approvals will be for a maximum 1500mg per treatment course.

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

- 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.

## *DAPTOMYCIN *(Cubicin RF 500mg/10mL Single-Use Vial)*

- For the treatment of patients with resistant gram-positive infections, including methicillin-resistant Staphylococcus aureus (MRSA) who failed to respond, or have a contraindication or intolerance to vancomycin, or for whom IV vancomycin is not appropriate.

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

**Clinical Note:**

- Daptomycin is inhibited by pulmonary surfactant and should not be used to treat respiratory tract infections.

**Claim Note:**

- Must be prescribed by, or in consultation with, an infectious disease specialist or medical microbiologist.

## *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 6 months with the documentation of dose, hemoglobin and therapeutic outcome (number of transfusions).
- Subsequent 6-month approvals are dependent on evidence of satisfactory clinical response or reduced treatment requirement to less than 2 units of PRBC monthly.

## *DAROLUTAMIDE *(Nubeqa 300mg Tablet)*

### NON-METASTATIC CASTRATION-RESISTANT PROSTATE CANCER (NMCRPC)

- In combination with androgen deprivation therapy (ADT) for the treatment of patients with non-metastatic castration-resistant prostate cancer (nmCRPC) who have no detectable distant metastases (M0) by either CT, MRI or technetium-99m bone scan and who are at high risk of developing metastases[1].

[1]High risk of developing metastases is defined as a prostate-specific antigen (PSA) doubling time of ≤ 10 months during continuous ADT.

**Clinical Notes:**

- Patients should have a good performance status.
- Treatment should continue until radiographic disease progression or unacceptable toxicity.
- Castration-resistance must be demonstrated during continuous ADT and is defined as 3 PSA rises at least one week apart, with the last PSA greater than 2 ng/mL.
- Castrate levels of testosterone must be maintained.
- Patients with N1 disease, pelvic lymph nodes less than 2cm in short axis located below the aortic bifurcation are eligible for darolutamide.
- Darolutamide will not be funded for patients who experience disease progression on apalutamide or enzalutamide.

### METASTATIC CASTRATION-SENSITIVE PROSTATE CANCER (MCSPC)

- In combination with docetaxel and androgen deprivation therapy (ADT) for the treatment of patients with metastatic castration-sensitive prostate cancer (mCSPC).

**Clinical Notes:**

- Patients should have a good performance status and be eligible for chemotherapy.
- Treatment should continue until disease progression or unacceptable toxicity.
- Patients should have had no prior ADT in the metastatic setting, or are within 6 months of initiating ADT in the metastatic setting with no disease progression.
- Patients will be eligible if they received ADT in the non-metastatic setting as long as at least a one year interval has passed since completion.
- Darolutamide will not be funded for patients who experience disease progression on enzalutamide or apalutamide.

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

## *DASATINIB *(Sprycel 20mg, 50mg, 70mg, 100mg Tablet and generic brands)*

- For the treatment of adult patients with Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic, accelerated, or blast phase.
- For the treatment of patients with Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL).

## *DECITABINE AND CEDAZURIDINE *(Inqovi 35mg/100mg Tablet)*

**MYELODYSPLASTIC SYNDROME**

- For the treatment of patients with myelodysplastic syndromes (MDS), including previously treated and untreated, who meet all of the following criteria:
    - De novo or secondary MDS including all French-American-British subtypes (i.e., refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, refractory anemia with excess blasts in transformation, and chronic myelomonocytic leukemia)
    - Intermediate-1, intermediate-2, or high-risk MDS, according to the International Prognostic Scoring System
    - Have not experienced disease progression on a hypomethylating agent

**Clinical Notes:**

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

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

- For the treatment of chronic iron overload.

## DEFERASIROX *(Jadenu 90mg, 180mg, 360mg Tablet and generic brands)*

- For the treatment of chronic iron overload.

## DEFERIPRONE *(Ferriprox 1000mg Tablet and generic brands and 100mg/mL Solution, 1000mg MR Tablet)*

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

## *DENOSUMAB *(Jubbonti 60mg/mL Prefilled Syringe)*

**Effective October 1, 2024, patients currently taking the originator drug product Prolia, are required to switch to a biosimilar version by October 1, 2025.**

**For denosumab-naïve patients whose therapy is initiated after October 1, 2024, a denosumab biosimilar will be the product approved.**

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

**Effective October 1, 2024, patients currently taking the originator drug product Prolia, are required to switch to a biosimilar version by October 1, 2025.**

**For denosumab-naïve patients whose therapy is initiated after October 1, 2024, a denosumab biosimilar will be the product approved.**

- 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 *(Wyost 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 and generic brands)*

- 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 and generic brands)*

- For the treatment of adult patients with relapsing remitting multiple sclerosis (RRMS) who meet all of the following criteria:
  - Ambulatory with or without aid (i.e. has a recent Expanded Disability Status Scale (EDSS) score of less than or equal to 6.5)
  - Experienced one or more disabling relapses or new MRI activity in the past two years

**Clinical Note:**

- Treatment should be discontinued for patients with an EDSS score of greater than or equal to 7.

**Claim Notes:**

- Must be prescribed by a neurologist with experience in the diagnosis and management of multiple sclerosis.
- Combined use with other disease modifying therapies to treat RRMS will not be reimbursed.
- Initial Approval: 2 years
- Renewal Approval: 5 years

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

## DUPILUMAB *(Dupixent 200mg/1.14mL Prefilled Syringe/Pen and 300mg/2mL Prefilled Syring/Pen)*

### ATOPIC DERMATITIS

- For the treatment of moderate to severe atopic dermatitis (AD) in patients 12 years of age and older who meet all of the following criteria:
    - Patients must have had an adequate trial (with a documented refractory disease), or were intolerant (with documented intolerance), or are ineligible for each of the following therapies:
        - maximally tolerated medical topical therapies for AD combined with phototherapy (where available), and;
        - maximally tolerated medical topical therapies for AD combined with at least 1 of the 4 systemic immunomodulators (methotrexate, cyclosporine, mycophenolate mofetil, or azathioprine).
    - Baseline Physician Global Assessment score of 3 or greater and Eczema Area and Severity Index (EASI) of 7.1 or greater.

**Renewal criteria:**

- Requests for renewal must provide proof of beneficial clinical effect defined as a 75% or greater improvement from baseline in the Eczema Area and Severity Index (EASI-75) score six months after treatment initiation.
- Proof of maintenance of EASI-75 response from baseline must be provided for subsequent authorizations.

**Clinical Note:**

- Not to be used in combination with phototherapy or any immunomodulatory drugs (including biologics) or a Janus kinase inhibitor treatment for moderate-to-severe AD.

**Claim Notes:**

- The patient must be under the care of a dermatologist, allergist, clinical immunologist, or pediatrician who has expertise in the management of moderate to severe AD.
- Approvals will be for a maximum of 600 mg at week 0, then 300 mg every two weeks thereafter.
- Initial Approval: 6 months.
- Renewal Approval: 1 year.

### SEVERE ASTHMA (PEDIATRIC)

- For the adjunctive treatment of severe asthma with a type 2 or eosinophilic phenotype in patients aged 6 to 11 years of age who are inadequately controlled with medium-to high-dose inhaled corticosteroids (ICS) plus one or more additional asthma controller(s) (e.g., long-acting beta-agonist) or high-dose ICS alone and meet the following criteria:
    - blood eosinophil count ≥ 0.15 × 109/L within the past 12 months; and
    - uncontrolled asthma with at least one clinically significant asthma exacerbation in the past 12 months.

**Initial Discontinuation Criteria:**

- Baseline asthma control questionnaire score has not improved at 12 months since initiation of treatment, or
- The number of clinically significant asthma exacerbations has increased within the previous 12 months

**Subsequent Discontinuation Criteria:**

- Asthma control questionnaire score achieved after the first 12 months of therapy has not been maintained subsequently, or
- The number of clinically significant asthma exacerbations has increased within the previous 12 months.

**Clinical Notes:**

- A baseline and annual assessment of asthma symptom control using a validated asthma control questionnaire must be provided.
- Medium dose ICS is defined as between 200 mcg and 400 mcg of fluticasone propionate or equivalent daily dose and high-dose ICS is defined as greater than 400 mcg of fluticasone propionate or equivalent daily dose.
- A significant clinical exacerbation is defined as worsening of asthma such that the treating physician elected to administer systemic glucocorticoids for at least 3 days or the patient visited an emergency department or was hospitalized.

**Claim Notes:**

- Must be prescribed by a pediatric respirologist or allergist experienced in the treatment of severe asthma.
- Combined use of dupilumab with other biologics used to treat asthma will not be reimbursed.
- Approvals will be for a maximum of 200 mg every two weeks or 300 mg every four weeks.
- Approval period: 1 year.

**SEVERE ASTHMA**

- For the adjunctive treatment of severe asthma with a type 2 or eosinophilic phenotype or oral corticosteroid (OCS) dependent severe asthma in patients 12 years of age and older who are inadequately controlled with high-dose inhaled corticosteroids (ICS) and one or more additional asthma controller(s) (e.g., long-acting beta-agonist) and meets one of the following criteria:
    - blood eosinophil count ≥ 0.15 × 109/L within the past 12 months, or
    - have OCS dependent asthma.

**Initial Discontinuation Criteria:**

- Baseline asthma control questionnaire score has not improved at 12 months since 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:**

- 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:**

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

**Claim Notes:**

- Must be prescribed by a respirologist, clinical immunologist, allergist or internist experienced in the treatment of

severe asthma.

- Combined use of dupilumab with other biologics used to treat asthma will not be reimbursed.
- Approvals will be for a maximum of 600 mg at week 0, then 300 mg every two weeks thereafter.
- Approval period: 1 year.

## EDARAVONE *(Radicava 105mg/5mL Suspension)*

For the treatment of amyotrophic lateral sclerosis (ALS), if the following criteria are met:

**Initiation Criteria:**

- Patient with a diagnosis of probable ALS or definite ALS; AND
- Patient who meets all of the following:
    - has scores of at least two points on each item of the ALS Functional Rating Scale – Revised (ALSFRS-R)
    - has a forced vital capacity greater than or equal to 80% of predicted
    - has had ALS symptoms for two years or less
    - patient is not currently requiring permanent non-invasive or invasive ventilation.

**Renewal Criteria:**

- Reimbursement of treatment should be discontinued in patients who meet any one of the following criteria:
    - patient becomes non-ambulatory (ALSFRS-R score ≤ 1 for item 8) AND is unable to cut food and feed themselves without assistance, irrespective of whether a gastrostomy is in place (ALSFRS-R score < 1 for item 5a or 5b);

      OR
    - patient requires permanent non-invasive or invasive ventilation.

**Claim Notes:**

- Patient must be under the care of a specialist with experience in the diagnosis and management of ALS.

## EFGARTIGIMOD ALFA *(Vyvgart 20mg/mL IV Inj)*

For the treatment of adult patients with generalized myasthenia gravis (gMG) who have all the following:

- Positive serologic test for anti-AChR antibodies
- An MG-ADL score at baseline of ≥ 5
- MGFA class II to IV disease
- MG symptoms persist despite an adequate trial and stable dose of the below conventional therapies in the previous 12 months:
    - Acetylcholinesterase inhibitors (pyridostigmine) AND
    - Corticosteroids (prednisone) AND/OR nonsteroidal immunosuppressants (azathioprine, cyclosporine, mycophenolate mofetil, methotrexate or tacrolimus)

**Exclusion criteria**

Efgartigimod alfa should not be initiated:

- During a gMG exacerbation or crisis OR
- Within 3 months of thymectomy.

**Renewal:**

- Reimbursement of treatment with efgartigimod alfa should be continued if, after the initial 3 cycles of treatment, there is documented improvement in MG-ADL score of 2 points or greater.
- Reassessment should occur every 12 months thereafter.

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

**Subsequent Renewal:**

- The physician must provide proof of no worsening of MG-ADL score.

**Claim Notes:**

- MG-ADL score must be measured and provided by the physician at baseline.
- Efgartigimod alfa should be prescribed by or in consultation with a neurologist with expertise in managing patients with gMG.
- Efgartigimod alfa should not be used concomitantly with rituximab or complement inhibitors.
- Approvals will be for a dose of 10mg/kg up to a maximum of 1200 mg per infusion administered once weekly for 4 weeks (one treatment cycle)
- Initial Approval: The maximum duration of initial authorization is 3 treatment cycles
- Renewal Approval: 12 months

## ELOSULFASE ALFA *(Vimizim 1mg/mL IV Solution)*

### MUCOPOLYSACCHARIDOSIS TYPE IVA

**Initiation Criteria:**

- For the treatment of mucopolysaccharidosis type IVA (MPS IVA) in patients meeting all the following criteria:
    - Diagnosis is confirmed by enzymatic assay for N-acetylgalactosamine-6-sulfate sulfatase (GALNS) activity in peripheral blood leukocytes or fibroblasts (excluding multiple sulfatase deficiency) AND mutational analysis of GALNS[1]; AND
    - Patient is under the care of a specialist with experience in the diagnosis and management of MPS IVA; AND
- The following baseline evaluations prior to initiation of elosulfase alfa must be provided with the request for coverage:
    - Detailed medical history documenting surgeries, medical admissions, subspecialty assessments
    - Orthopedic evaluation including spinal and cranial MRI, skeletal x-rays, pain symptoms from bone and joints as appropriate to age and clinical disease
    - Mobility measure: 6MWT and stair climb (if appropriate for age and disease status)
    - Respiratory function testing including sleep study testing (if appropriate for age)
    - Age-appropriate quality of life measure (such as HAQ, PODCI, EQ5D5L or SF36)[2]
    - Documentation of mobility aide requirement, such as a walker or cane
    - Documentation of requirement for respiratory aides, including ventilation status and changes in respiratory support requirements
    - Ophthalmologic and ear, nose and throat (ENT) assessment (if appropriate)
    - Urine keratin sulfate (KS) determination: specific KS determination is preferred over total glycosaminoglycans (GAGs)
    - Cardiac echocardiogram

[1]Note: not all MPS IVA patients will have two known pathogenic alleles identified and parental mutation analysis to establish the phase of mutations should be performed.

[2]Note that academic goals (e.g. attendance or participation in school) may be considered case-by-case in pediatric patients.

**Exclusion Criteria:**

- The patient is diagnosed with an additional progressive life limiting condition where treatment would not provide

long term benefit (such as cancer or multiple sclerosis).

- The patient has a forced vital capacity (FVC) of less than 0.3 liters and requires continuous ventilator assistance.
- The patient/family is unwilling to comply with the associated monitoring criteria.
- The patient/family is unwilling to attend clinics for assessment and treatment purposes.

Approval duration of initial approval: 1 year

Recommended dose: 2mg/kg IV infusion once a week.

**Renewal criteria:**

- Patients must demonstrate at least 3 of the 5 following treatment effects for continuation of coverage of treatment with elosulfase alfa:
    - 6 MWT or Stair Climb test stabilized at or improved by at least 5% of baseline measure
    - FVC or forced expiratory volume in one second (FEV-1) stabilized at or improved by at least 5% of baseline measure or remaining within 2 standard deviations of normal for the patient's age
    - Improvement or no change (if minimal effect) in age-appropriate quality of life measure[3]
    - Reduction of urine KSs of 20%
    - Stability of cardiac ejection fraction reduction (within 5% of baseline)

[3]Note that academic goals (e.g. attendance or participation in school) may be considered case-by-case in pediatric patients.

**Discontinuation criteria:**

- Patients will not be eligible for coverage of treatment if they:
    - Fail to meet 3 of the 5 renewal criteria
    - Are unable to tolerate infusions due to infusion related adverse events that cannot be resolved
    - Require permanent invasive ventilation
    - Miss more than 6 infusions in a 12-month interval, unless for medically related issues
    - Meet any one of the Exclusion Criteria

Approval duration of renewals: 1 year

Recommended dose: 2mg/kg IV infusion once a week.

## **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)

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

- 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.

## EMPAGLIFLOZIN/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)*

- For individuals who are considered at risk of acquiring HIV-1 infection as defined by clinical guidelines, for use as pre-exposure prophylaxis (PrEP) to reduce the risk of acquiring HIV-1 infection.

**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 for clinical use where there is no or negligible risk of transmissible HIV-1.

## *ENCORAFENIB *(Braftovi 75mg Capsule)*

### METASTATIC MELANOMA

- In combination with binimetinib for the treatment of patients with BRAF V600 mutation-positive unresectable or metastatic melanoma.

**Clinical Notes:**

- Patients should have a good performance status.
- If brain metastases are present, patients should be asymptomatic or have stable symptoms.
- Treatment should be discontinued upon disease progression or unacceptable toxicity.

**Claim Notes:**

- Encorafenib in combination with binimetinib will not be reimbursed in patients who have progressed on BRAF targeted therapy.
- Requests will be considered for patients who received adjuvant BRAF targeted therapy if disease progression occurred at least 6 months following completion of therapy.

### METASTATIC COLORECTAL CANCER

- In combination with panitumumab or cetuximab for the treatment of patients with metastatic colorectal cancer who meet all of the following criteria:
  - Presence of BRAF V600E mutation
  - Disease progression following at least one prior therapy in the metastatic setting
  - No previous treatment with an EGFR inhibitor

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

**Clinical Notes:**

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

**Claim Note:**

- Encorafenib will not be reimbursed in patients who have progressed on BRAF targeted therapy.

## ENTACAPONE *(200mg 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 a levodopa and a decarboxylase inhibitor.

## *ENTRECTINIB *(Rozlytrek 100mg and 200mg Capsule)*

### ROS-1 POSITIVE NON-SMALL CELL LUNG CANCER OR METASTATIC NON-SMAL CELL LUNG CANCER

- For the first-line treatment of patients with ROS-1 positive locally advanced (not amenable to curative therapy) or metastatic non-small cell lung cancer (NSCLC).

**Clinical Notes:**

- Patients should have a good performance status.
- Treatment should continue until disease progression or unacceptable toxicity.

### UNRESECTABLE LOCALLY ADVANCED OR METASTATIC EXTRACRANIAL SOLID TUMORS WITH A NTRK GENE FUSION

- For the treatment of adult patients with unresectable locally advanced or metastatic extracranial solid tumors with NTRK gene fusion without a known acquired resistance mutation. Eligible patients are not candidates for surgery and/or radiation due to risk of substantial morbidity and have no satisfactory treatment options.

**Clinical Notes:**

- Patients should have a good performance status.
- Treatment should be discontinued upon disease progression or unacceptable toxicity.
- CNS metastases are stable if present.
- Patients with prior progression on an NTRK inhibitor are not eligible.

## *ENZALUTAMIDE *(Xtandi 40mg Capsule)*

### METASTATIC CASTRATION-RESISTANT PROSTATE CANCER (MCRPC)

- For the treatment of patients with metastatic castration-resistant prostate cancer (mCRPC).

**Clinical Notes:**

- Patients should have a good performance status and no risk factors for seizures.
- Treatment should continue until disease progression or unacceptable toxicity.
- Requests for enzalutamide will not be considered for patients who experience disease progression on apalutamide or darolutamide.

### METASTATIC CASTRATION-SENSITIVE PROSTATE CANCER (MCSPC)

- In combination with androgen deprivation therapy (ADT) for the treatment of patients with metastatic castration-sensitive prostate cancer (mCSPC).

**Clinical Notes:**

- Patients should have a good performance status and no risk factors for seizures.
- Treatment should continue until disease progression or unacceptable toxicity.
- Patients should have had no prior ADT in the metastatic setting, or are within 6 months of initiating ADT in the metastatic setting with no disease progression.
- Patients will be eligible if they received ADT in the non-metastatic setting as long as at least a one year interval has passed since completion.
- Requests for enzalutamide will not be considered for patients who experience disease progression on apalutamide or darolutamide.

### NON-METASTATIC CASTRATION-RESISTANT PROSTATE CANCER (NMCRPC)

- In combination with androgen deprivation therapy (ADT) for the treatment of patients with non-metastatic castration-resistant prostate cancer (nmCRPC) who have no detectable distant metastases (M0) by either CT, MRI or technetium-99m bone scan and who are at high risk of developing metastases[1].

[1] High risk of developing metastases is defined as a prostate-specific antigen (PSA) doubling time of ≤ 10 months during continuous ADT.

**Clinical Notes:**

- Patients should have a good performance status and no risk factors for seizures.
- Treatment should continue until radiographic disease progression or unacceptable toxicity.
- Castration-resistance must be demonstrated during continuous ADT and is defined as 3 PSA rises at least one week apart, with the last PSA greater than 2 ng/mL.
- Castrate levels of testosterone must be maintained.
- Patients with N1 disease, pelvic lymph nodes less than 2cm in short axis located below the common iliac vessels are eligible for enzalutamide.
- Enzalutamide will not be funded for patients who experience disease progression on apalutamide or darolutamide.

### NON-METASTATIC CASTRATION-SENSITIVE PROSTATE CANCER

- For the treatment of patients with non-metastatic castration-sensitive prostate cancer (nmCSPC) with biochemical recurrence at high risk for metastasis after radical prostatectomy or radiation, with or without androgen deprivation therapy (ADT).

**Clinical Notes:**

- Patients should meet all of the following:
    - PSA doubling time of ≤9 months
    - PSA level ≥1 mcg/mL if prior radical prostatectomy (with or without radiation) or ≥2 mcg/mL above nadir in prior radiation
    - Testosterone ≥5.2 nmol/L (150 mg/dl)
    - No evidence of metastases on conventional imaging.
    - Not a candidate for salvage radiation

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

- Patients should have a good performance status.
- Treatment should continue until progression or unacceptable toxicity. Enzalutamide should be held after 36 weeks if PSA is suppressed to ≤0.2mcg/mL and may be restarted based on PSA level. For patients with no prior radical prostatectomy, the PSA level threshold to restart treatment is ≥5 mcg/mL. For patients with prior radical prostatectomy, the PSA level threshold to restart treatment is ≥2 mcg/mL.

## **EPINEPHRINE** *(Allerject 0.3mg and 0.15mg Autoinjector, Emerade 0.15mg, 0.3 mg and 0.5mg Prefilled Pen and Epipen 0.15mg and 0.3mg 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.

## **EPLONTERSEN** *(Wainua 45mg/0.8mL Autoinjector)*

For the treatment of polyneuropathy in adult patients with hereditary transthyretin-mediated amyloidosis (hATTR) who meet all of the following criteria:

- Confirmed genetic diagnosis of hATTR.
- Symptomatic with early-stage neuropathy[1].
- Does not have New York Heart Association class III or IV heart failure.
- Has not previously undergone a liver transplant.

**Discontinuation Criteria:**

- The patient is permanently bedridden and dependent on assistance for basic activities of daily living.

OR

- The patient is receiving end-of-life care.

**Clinical Note:**

1. Symptomatic early-stage neuropathy is defined as polyneuropathy disability stage I to IIIB or familial amyloidotic polyneuropathy stage I or II.

**Claim Notes:**

- The patient must be under the care of a physician with experience in the diagnosis and management of hATTR.
- Combination therapy with other interfering ribonucleic acid drugs or transthyretin stabilizers used to treat hATTR

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

will not be reimbursed.

- Initial Approval: 9 months.
- Renewal Approval: 12 months. Confirmation of continued response is required.

## EPTINEZUMAB *(Vyepti 100mg/1mL and 300mg/3mL IV)*

- For the treatment of patients with episodic[1] or chronic migraine[2], who have experienced an inadequate response, intolerance, or contraindication to at least two oral prophylactic migraine medications of different classes.

**Renewal:**

- Proof of beneficial clinical effect, defined as a reduction of at least 50% in the average number of migraine days per month at the time of first renewal compared with baseline.
- For subsequent renewals, proof that the initial 50% reduction in the average number of migraine days per month has been maintained.

**Clinical Notes:**

- Baseline number of headache and migraine days per month must be provided at the time of initial request.
- [1]Episodic migraine: migraine headaches on at least 4 days per month and less than 15 headache days per month for more than 3 months.
- [2]Chronic migraine: headaches for at least 15 days per month for more than 3 months of which at least eight days per month are with migraine.

**Claim Notes:**

- Initial Approval: 6 months
- Renewal Approval: 1 year
- Must be prescribed by a physician who has experience in the management of migraine headaches.

## *ERYTHROPOIETIN *(Eprex Multidose Vial and 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 6 months with the documentation of dose, hemoglobin and therapeutic outcome (number of transfusions).
- Subsequent 6-month approvals 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 ≥ 2 units/ month (over a 3-month period), one dose increase may be attempted (maximum dose 60,000iu per week).

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

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

**Claim Note:**

- The patient must be under the care of a physician experienced in the treatment of epilepsy.

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

## *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/Prefilled Syringe; Erelzi 25mg/0.5mL and 50mg/mL Prefilled Syringe/Prefilled Autoinjector; Rymti 50mg/mL Prefilled Syringe/Prefilled Autoinjector)*

### 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 symptoms1 and who have failed to respond to the sequential use of at least 2 NSAIDs at the optimum dose for a minimum period of 2 weeks each, 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 2 weeks each 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").

**Claim Notes:**

- Maximum dose 50mg per week.
- Concurrent use of biologics not approved.
- Initial Approval: 6 months.
- Renewal Approval: Long term.

[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.

### 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.

**Claim Notes:**

- Initial Approval: 6 months.
- Renewal Approval: Long term.

### PLAQUE PSORIASIS

- For the treatment of patients with chronic moderate to severe plaque psoriasis who meet all of the following:
    - Psoriasis Area Severity Index (PASI) greater than 10 and Dermatology Life Quality Index (DLQI) greater than 10, OR major involvement of visible areas, scalp, genitals, or nails;

- Refractory, intolerant to or unable to access phototherapy;
- Refractory, intolerant to or have contraindications to methotrexate (oral or parenteral) at a dose of greater than or equal to 20 mg weekly (greater than or equal to 15 mg if patient is 65 years of age or older) for a minimum of 12 weeks **OR** cyclosporine (6 weeks treatment).

- For continued coverage, patients must meet the following criteria:
  - Greater than or equal to 75% reduction in PASI score, **OR**
  - Greater than or equal to 50% reduction in PASI and greater than or equal to 5 points in the DLQI **OR**
  - Significant reduction in BSA involved, with consideration of specific regions such as face, hands, feet or genital region and situations such as itch and recalcitrant plaques.

**Clinical Notes:**

- For patients who do not demonstrate a clinical response to oral methotrexate, or who experience gastrointestinal intolerance, a trial of parenteral methotrexate may be considered if clinically appropriate.
- 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 dermatologist or prescriber with a specialty in dermatology.
- Maximum dose 50mg biweekly for initial, then 50mg per week.
- Combined use of more than one biologic will not be reimbursed.
- Initial Approval: 6 months.
- Renewal Approval: Long term.

**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.

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

**Claim Notes:**

- Must be prescribed by a rheumatologist.
- Concurrent use of biologics not approved.
- Maximum dose of 50mg per week.
- Initial Approval: 6 months.
- Renewal Approval: Long term.

**RHEUMATOID ARTHRITIS**

- For the treatment of moderately to severely active rheumatoid arthritis, in combination with methotrexate or other 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.
- Concurrent use of biologics not approved.
- Initial Approval: 6 months.
- Renewal Approval: Long term.
- Maximum Dosage Approved: 25mg twice a week or 50mg once a week with no dose escalation permitted.

## ETRASIMOD *(Velsipity 2mg Tablet)*

- 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 etrasimod with a biologic DMARD or JAK inhibitor will not be reimbursed.
- Approvals will be for a maximum dose of 2 mg daily
- Initial Approval: 6 months
- Renewal Approval: 1 year

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

### METASTATIC RENAL CELL CARCINOMA (RCC)

- For the treatment of patients with advanced or metastatic renal cell carcinoma following disease progression on tyrosine kinase inhibitor therapy.

**Clinical Notes:**

- Patients must have a good performance status.
- Treatment should be discontinued upon disease progression or unacceptable toxicity.
- Requests for everolimus will not be considered for patients who experience disease progression on axitinib, cabozantinib or nivolumab monotherapy.

### 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.

**NEUROENDOCRINE TUMOURS OF GASTROINTESTINAL OR LUNG ORIGIN**

- As a single agent treatment for patients with unresectable, locally advanced or metastatic; well-differentiated non-functional neuroendocrine tumours (NETs) of gastrointestinal or lung origin (GIL) in adults with documented radiological disease progression within six months and with a good performance status. Treatment should continue until confirmed disease progression or unacceptable toxicity.

## EVOLOCUMAB *(Repatha 140mg/mL Prefilled Syringe)*

- 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

## FARICIMAB *(Vabysmo 6mg/0.05mL Vial and 6mg/0.05mL Prefilled Syringe)*

### ACTIVE (WET) AGE-RELATED MACULAR DEGENERATION

- For the treatment of patients with neovascular (wet) age-related macular degeneration (AMD) who meet all of the following criteria:
    - Best Corrected Visual Acuity (BCVA) is greater than 6/96
    - The lesion size is ≤12 disc areas in greatest linear dimension
    - There is evidence of recent (<3 months) presumed disease progression [blood vessel growth, as indicated by fluorescein angiography, optical coherence tomography (OCT), or recent visual acuity changes]
    - There is active disease activity and no permanent structural damage to the central fovea (as defined in the Royal College of Ophthalmologists guidelines)

**Renewal Criteria:**

- Patients must meet all of the following criteria:
    - Evidence of continued disease activity
    - Maintaining adequate response to therapy
    - Absolute BCVA maintained above 6/120
    - Reductions in BCVA of < 6 lines compared to either baseline and/or best recorded level since baseline.

**Claim Notes:**

- Must be prescribed and administered by a retina specialist or an ophthalmologist with experience in administering intravitreal injections.
- Approvals will be for a maximum of 1 vial per eye every 4 weeks for 16 weeks, followed by 1 vial per eye every 8 weeks thereafter.
- Approval period: 1 year. Confirmation of continued response is required.

### DIABETIC MACULAR EDEMA

- For the treatment of patients with diabetic macular edema (DME) who meet the following criteria:
    - Clinically significant center-involving macular edema
    - Best Corrected Visual Acuity (BCVA) is greater than 6/120

**Renewal Criteria:**

- Patients must meet all of the following criteria:
    - Evidence of continued disease activity
    - Maintaining adequate response to therapy
    - Absolute BCVA maintained above 6/120
    - Reductions in BCVA of < 6 lines compared to either baseline and/or best recorded level since baseline.

**Claim Notes:**

- Must be prescribed and administered by a retina specialist or an ophthalmologist with experience in administering intravitreal injections. Approvals will be for a maximum of 1 vial per eye every 4 weeks.
- Approval period: 1 year. Confirmation of continued response is required.

**RETINAL VEIN OCCLUSION**

- For the treatment of patients with clinically significant center-involving macular edema secondary to non-ischemic branch retinal vein occlusion (BRVO), or central retinal vein occlusion (CRVO) who meet the following criteria:
    - Best Corrected Visual Acuity (BCVA) is greater than 6/120

**Renewal Criteria:**

- Patients must meet all of the following criteria:
    - Evidence of continued disease activity
    - Maintaining adequate response to therapy
    - Absolute BCVA maintained above 6/120
    - Reductions in BCVA of <6 lines compared to either baseline and/or best recorded level since baseline

**Claim Notes:**

- Must be prescribed and administered by a retina specialist or an ophthalmologist with experience in administering intravitreal injections.
- Approvals will be for a maximum of 1 vial per eye every 4 weeks.
- Approval period: 1 year. Confirmation of continued response is required.

## FEBUXOSTAT *(80mg Tablet)*

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

## *FEDRATINIB *(Inrebic 100mg Capsule)*

- For the treatment of splenomegaly and/or disease-related symptoms in adult patients with intermediate-2 or high-risk primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis, who have a contraindication or intolerance to ruxolitinib.

**Clinical Notes:**

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

## *FENTANYL *(12mcg/hr, 25mcg/hr, 50mcg/hr, 75mcg/hr, 100mcg/hr Transdermal System)*

- 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 and generic brands)*

- See **OAB Medications**

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

## *FERRIC DERISOMALTOSE *(Monoferric 100 mg/mL IV Injection)*

- For the treatment of iron deficiency anemia in patients who:
    - are intolerant to oral iron replacement products,

      OR
    - have not responded to an adequate trial of 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.

## 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.

## FINERENONE *(Kerendia 10mg and 20mg Tab)*

- For the treatment of patients with chronic kidney disease (CKD) and type 2 diabetes (T2D) who have an estimated glomerular filtration rate (eGFR) level of at least 25mL/min/1.73 $m^2$ and albuminuria level of at least 30mg/g (or 3mg/mmol).

**Exclusion Criteria:**

- Patients with chronic heart failure (CHF) New York Heart Association (NYHA) class II to IV; OR
- Patients receiving a mineralocorticoid receptor antagonist (MRA).

**Discontinuation Criteria:**

- eGFR less than 15 mL/min/1.73 $m^2$; OR
- Urinary albumin-to-creatinine ratio (UACR) increased from baseline level.

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

**Claim Notes:**

- Must be prescribed by, or in consultation with, a nephrologist or prescriber with experience in the diagnosis and management of patients with CKD and T2D.
- Approval: 1 year

### FINGOLIMOD *(Gilenya 0.5mg Capsule and generic brands)*

- For the treatment of patients with relapsing remitting multiple sclerosis (RRMS) who meet all of the following criteria:
    - Ambulatory with or without aid (i.e. has a recent Expanded Disability Status Scale (EDSS) score of less than or equal to 6.5)
    - Experienced one or more disabling relapses or new MRI activity in the past two years

**Clinical Note:**

- Treatment should be discontinued for patients with an EDSS score of greater than or equal to 7.

**Claim Notes:**

- Must be prescribed by a neurologist with experience in the diagnosis and management of multiple sclerosis.
- Combined use with other disease modifying therapies to treat RRMS will not be reimbursed.
- Initial Approval: 2 years
- Renewal Approval: 5 years

### *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, Gatifloxacin, Moxifloxacin and 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, RESPIRATORY *(Levofloxacin, Moxifloxacin)*

- For the completion of therapy instituted in hospital setting for the treatment of nosocomial pneumonia, community acquired pneumonia (CAP) or acute exacerbation of chronic obstructive pulmonary disease (AECOPD). **[Criteria Code 01]**
- For the treatment of severe pneumonia in nursing home patients. **[Criteria Code 02]**
- For the treatment of CAP in patients with radiographic conformation of pneumonia, who have failed treatment with at least one first-line therapy (doxycycline, beta-lactam, or macrolide) or are intolerant or have contraindication(s) to at least two first-line therapies. **[Criteria Code 03]**
- For the treatment of complicated AECOPD in patients who have failed treatment with at least one first-line therapy

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

(doxycycline, beta-lactam, trimethoprim-sulfamethoxazole, or macrolide) or are intolerant or have contraindication(s) to at least first-line therapies. **[Criteria Code 04]**

- For the treatment of complicated osteomyelitis or joint infections. **[Criteria Code 05]**
- For the treatment of pulmonary infections with cystic fibrosis. **[Criteria Code 06]**
- For the treatment of tuberculosis in patients who have lab-verified drug resistance or a contraindication or intolerance to first-line drugs. **[Criteria Code 07]**
- For the treatment of pyelonephritis (levofloxacin only). **[Criteria Code 08]**

**Clinical Notes:**

- If the patient has been treated with an antibiotic within the past 3 months, consider an antibiotic from a different class.
- Complicated AECOPD is defined as patients with COPD (FEV1/FVC < 0.7) experiencing increased sputum purulence, and either increased dyspnea or sputum volume, and one of the following:
  - FEV1 < 50% predicted
  - ≥ 4 exacerbations per year
  - Ischemic heart disease
  - Home oxygen use
  - Chronic oral steroid use

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

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

### FLUTICASONE FUROATE/UMECLIDINIUM/VILANTEROL *(Trelegy Ellipta 100mcg/62.5mcg/25mcg)*

- See **Long-Acting Muscarinic Antagonists/Long-Acting Beta2-Agonists/Inhaled Corticosteroids**

### FORMOTEROL, IN COMBINATION *(Symbicort 100/6mcg, 200/6mcg Turbuhaler and Zenhale 100/5mcg, 200/5mcg Inh)*

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

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

- A maximum of 3 doses will be reimbursed annually without a special authorization request.
- Prescribers may submit a request for consideration should beneficiaries require more than 3 doses annually.

### FOSLEVODOPA/FOSCARBIDOPA *(Vyalev 240mg/12mg/mL SC Solution)*

For the treatment of patients with advanced levodopa-responsive Parkinson disease (PD) who meet all of the following criteria:

- Experiences severe disability associated with at least 25% of the waking day in the off state and/or ongoing, bothersome levodopa-induced dyskinesias, despite having tried frequent dosing of levodopa (at least five doses per day).
- Have received an adequate trial of maximally tolerated doses of levodopa, with previously demonstrated clinical response.
- Have failed an adequate trial of the following adjunctive medications, if not contraindicated and/or contrary to the clinical judgment of prescriber: maximally tolerated doses of levodopa in combination with carbidopa, a COMT inhibitor, a dopamine agonist, a MAO-B inhibitor, and amantadine.

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

- Must be able to administer the medication and correctly use the delivery system. Alternatively, trained personnel or a care partner must be available to perform these tasks reliably.

**Exclusion Criteria:**

- Patients with severe psychosis or severe dementia.

**Renewal:**

- Patients continue to demonstrate a significant reduction in the time spent in the off state and/or in ongoing levodopa-induced dyskinesias, along with an improvement in the related disability.

**Claim Note:**

- Must be prescribed by neurologists who are movement disorder subspecialists or who have expertise in managing advanced PD.
- Approval period: 1 year

## FREMANEZUMAB *(Ajovy 225mg/1.5mL Prefilled Syringe and 225mg/1.5mL Autoinjector)*

- For the treatment of patients with episodic[1] or chronic migraine[2], who have experienced an inadequate response, intolerance, or contraindication to at least two oral prophylactic migraine medications of different classes.

**Renewal:**

- Proof of beneficial clinical effect, defined as a reduction of at least 50% in the average number of migraine days per month at the time of first renewal compared with baseline
- For subsequent renewals, proof that the initial 50% reduction in the average number of migraine days per month has been maintained

**Clinical Notes:**

- Baseline number of headache and migraine days per month must be provided at the time of initial request.
- [1] Episodic migraine: migraine headaches on at least 4 days per month and less than 15 headache days per month for more than 3 months
- [2] Chronic migraine: headaches for at least 15 days per month for more than 3 months of which at least eight days per month are with migraine.

**Claim Notes:**

- Approvals: 6 months
- Renewal Approval: 1 year
- Must be prescribed by a physician who has experience in the management of migraine headaches.

## GALCANEZUMAB *(Emgality 120mg/mL Prefilled Pen and 120mg/mL Prefilled Syringe)*

**Initiation:**

- For the treatment of patients with episodic[1] or chronic migraine[2], who have experienced an inadequate response, intolerance, or contraindication to at least two oral prophylactic migraine medications of different classes.

**Renewal:**

- Proof of beneficial clinical effect, defined as a reduction of at least 50% in the average number of migraine days per month at the time of first renewal compared with baseline.
- For subsequent renewals, proof that the initial 50% reduction in the average number of migraine days per month has been maintained.

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

**Clinical Notes:**

- Baseline number of headache and migraine days per month must be provided at the time of initial request.
- [1]Episodic migraine: migraine headaches on at least 4 days per month and less than 15 headache days per month for more than 3 months.
- [2]Chronic migraine: headaches for at least 15 days per month for more than 3 months of which at least eight days per month are with migraine.

**Claim Notes:**

- Initial Approval: 6 months
- Renewal Approval: 1 year
- Must be prescribed by a physician who has experience in the management of migraine headaches.

## GATIFLOXACIN *(Zymar 0.3% Ophthalmic Solution and generic brands)*

- See **Fluoroquinolones, Ophthalmic**

## *GILTERITINIB *(Xospata 40mg Tablet)*

- As monotherapy for the treatment of adult patients with relapsed or refractory FMS-like tyrosine kinase 3 (FLT3)-mutated acute myeloid leukemia (AML) who meet the following criteria:
    - Confirmed positive for FLT3 mutation at the time of relapse or determination of refractory disease, eligible FLT3 mutations include FLT3-ITD, and FLT3-TKD.

**Clinical Notes:**

- Patients should have a good performance status.
- Treatment with gilteritinib should be continued as long as clinical benefit is observed, or until disease progression or unacceptable toxicity, whichever occurs first.
- Patients previously treated with midostaurin are eligible for gilteritinib provided all other criteria are met.

## GIVOSIRAN *(Givlaari 189mg/mL Vial)*

- For the treatment of acute hepatic porphyria (AHP) in adults:

**Initiation:**

- Reimbursement of givosiran should be restricted to patients with 4 or more attacks requiring either hospitalization, an urgent health care visit, or IV hemin in the year before the prescribing date.

**Renewal:**

- A reduction in the annualized attack rate after 12 months of therapy compared to baseline.

**Claim Notes:**

- Prescription should be restricted to a clinician experienced in the management of AHP.
- Should not be used in combination with prophylactic hemin.

## GLATIRAMER ACETATE *(Copaxone 20mg/mL Syringe Injection and generic brands)*

**Effective June 1, 2025, patients currently receiving the originator drug product Copaxone (glatiramer acetate), will be required to transition to an alternate funded glatiramer acetate product by December 1, 2025.**

**Glatiramer acetate-naïve patients whose therapy is initiated after June 1, 2020, will continue to be approved for an alternate funded glatiramer acetate product.**

- For the treatment of patients with relapsing remitting multiple sclerosis (RRMS) or secondary progressive MS with clear superimposed relapses; who meet all of the following criteria:
    - Ambulatory with or without aid (i.e. has a recent Expanded Disability Status Scale (EDSS) score of less than or equal to 6.5)

**Clinical Note:**

- Treatment should be discontinued for patients with an EDSS score of greater than or equal to 7.

**Claim Notes:**

- Must be prescribed by a neurologist with experience in the diagnosis and management of multiple sclerosis.
- Combined use with other disease modifying therapies to treat RRMS will not be reimbursed.
- Initial Approval: 2 years
- Renewal Approval: long term

## GLATIRAMER ACETATE *(Glatect 20mg Pre-Filled Syringe)*

**Effective June 1, 2025, patients currently receiving the originator drug product Copaxone (glatiramer acetate), will be required to transition to an alternate funded glatiramer acetate product by December 1, 2025.**

**Glatiramer acetate-naïve patients whose therapy is initiated after June 1, 2020, will continue to be approved for an alternate funded glatiramer acetate product.**

- For the treatment of patients with relapsing remitting multiple sclerosis (RRMS) or secondary progressive MS with clear superimposed relapses; who meet all of the following criteria:
    - Ambulatory with or without aid (i.e. has a recent Expanded Disability Status Scale (EDSS) score of less than or equal to 6.5)

**Clinical Note:**

- Treatment should be discontinued for patients with an EDSS score of greater than or equal to 7.

**Claim Notes:**

- Must be prescribed by a neurologist with experience in the diagnosis and management of multiple sclerosis.
- Combined use with other disease modifying therapies to treat RRMS will not be reimbursed.
- Initial Approval: 2 years
- Renewal Approval: long term

## GLECAPREVIR/PIBRENTASVIR *(Maviret 100mg/40mg Tablet and 50mg/20mg Sachet)*

- For treatment-naïve or treatment-experienced patients aged 3 and older with chronic hepatitis C virus (HCV) with a confirmed quantitative HCV RNA value within the last 12 months.

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

**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).
- Sachets will only be considered for pediatric patients 3 years of age and older weighing between 12 kg and 45 kg.
- Claims will be limited to a 28-day supply.

** **[Criteria Code 34]** has been added to allow payment of a patient's initial 28 day supply only. Criteria code 34 should be provided by the prescribing physician only.

## GLUCAGON *(Baqsimi 3mg Nasal Powder)*

- For the emergency treatment of severe hypoglycemia (SH) reactions for patients who are receiving insulin and at high risk for SH, when impaired consciousness precludes oral carbohydrate.

**Claim Note:**

- Regular benefit, but with a quantity limit of two (2) devices per fiscal year. Prescribers can submit a request for consideration or contact the Pharmacare Office should beneficiaries require more than two (2) devices per fiscal year (e.g., need for frequent use).

## 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.

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

**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[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 2 weeks each, 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 2 weeks each 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").

**Claim Notes:**

- Initial Approval: 6 months.
- Renewal Approval: 1 year.
- Maximum dose of 50mg once a month.
- Concurrent use of biologics not approved.

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.

**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.
- Concurrent use of biologics not approved.
- Maximum dose 50mg per month.
- Initial Approval: 6 months.
- Renewal Approval: 1 year. Confirmation of continued response required.

**RHEUMATOID ARTHRITIS**

- For the treatment of moderately to 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.

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

- 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.
- Concurrent use of biologics not approved.
- Maximum dose 50mg once a month with no escalation permitted.
- Initial Approval: 6 months.
- Renewal Approval: 1 year. Confirmation of continued response is required.

**ULCERATIVE COLITIS**

- For the treatment of patients with moderately to severely active ulcerative colitis who have a partial Mayo score > 4, and a rectal bleeding subscore ≥ 2 and are:
    - 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.
- Concurrent use of biologics not approved.
- Maximum dose 50mg once a month with no escalation permitted
- Initial Approval: 6 months.
- Renewal Approval: 1 year.

## *GRANISETRON *(1mg Tablet)*

- 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.

## GUSELKUMAB *(Tremfya 100mg/mL Autoinjector and Prefilled Syringe)*

### PLAQUE PSORIASIS

- For the treatment of patients with chronic moderate to severe plaque psoriasis who meet all of the following:
    - Psoriasis Area Severity Index (PASI) greater than 10 and Dermatology Life Quality Index (DLQI) greater than 10, OR major involvement of visible areas, scalp, genitals, or nails;
    - Refractory, intolerant to or unable to access phototherapy;
    - Refractory, intolerant to or have contraindications to methotrexate (oral or parenteral) at a dose of greater than or equal to 20 mg weekly (greater than or equal to 15 mg if patient is 65 years of age or older) for a minimum of 12 weeks **OR** cyclosporine (6 weeks treatment).
- For continued coverage, patients must meet the following criteria:
    - Greater than or equal to 75% reduction in PASI score, **OR**
    - Greater than or equal to 50% reduction in PASI and greater than or equal to 5 points in the DLQI **OR**
    - Significant reduction in BSA involved, with consideration of specific regions such as face, hands, feet or genital region and situations such as itch and recalcitrant plaques.

**Clinical Notes:**

- For patients who do not demonstrate a clinical response to oral methotrexate, or who experience gastrointestinal intolerance, a trial of parenteral methotrexate may be considered if clinically appropriate.
- 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 dermatologist or prescriber with a specialty in dermatology.
- Approvals will be for 100mg by subcutaneous injection at weeks 0, 4, followed by maintenance dosing of 100mg every 8 weeks.
- Combined use of more than one biologic will not be reimbursed.
- Initial Approval: 6 months.
- Renewal Approval: 1 year.

### 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 100mg at weeks 0, 4 and 8 followed by a maximum of 100 mg every 8 weeks.
- Initial Approval: 6 months.
- Renewal Approval: 1 year. Confirmation of continued response required.

## HALOBETASOL PROPIONATE AND TAZAROTENE *(Duobrii 0.01%/0.045% Topical Lotion)*

- Patients must have a clinical diagnosis of moderate to severe plaque psoriasis and an inadequate response to a topical high-potency corticosteroid.

## 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

## HUMAN INSULIN R *(Entuzity 500 U/mL KwikPen)*

- For the treatment of patients with diabetes mellitus with unacceptable glycemic control who require more than 200 units of insulin per day, with or without other therapies.

**Claims Notes:**

- Treatment must be initiated by an endocrinologist or prescriber with a specialty in endocrinology.

## *IBRUTINIB *(Imbruvica 140mg Capsule)*

### CHRONIC LYMPHOCYTIC LEUKEMIA

- As a treatment option for adult patients with previously untreated chronic lymphocytic leukemia (CLL), including those with 17p deletion, in combination with venetoclax.

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

**Clinical Notes:**

- Patients should have a good performance status and no evidence of disease transformation.
- Treatment should be discontinued upon disease progression, unacceptable toxicity, or to a maximum of 15 cycles (three cycles as monotherapy followed by 12 cycles in combination with venetoclax).
- Patients who have progressed on a BTK inhibitor are not eligible.
- No active CNS involvement (eligible if treated/stable).
- If ibrutinib is discontinued for intolerance, venetoclax monotherapy may be continued.
- Patients with small lymphocytic lymphoma (SLL) are eligible for treatment.

### 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.

### RELAPSED/REFRACTORY WALDENSTROM'S MACROGLOBULINEMIA

- As a treatment option for adult patients with previously treated relapsed or refractory Waldenström's Macroglobulinemia as monotherapy or in combination with rituximab.

**Clinical Notes:**

- Patients should have a good performance status and no evidence of disease transformation.

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

- Treatment should be discontinued upon disease progression or unacceptable toxicity.
- Patients who have progressed on a BTK inhibitor are not eligible

## ICATIBANT *(Firazyr 30mg/30mL Prefilled Syringe and generic brands)*

- 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.

## ICOSAPENT ETHYL *(Vascepa 1g Capsule)*

To reduce the risk of cardiovascular events (cardiovascular death, non-fatal myocardial infarction, non-fatal stroke, coronary revascularization, or hospitalization for unstable angina) in statin-treated patients with elevated triglycerides, who meet all of the following criteria:

- Aged 45 years and older;
- Established cardiovascular disease (secondary prevention);
- Concomitantly treated with a statin;
- Have a fasting triglyceride of 1.7 mmol/L or greater and lower than 5.6 mmol/L at baseline, measured within the preceding three months before starting treatment with icosapent ethyl;
- Have a low-density lipoprotein cholesterol greater than 1.0 mmol/L and lower than 2.6 mmol/L at baseline and be receiving a maximally tolerated statin dose, targeted to achieve a low-density lipoprotein cholesterol lower than 2 mmol/L, for a minimum of four weeks.

**Renewal Criteria:**

- Patient continues to be treated with a maximally tolerated statin dose.

**Claims Notes:**

- Approvals will be for a maximum of 4 g daily
- Approvals: 12 months.

## *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

## *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.

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

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

- See **Long-Acting Beta$_2$-Agonists/Long-Acting Muscarinic Antagonists**

## INDACATEROL, GLYCOPYRRONIUM AND MOMETASONE FUROATE *(Enerzair Breezhaler 150mcg/50mcg/160mcg Capsule for Inhalation)*

- For the treatment of asthma in adult patients not adequately controlled with a maintenance combination of a long-acting beta2-agonist (LABA) and a medium or high dose of an inhaled corticosteroid (ICS) who experienced one or more asthma exacerbations in the previous 12 months.

**** [Criteria Code 16]** has been added for use effective June 3, 2024. Criteria code 16 is for inhalers prescribed by respirologist, clinical immunologist, allergist, internist, medical oncologist or thoracic surgeons.

**Clinical Note:**

- Asthma exacerbation is defined as: worsening signs or symptoms of asthma (shortness of breath, cough, wheezing or chest tightness and progressive decrease in lung function) requiring administration of systemic corticosteroids for at least three days, or asthma-related hospitalization

## INDACATEROL, IN COMBINATION *(Atectura Breezhaler 150mcg/80mcg, 150mcg/160mcg and 150mcg/320mcg Capsule for Inhalation)*

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

## INFLIXIMAB *(Avsola, Ixifi, Remdantry, Remsima SC and Renflexis 100mg Powder For Injection)*

### 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[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 2 weeks each, 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 2 weeks each 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").

**Claim Notes:**

- Maximum dose 5mg/kg at 0, 2, and 6 weeks then every 6-8 weeks thereafter.
- Concurrent use of biologics not approved.
- Initial period 6 months.
- Renewal Approval: Long term.

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.

### CROHN'S DISEASE

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

**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 to treatments. The nature of intolerance(s) must be clearly documented.

**Claim Notes:**

- Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology.
- Combined use with other biologic drugs or janus kinase (JAK) inhibitors will not be reimbursed.
- The patient who completed an induction regimen with three IV infliximab doses must have achieved a clinical response to induction therapy with infliximab IV at week 10 of treatment to continue to maintenance therapy with infliximab SC.
- Initial Approval: 6 months.
- Renewal Approval: Long term.
- Approvals will be for both SC and IV formulations.
- Maintenance with SC will be for a maximum of 120 mg every two weeks
- IV will be for 5 mg/kg/dose given at 0, 2 and 6 weeks for induction then every 8 weeks thereafter for maintenance.

### PLAQUE PSORIASIS

- For the treatment of patients with chronic moderate to severe plaque psoriasis who meet all of the following:
    - Psoriasis Area Severity Index (PASI) greater than 10 and Dermatology Life Quality Index (DLQI) greater than 10, OR major involvement of visible areas, scalp, genitals, or nails;
    - Refractory, intolerant to or unable to access phototherapy;
    - Refractory, intolerant to or have contraindications to methotrexate (oral or parenteral) at a dose of greater than or equal to 20 mg weekly (greater than or equal to 15 mg if patient is 65 years of age or older) for a minimum of 12 weeks **OR** cyclosporine (6 weeks treatment).

- For continued coverage, patients must meet the following criteria:
    - Greater than or equal to 75% reduction in PASI score, **OR**
    - Greater than or equal to 50% reduction in PASI and greater than or equal to 5 points in the DLQI **OR**
    - Significant reduction in BSA involved, with consideration of specific regions such as face, hands, feet or genital region and situations such as itch and recalcitrant plaques.

**Clinical Notes:**

- For patients who do not demonstrate a clinical response to oral methotrexate, or who experience gastrointestinal intolerance, a trial of parenteral methotrexate may be considered if clinically appropriate.
- 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 dermatologist or prescriber with a specialty in dermatology.
- Dosage restricted to infliximab 5mg/kg 0, 2 and 6 weeks then every 8 weeks.
- Combined use of more than one biologic will not be reimbursed.
- Initial Approval: 6 months.
- Renewal Approval: Long term.

**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.
- Concurrent use of biologics not approved.
- Maximum dose 5mg/kg 0, 2 and 6 weeks then every 8 weeks.

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

- Initial Approval: 6 months.
- Renewal Approval: Long term.

**RHEUMATOID ARTHRITIS**

- For the treatment of moderately to 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), 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 with other biologic drugs or janus kinase (JAK) inhibitors will not be reimbursed.
- Initial Approval: 6 months.
- Renewal Approval: Long term.
- Approvals will be for both SC and IV formulations.
- SC will be for a maximum of 120 mg once weekly at 0, 1, 2, 3, and 4 weeks for induction, and then every 2 weeks thereafter for maintenance.
- IV will be for 3mg/kg/dose at 0, 2 and 6 weeks for induction, then every 8 weeks thereafter for maintenance.

**ULCERATIVE COLITIS**

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

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

**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 with other biologic drugs or janus kinase (JAK) inhibitors will not be reimbursed.
- The patient who completed an induction regimen with three IV infliximab doses must have achieved a clinical response to induction therapy with infliximab IV at week 10 of treatment to continue to maintenance therapy with infliximab SC.
- Initial Approval: 6 months.
- Renewal Approval: Long term.
- Approvals will be for both SC and IV formulations.
- Maintenance with SC will be for a maximum of 120 mg every two weeks.
- IV will be for 5 mg/kg/dose given at 0, 2 and 6 weeks for induction then every 8 weeks thereafter for maintenance.

## INEBILIZUMAB *(Uplizna 10mg/mL Vial)*

**Initiation:**

- For the treatment of adult patients with neuromyelitis optica spectrum disorder (NMOSD) who meet all of the following criteria:
    - Anti-aquaporin-4 immunoglobulin G (AQP4-IgG) seropositive
    - Have had ≥ 1 attack in the prior 12 months or ≥ 2 attacks in the prior 2 years
    - Patients must have an EDSS score of 8 points or less

**Renewal:**

- The physician should measure and provide EDSS scores every 12 months after the initial authorization to determine if the continuation of inebilizumab reimbursement should occur.

**Discontinuation:**

- Reimbursement of inebilizumab treatment should be discontinued if the patient's EDSS score is greater than 8 points.

**Claim Notes:**

- Initial and renewal approval: 12 months
- The prescribing of inebilizumab for the treatment of NMOSD should be restricted to neurologists with expertise in treating NMOSD.
- Inebilizumab should not be initiated during a NMOSD relapse episode.
- Inebilizumab should not be reimbursed when used in combination with rituximab, satralizumab, eculizumab, or ravulizumab.
- Approvals will be a for a maximum of 300 mg at 0 and 2 weeks and 300 mg every 6 months thereafter.

## INSULIN DETEMIR *(Levemir 100iu/mL Penfill)*

- 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)
- For the treatment of pediatric and adolescent patients (under 18 years of age) with Type 1 diabetes.
- For the treatment of pregnant individuals with Type 1 or Type 2 diabetes requiring insulin.

## 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)*

- For the treatment of patients with relapsing remitting multiple sclerosis (RRMS) or secondary progressive MS with clear superimposed relapses; who meet all of the following criteria:
  - Ambulatory with or without aid (i.e. has a recent Expanded Disability Status Scale (EDSS) score of less than or equal to 6.5)

**Clinical Note:**

- Treatment should be discontinued for patients with an EDSS score of greater than or equal to 7.

**Claim Notes:**

- Must be prescribed by a neurologist with experience in the diagnosis and management of multiple sclerosis.
- Combined use with other disease modifying therapies to treat RRMS will not be reimbursed.
- Initial Approval: 2 years
- Renewal Approval: long term

## *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**

## *ISAVUCONAZOLE *(Cresemba 100mg Capsule and 200mg Vial)*

- For the treatment of adult patients with invasive aspergillosis who have a contraindication, intolerance or have failed to respond to oral voriconazole and caspofungin.
- For the treatment of adult patients with invasive mucormycosis.

**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.

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

## *ITRACONAZOLE *(10mg/mL Oral Solution)*

- For the treatment of immunocompromised adult patients with oral and/or esophageal candidiasis.

**Clinical Note:**

- Itraconazole oral solution is not interchangeable with itraconazole capsules due to differences in bioavailablilty

## 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.

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

### PLAQUE PSORIASIS

- For the treatment of patients with chronic moderate to severe plaque psoriasis who meet all of the following:
    - Psoriasis Area Severity Index (PASI) greater than 10 and Dermatology Life Quality Index (DLQI) greater than 10, OR major involvement of visible areas, scalp, genitals, or nails;
    - Refractory, intolerant to or unable to access phototherapy;
    - Refractory, intolerant to or have contraindications to methotrexate (oral or parenteral) at a dose of greater than or equal to 20 mg weekly (greater than or equal to 15 mg if patient is 65 years of age or older) for a minimum of 12 weeks **OR** cyclosporine (6 weeks treatment).
- For continued coverage, patients must meet the following criteria:
    - Greater than or equal to 75% reduction in PASI score, **OR**
    - Greater than or equal to 50% reduction in PASI and greater than or equal to 5 points in the DLQI **OR**
    - Significant reduction in BSA involved, with consideration of specific regions such as face, hands, feet or genital region and situations such as itch and recalcitrant plaques.

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

**Clinical Notes:**

- For patients who do not demonstrate a clinical response to oral methotrexate, or who experience gastrointestinal intolerance, a trial of parenteral methotrexate may be considered if clinically appropriate.
- 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 dermatologist or prescriber with a specialty in dermatology.
- 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.
- Combined use of more than one biologic will not be reimbursed.
- Initial Approval: 6 months.
- Renewal Approval: 1 year.

**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 dermatologist.
- Concurrent use of biologics not approved.
- Approvals will be for 160mg at week 0, followed by 80mg every 4 weeks.
- Initial Approval: 6 months.
- Renewal Approval: 1 year. Confirmation of continued response required.

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

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

## LANADELUMAB *(Takhzyro 300mg/2mL Vial and 300mg/2mL Prefilled Syringe)*

- For the routine prevention of attacks of type I or II hereditary angioedema (HAE) in patients 12 years of age and older who have experienced at least three HAE attacks within any four-week period and required the use of an acute injectable treatment.

**Discontinuation Criteria:**

- No reduction in the number of HAE attacks for which acute injectable treatment was received during the first three months of treatment with lanadelumab compared to the number of attacks observed before initiating treatment with lanadelumab;

  **OR**

- Increase in the number of HAE attacks for which acute injectable treatment was received compared to the number of attacks before initiating treatment with lanadelumab.

**Clinical Note:**

- The pre-treatment attack rate must be provided for those patients who are already receiving long-term prophylactic treatment for HAE and intend to transition to lanadelumab.

**Claim Notes:**

- Must be prescribed by a physician experienced in the diagnosis and treatment of HAE.
- Combination use of Takhzyro (lanadelumab) with other long-term prophylactic treatment of HAE (e.g., C1 esterase inhibitor, berotralstat) will not be funded.
- Approvals will be for a maximum of 300 mg every two weeks.
- Initial Approval: 3 months.
- Renewal Approval: 6 months.

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

- For patients who require the use of a proton pump inhibitor and require administration through a feeding tube. **[Criteria code 37]**
- For patients 19 years of age and younger, who require the use of a proton pump inhibitor and who cannot use a tablet or capsule. **[Criteria code 38]**

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

- Failure of a trial of all open benefit PPIs (omeprazole, pantoprazole sodium and rabeprazole).

## *LAPATINIB *(Tykerb 250mg Tablet)*

- For the treatment of patients with unresectable locally advanced or metastatic HER2-positive breast cancer in combination with capecitabine for use as:
  - First line therapy following disease relapse during or within six months of completing adjuvant treatment with trastuzumab or trastuzumab emtansine; or

- Second line therapy following disease progression during treatment with trastuzumab, with or without pertuzumab, in the advanced setting.

**Clinical Note:**

- Patients should have a good performance status.

## *LAROTRECTINIB *(Vitrakvi 25mg and 100mg Capsule and 20mg/mL Oral Liquid)*

**LOCALLY ADVANCED UNRESECTABLE OR METASTATIC SOLID TUMORS WITH A NEUROTROPHIC TYROSINE RECEPTOR KINASE (NTRK) GENE FUSION**

- For the treatment of adult and pediatric patients with locally advanced unresectable or metastatic solid tumors with NTRK gene fusion without a known acquired resistance mutation. Patient is not a candidate for surgery and/or radiation due to risk of substantial morbidity and have no satisfactory treatment options.

**Clinical Notes:**

- Patients should have a good performance status.
- Treatment should be discontinued upon disease progression or unacceptable toxicity.
- Brain metastases are stable, if present.
- Patients with prior progression on an NTRK inhibitor are not 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**<br>▪ Treatment-naïve without cirrhosis, who have pre-treatment HCV RNA level < 6 million IU/mL and mono-HCV infected only | ▪ 8 weeks |
| **Genotype 1**<br>▪ Treatment-naïve without cirrhosis, who have pre-treatment HCV RNA level ≥ 6 million IU/mL<br>▪ Treatment-naïve with compensated cirrhosis<br>▪ Treatment-naïve with advanced liver fibrosis (Fibrosis stage F3-F4)<br>▪ Treatment-experienced without cirrhosis<br>▪ HCV/HIV co-infected without cirrhosis or with compensated cirrhosis | ▪ 12 weeks |
| **Genotype 1**<br>▪ Treatment-experienced with compensated cirrhosis | ▪ 24 weeks |
| **Genotype 1**<br>▪ Decompensated cirrhosis<br>▪ 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;

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

- 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 Note:**

- Claims will be limited to a 28-day supply.

**** [Criteria Code 34]** has been added to allow payment of a patient's initial 28 day supply only. Criteria code 34 should be provided by the prescribing physician only.

## *LENALIDOMIDE *(Revlimid 2.5mg, 5mg, 10mg, 15mg, 20mg, 25mg Capsule and generic brands)*

### 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)

- For the treatment of relapsed or refractory multiple myeloma when used:
  - In combination with dexamethasone for patients who have received at least one prior treatment; or
  - In combination with carfilzomib and dexamethasone (KRd regimen) for patients who have received at least one prior treatment; or
  - In combination with daratumumab and dexamethasone (DRd regimen) for patients who have received at least one prior treatment.

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

- For the maintenance treatment of patients with newly diagnosed multiple myeloma who have stable or improved disease following autologous stem-cell transplantation (ASCT) and no evidence of disease progression.

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

- As first-line treatment for newly diagnosed patients with multiple myeloma who are not eligible for autologous stem cell transplantation when used:
  - In combination with dexamethasone, with or without bortezomib; or
  - In combination with daratumumab and dexamethasone

### MULTIPLE MYELOMA PRIOR TO AUTOLOGOUS STEM CELL TRANSPLANT (MM PRE-ASCT)

- For the treatment of patients with multiple myeloma when used in combination with bortezomib and dexamethasone as induction therapy prior to autologous stem cell transplant.

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

**Clinical Notes:**

- Patients should have a good performance status.
- Treatment should be continued until unacceptable toxicity or disease progression.

## *LENVATINIB *(Lenvima 4mg, 8mg, 10mg, 12mg, 14mg, 20mg, 24mg Compliance Pack)*

### ADVANCED AND METASTATIC RENAL CELL CARCINOMA

- In combination with pembrolizumab for the treatment of adult patients with advanced (not amenable to curative surgery or radiation therapy) or metastatic renal cell carcinoma who have not had prior systemic therapy for metastatic disease.

**Clinical Notes:**

- Patients should have a good performance status.
- Treatment should continue until disease progression or unacceptable toxicity (can be continued as monotherapy after completing 2 years of combination therapy with pembrolizumab).
- If pembrolizumab or lenvatinib is discontinued for toxicity, the other agent can be continued at the discretion of the physician.
- Patients treated with immunotherapy in the adjuvant setting will be eligible provided that there has been a 6-month interval between the completion of immunotherapy and metastatic disease.
- If patient requires and qualifies for re-treatment with pembrolizumab, lenvatinib may also be given at the discretion of the treating physician.
- Funding is limited to one line of immunotherapy for patients with advanced or metastatic RCC.

### ADVANCED ENDOMETRIAL CARCINOMA

- In combination with pembrolizumab for the treatment of adult patients with advanced endometrial carcinoma that is not microsatellite instability high (MSI-H) or mismatch repair deficient (dMMR), who have disease progression following prior platinum-based systemic therapy are and are not candidates for curative surgery or radiation.

**Clinical Notes:**

- Patients should have a good performance status.
- Treatment should continue until disease progression or unacceptable toxicity (can be continued as monotherapy after completing 2 years of combination therapy with pembrolizumab).
- Confirmation that patient does not have MSI-H or dMMR disease must be done prior to initiating treatment.
- No active CNS metastases (eligible if treated/stable).
- If pembrolizumab or lenvatinib is discontinued for toxicity, the other agent can be continued at the discretion of the physician.
- If patient requires and qualifies for re-treatment with pembrolizumab, lenvatinib can also be given at the discretion of the treating physician.

### LOCALLY RECURRENT OR METASTATIC, PROGRESSIVE, RADIOACTIVE-IODINE-REFRACTORY DIFFERENTIATED THYROID CANCER (DTC) (LENVIMA 10MG,14MG, 20MG AND 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.

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

**UNRESECTABLE OR METASTATIC HEPATOCELLULAR CARCINOMA (HCC) (LENVIMA 4MG, 8MG AND 12MG COMPLIANCE PACK)**

- For the treatment of adult patients with unresectable or metastatic hepatocellular carcinoma as either first-line treatment, or second-line treatment following atezolizumab in combination with bevacizumab or durvalumab in combination with tremelimumab, who meet all the following criteria:
    - Child-Pugh class status of A.
    - Good performance status.
    - No brain metastases or prior liver transplantation.

**Clinical Notes:**

- Treatment should be continued until disease progression or unacceptable toxicity.
- Patients who are unable to tolerate sorafenib may be switched to lenvatinib if there is no disease progression and provided all other funding criteria are met.
- Patients with disease progression on sorafenib are not eligible for reimbursement of lenvatinib.

## LETERMOVIR *(Prevymis 240mg and 480mg Tablet and 240mg and 480mg IV Solution)*

- For the prevention of cytomegalovirus (CMV) infection in adult CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT) who have undetectable CMV viremia at baseline and meet one of the following criteria:
    - umbilical cord blood as a stem cell source
    - recipient of a haploidentical transplant
    - recipient of T-cell depleted transplant
    - treated with antithymocyte globulin (ATG) for conditioning
    - requiring high-dose steroids or other immunosuppression for acute graft versus host disease (GVHD)
    - treated with ATG for steroid-refractory acute GVHD
    - documented history of CMV disease prior to transplantation

**Clinical Note:**

- High-dose steroids is defined as the use of greater than or equal to 1 mg/kg/day of prednisone or equivalent dose of another corticosteroid.

**Claim Notes:**

- Must be prescribed by a medical oncologist, hematologist, or infectious disease specialist or other physician with experience in the management of HSCT.
- Approvals will be for a maximum dose of 480 mg per day.
- Approval period: 100 days per HSCT.

## LEVOCARNITINE *(Carnitor 100mg/mL Oral Liquid, generic brands 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.

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

## LEVODOPA/CARBIDOPA *(Duodopa 20mg/5mg Intestinal Gel Cassettes)*

- For the treatment of patients with advanced levodopa-responsive Parkinson's Disease (PD) who meet all of the following criteria:
    - Experiences severe disability with at least 25% of the waking day in the off state and/or ongoing levodopa-induced dyskinesias, despite having tried frequent dosing of levodopa (at least five doses per day).
    - Have received an adequate trial of maximally tolerated doses of levodopa, with demonstrated clinical response.
    - Have failed an adequate trial of the following adjunctive medications, if not contraindicated and/or contrary to the clinical judgment of prescriber: entacapone, a dopamine agonist, a monoamine oxidase-B (MAO-B) inhibitor and amantadine.
    - Must be able to administer the medication and care for the administration port and infusion pump. Alternatively, trained personnel or a care partner must be available to perform these tasks reliably.

**Exclusion Criteria:**

- Patients with a contraindication to the insertion of a PEG-J tube.
- Patients with severe psychosis or dementia.

**Renewal Criteria:**

- Patients continue to demonstrate a significant reduction in the time spent in the off state and/or in ongoing levodopa-induced dyskinesias, along with and an improvement in the related disability.

**Clinical Note:**

- Time in the off state, frequency of motor fluctuations, and severity of associated disability should be assessed by a movement disorder subspecialist and be based on an adequate and reliable account from longitudinal specialist care, clinical interview of a patient and/or care partner, or motor symptom diary.

**Claim Notes:**

- Must be prescribed by a movement disorder subspecialist who has appropriate training in the use of Duodopa and is practicing in a movement disorder clinic that provides ongoing management and support for patients receiving treatment with Duodopa.
- Approval period: 1 year.

## 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 *(250mg, 500mg Tablet)*

- See **Fluoroquinolones, Respiratory**

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

## LINEZOLID *(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 and 10mg, 20mg, 30mg, 40mg, 50mg, and 60mg Chewable Tablet and generic brands)*

- For treatment of patients with attention deficit hyperactivity disorder who have tried extended-release methylphenidate, dexamphetamine or mixed salts amphetamine with unsatisfactory results.

**Claim Note:**

- The maximum dose reimbursed is 60mg daily.

## LONG-ACTING BETA$_2$-AGONISTS *(Salmeterol)*

- For the treatment of chronic obstructive pulmonary disease (COPD), as defined by spirometry, in patients who:
    - experience inadequate control while being treated with a long-acting muscarinic antagonist; OR
    - are intolerant to a long-acting muscarinic antagonist.

**** [Criteria Code 16]** has been added for use effective June 3, 2024. Criteria code 16 is for inhalers prescribed by a respirologist, clinical immunologist, allergist, internist, medical oncologist or thoracic surgeons.

**Clinical Note:**

- COPD is defined by spirometry as a post-bronchodilator FEV1/FVC ratio less than 0.7. 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. mMRC score and/or CAT score).

## LONG-ACTING BETA$_2$-AGONISTS/INHALED CORTICOSTEROIDS *(Formoterol, In Combination; Indacterol, in Combination; Salmeterol, In Combination; Vilanterol, In Combination)*

### ASTHMA

- For the treatment of asthma in patients who:
    - are compliant with optimal doses of inhaled corticosteroids; AND
    - remain poorly controlled.

** **[Criteria Code 16]** has been added for use effective June 3, 2024. Criteria code 16 is for inhalers prescribed by a

respirologist, clinical immunologist, allergist, internist, medical oncologist or thoracic surgeons.

**Clinical Notes:**

- Poorly controlled asthma is defined by the presence of persistent symptoms (such as frequent daytime symptoms, nighttime awakenings, activity limitations, increased use of short-acting beta2-agonists, and/or frequent exacerbations) indicating the need for additional symptom management.

**Products and Strengths Approved:**

| | |
|---|---|
| **Atectura** | • 150mcg/80mcg, 150mcg/160mcg and 150mcg/320mcg Capsule for Inhalation |
| **Advair and generic brands** | • 50/100mcg, 50/250mcg and 50/500mcg Diskus<br>• HFA 25/125 mcg/dose<br>• HFA 25/250 mcg/dose Inhaler |
| **Breo Ellipta** | • 100mcg/25mcg and 200mcg/25mcg dry powder for inhalation |
| **Symbicort** | • 100/6mcg Turbuhaler<br>• 200/6mcg Turbuhaler |
| **Zenhale** | • 5/100mcg and 5/200mcg |

**OVERLAPPING ASTHMA AND CHRONIC OBSTRUCTIVE PULMONARY DISEASE**

- For the treatment of patients with asthma and chronic obstructive pulmonary disease (ACO) overlap, based on patient history and lung function studies indicating an ACO diagnosis.
    - Please provide details to support the ACO diagnosis (patient symptoms, risk factors, spirometry etc.).

**** [Criteria Code 16]** has been added for use effective June 3, 2024. Criteria code 16 is for inhalers prescribed by a respirologist, clinical immunologist, allergist, internist, medical oncologist or thoracic surgeons.

**Products and Strengths Approved:**

| | |
|---|---|
| **Advair and generic brands** | • 50/100mcg Diskus<br>• 50/250mcg Diskus<br>• 50/500mcg Diskus |
| **Breo Ellipta** | • 100mcg/25mcg dry powder for inhalation |
| **Symbicort** | • 100/6mcg Turbuhaler<br>• 200/6mcg Turbuhaler |

**CHRONIC OBSTRUCTIVE PULMONARY DISEASE**

- For the treatment of chronic obstructive pulmonary disease (COPD), as defined by spirometry, in combination with a long-acting muscarinic antagonist (LAMA), for patients who:
    - meet criteria for triple therapy (LAMA/LABA/ICS); AND
    - are unable to use fixed dose triple therapy options (Trelegy 100-62.5-25 mcg or Breztri 160-7.2-5 mcg).

**** [Criteria Code 16]** has been added for use effective June 3, 2024. Criteria code 16 is for inhalers prescribed by a respirologist, clinical immunologist, allergist, internist, medical oncologist or thoracic surgeons.

**Clinical Note:**

- COPD is defined by spirometry as a post-bronchodilator FEV1/FVC ratio less than 0.7. 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. mMRC score and/or CAT score).

**Products and Strengths Approved:**

| | |
|---|---|
| **Advair and generic brands** | • 50/100mcg Diskus<br>• 50/250mcg Diskus<br>• 50/500mcg Diskus |
| **Breo Ellipta** | • 100mcg/25mcg dry powder for inhalation |
| **Symbicort** | • 100/6mcg Turbuhaler<br>• 200/6mcg Turbuhaler |

## LONG-ACTING BETA$_2$-AGONISTS/LONG-ACTING MUSCARINIC ANTAGONISTS *(Formoterol and Aclidinium Bromide; Indacaterol and Glycopyrronium Bromide; Olodaterol and Tiotropium Bromide; Vilanterol and Umeclidinium Bromide)*

- For the treatment of chronic obstructive pulmonary disease (COPD), as defined by spirometry, in patients who:
  - have moderate to severe COPD (i.e. CAT score ≥ 10 or mMRC score ≥ 2); OR
  - have experienced an exacerbation in the previous year while on monotherapy i.e. long-acting beta-2 agonist (LABA) OR long-acting muscarinic antagonist (LAMA)

**** [Criteria Code 16]** has been added for use effective June 3, 2024. Criteria code 16 is for inhalers prescribed by a respirologist, clinical immunologist, allergist, internist, medical oncologist or thoracic surgeons.

**Clinical Notes:**

- COPD is defined by spirometry as a post-bronchodilator FEV1/FVC ratio less than 0.7. 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. mMRC score and/or CAT score).
- LAMA/LABA combinations are not intended to be used with an inhaled corticosteroid (ICS) unless criteria for triple inhaled therapy (LAMA/LABA/ICS) is met and the patient is unable to use fixed dose triple therapy options (Trelegy 100-62.5-25 mcg or Breztri 160-7.2-5 mcg).

## LONG-ACTING MUSCARINIC ANTAGONISTS/LONG-ACTING BETA2-AGONISTS/INHALED CORTICOSTEROIDS *(Formoterol, Glycopyrronium Bromide and Budesonide; Vilanterol, Umeclidinium Bromide and Fluticasone Furoate)*

- For the treatment of chronic obstructive pulmonary disease (COPD), as defined by spirometry, for patients who
  - have experienced two or more exacerbations of COPD requiring treatment with antibiotics and/or systemic corticosteroids; OR
  - at least one exacerbation of COPD requiring hospitalization or an emergency department visit; OR
  - have moderate symptom burden (i.e. CAT score ≥ 10 or mMRC score ≥ 2) despite treatment with dual therapy with a long-acting muscarinic antagonist plus a long-acting beta2-agonist (LAMA/LABA) or a long-acting beta2-agonist plus an inhaled corticosteroid (LABA/ICS).

**** [Criteria Code 16]** has been added for use effective June 3, 2024. Criteria code 16 is for inhalers prescribed by a respirologist, clinical immunologist, allergist, internist, medical oncologist or thoracic surgeons.

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

**Clinical Note:**

- COPD is defined by spirometry as a post-bronchodilator FEV1/FVC ratio less than 0.7. 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. mMRC score and/or CAT score).

## 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.

## *LORLATINIB *(Lorbrena 25mg and 100mg Tablet)*

- As monotherapy for the first-line treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive locally advanced (not amenable to curative therapy) or metastatic non-small cell lung cancer (NSCLC).

**Clinical Notes:**

- Patients should have a good performance status.
- Treatment should continue until disease progression or unacceptable toxicity.
- Patients must not have had any prior systemic treatment for advanced or metastatic disease.
- Patients are not eligible for subsequent ALK inhibitor therapy following disease progression on lorlatinib.
- Patients may be switched to an alternate ALK inhibitor in the case of intolerance without disease progression.

## LUMASIRAN *(Oxlumo 94.5mg/0.5mL Vial)*

For the treatment of pediatric and adult patients with primary hyperoxaluria type 1 (PH1) to lower urinary oxalate levels who meet the following criteria:

- A confirmed genetic diagnosis of PH1.
- In whom urinary oxalate can be measured must be unable to normalize urine oxalate excretion while staying compliant with standard of care therapy, including vitamin B6 for a duration of 3 to 6 months.

**Renewal Criteria:**

- Has not undergone a liver transplant with or without a kidney transplant.
- Has not shown evidence of loss of response or no response, defined as lowering 24-hour urine oxalate to less than 1.5 times the ULN or patients in whom urinary oxalate can be measured.

**Claim Notes:**

- Must be initially prescribed by a nephrologist or metabolic diseases specialist with experience in the diagnosis and management of PH1.
- Renewals can be through a pediatrician instead of nephrologist or metabolic diseases physician.
- Approvals will be for a maximum of:

| Body Weight Range (kg) | Loading Dose | Maintenance Dose |
|---|---|---|
| Less than 10 kg | 6mg/kg once monthly for 3 doses | 3 mg/kg once monthly, beginning 1 month after the last loading dose. |
| 10 kg to less than 20 kg | 6mg/kg once monthly for 3 doses | 6 mg/kg once every 3 months:<br>give the first maintenance dose 1 month after the last loading dose and quarterly thereafter |

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

| Body Weight Range (kg) | Loading Dose | Maintenance Dose |
|---|---|---|
| 20 kg and above | 3mg/kg once monthly for 3 doses | 3 mg/kg once every 3 months:<br>give the first maintenance dose 1 month after the last loading dose and quarterly thereafter. |

- Initial Approval: 6 months
- Renewals: 12 months

## LUSPATERCEPT *(Reblozyl 25mg and 75mg Vial)*

### BETA-THALASSEMIA ANEMIA

- For the treatment of adult patients with RBC transfusion-dependent anemia associated with beta-thalassemia. Patients must be receiving regular transfusions, defined as:
    - 6 to 20 RBC units in the 24 weeks prior to initiating treatment with luspatercept, AND
    - No transfusion-free period greater than 35 days in the 24 weeks prior to initiating treatment with luspatercept.

**Renewal Criteria:**

- Patients must demonstrate an initial response, defined as a ≥33% reduction in transfusion burden (RBC units/time) compared to the pre-treatment baseline RBC transfusion burden, measured over 24 weeks prior to initiating treatment with luspatercept.
- For continued coverage, patients should maintain a reduction in transfusion burden of ≥33% compared to the pre-luspatercept transfusion burden.
- Luspatercept should be discontinued if a patient does not respond after nine weeks of treatment (three doses) at the maximum dose.

**Claim Notes:**

- The patient should be under the care of a specialist with experience in managing patients with beta-thalassemia.
- The maximum dose of luspatercept should not exceed 1.25mg/kg (or 120mg total dose) once every three weeks.
- Initial Approval: 6 months
- Renewal Approval: 1 year

### MYELODYSPLASTIC SYNDROMES

- For the treatment of adult patients with red blood cell (RBC) transfusion–dependent anemia associated with very low- to intermediate-risk MDS who have ring sideroblasts and who have failed or are not suitable for erythropoietin-based therapy.

**Renewal Criteria:**

- Patients should be RBC transfusion independent over a minimum of 16 consecutive weeks within the first 24 weeks of treatment initiation.
- For continued coverage, patients should be RBC transfusion independent over a minimum of 16 consecutive weeks within the previous approval period.

**Claims Notes:**

- Treatment should be initiated by a specialist with expertise in managing and treating patients with MDS.
- The maximum dose of luspatercept should not exceed 1.75mg/kg (or 168mg total dose) once every three weeks.
- Approval: 6 months

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

## MACITENTAN *(Opsumit 10mg Tablet)*

- For the treatment of patients with Group 1 pulmonary arterial hypertension (PAH) with a World Health Organization (WHO) functional class of at least II.

**Clinical Note:**

- The diagnosis of PAH should be confirmed by right heart catheterization.

**Claim Notes:**

- Must be prescribed by, or in consultation with, a physician experienced in the treatment of PAH.
- Combined use of more than one endothelin receptor antagonists will not be reimbursed.
- The maximum dose of macitentan that will be reimbursed is 10mg daily.

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

- For the treatment of hypomagnesemia.

## MARALIXIBAT *(Livmarli 9.5mg/mL Oral Solution)*

- For treatment of patients aged 12 months and older with a diagnosis of Alagille syndrome (ALGS) who have demonstrated the following:
    - Evidence of cholestasis (must include at least 1 of the following):
        - total serum bile acid (sBA) > 3 × ULN for age
        - conjugated bilirubin > 1 mg/dL
        - fat-soluble vitamin deficiency otherwise unexplainable
        - GGT > 3 × ULN for age
        - intractable pruritus explainable only by liver disease
    - Moderate to severe itch defined as an average daily score of 2 or more on the ItchRO or CSS for 2 consecutive weeks.
    - Currently treated with, or have received an adequate trial with, a systemic treatment for pruritus before initiating maralixibat.

**Exclusion Criteria:**

- Patients with biliary diversion, previous liver transplant, decompensated cirrhosis, or history or presence of other concomitant liver disease.

**Renewal Criteria:**

- Requests for renewal must provide proof of beneficial clinical effect defined as an improvement in pruritus to minimal or no itch (a score of 1 or less) on the ItchRO or CSS.
- For patients who begin treatment with severe itch (equivalent to an ItchRO or CSS score of 4), an improvement in pruritus by a score of 1 will be considered for coverage renewal.

**Discontinuation Criteria:**

- Reimbursement of maralixibat will be discontinued if the patient receives liver transplantation or biliary diversion surgery.

**Clinical Notes:**

- An adequate trial for systemic treatment of pruritus is defined as a trial of 1 to 3 months with appropriate dosing of a systemic treatment for pruritus based on usual care. This may include UDCA, rifampicin, sertraline, naltrexone,

cholestyramine, or antihistamines.

**Claim Notes:**

- Initial approval duration: 6 months
- Renewal approval duration: 1 year
- The patient should be under the care of a hepatologist with experience in managing ALGS.
- Approvals will be for a maximum of 28.5 mg (3 mL) daily.

## MARIBAVIR *(Livtencity 200mg Tablet)*

- For the treatment of adult patients with post-transplant cytomegalovirus (CMV) infection/disease who are refractory[1] (with or without genotypic resistance) to 1 or more of the following antiviral therapies: valganciclovir, ganciclovir, foscarnet, or cidofovir.

[1]Refractory to an antiviral is defined as a lack of change in CMV viral load or increase in CMV viral load after at least 2 weeks of appropriately dosed treatment.

**Renewal Criteria:**

- Subsequent treatment may be considered for patients who have a recurrence of CMV viremia after a previous successful course of therapy with maribavir.

**Discontinuation Criteria:**

- Patients exhibit any of the following:
    - No change or an increase in CMV viral load after at least 2 weeks of maribavir treatment; OR
    - Confirmed CMV genetic mutation associated with resistance to maribavir.

**Claim Notes:**

- Must be prescribed by clinicians with experience and expertise in transplant medicine, transplant infectious disease, or infectious diseases.
- Approvals: 6 month

## MAVACAMTEN *(Camzyos 2.5mg, 5mg, 10mg and 15mg Capsule)*

For the treatment of patients with symptomatic obstructive hypertrophic cardiomyopathy (oHCM) of New York Heart Association (NYHA) class II to III who meet all of the following criteria:

- documented left ventricular ejection fraction (LVEF) ≥ 55% at rest determined by echocardiography.
- left ventricular (LV) wall thickness ≥15 mm (or ≥13 mm with a family history of hypertrophic cardiomyopathy).
- left ventricular outflow tract (LVOT) peak gradient ≥ 50 mm Hg at rest, after Valsalva maneuver, or post exercise, as confirmed by echocardiography.
- must be receiving beta-blocker or calcium channel blocker therapy and experience clinical deterioration in symptoms or echocardiography while receiving either of these treatments or for patients who have an intolerance or contraindication to treatments, details must be provided.

**Renewal Criteria:**

- Patients must not have any of the following:
    - a LVEF ≤ 30%
    - received septal reduction therapy.

**Claim Notes:**

- Must be prescribed by, or in consultation with a specialist in cardiology.
- Approvals will be for a maximum of up to 5mg daily for 12 weeks, then up to 15mg daily thereafter.
- Initial Approval:12 weeks.
- Renewal Approval: 1 year.

## MECASERMIN *(Increlex 10mg/mL Vial)*

- For the treatment of growth failure in children and adolescents from 2 to 18 years with confirmed severe primary insulin-like growth factor-1 deficiency (SPIGFD) who meet the following criteria:
    - Epiphyseal closure has not yet occurred; AND
    - Have a confirmed diagnosis of SPIGFD, defined by:
        - a known genetic mutation recognized as a cause of SPIGFD, AND/OR
        - has clinical and biochemical features of SPIGFD

**Renewal Criteria:**

- Treatment with mecasermin must be discontinued upon the occurrence of any of the following:
    - Height velocity is less than 1cm per 6 months or less than 2cm per year, OR
    - Bone age is more than 16 years in boys and 14 years in girls.

**Claim Notes:**

- The patient must be under the care of a pediatric endocrinologist
- Mecasermin must not be prescribed concomitantly with recombinant GH treatment
- Approvals: 1 year

## MEPOLIZUMAB *(Nucala 100mg/mL Autoinjector and 100mg/mL Prefilled Syringe)*

### EOSINOPHILIC ASTHMA

- 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: 1 year.
- Renewal Approval: 1 year.

### SEVERE CHRONIC RHINOSINUSITIS WITH NASAL POLYPS

For the treatment of patients with severe chronic rhinosinusitis with nasal polyps (CRSwNP) who meet all of the following criteria:

- have endoscopically or CT-documented bilateral nasal polyps, and
- have undergone at least 1 prior surgical intervention for nasal polyps or have a contraindication to surgery, and
- are tolerant and able to continue use of inhaled nasal corticosteroids but have refractory symptoms despite use of inhaled corticosteroids for 3 months at maximally tolerated doses.

**Renewal Criteria:**

- Requests for renewal must exhibit a clinically meaningful response defined as:
    - a decrease of 8.9 points or greater on the Sino-nasal Outcome Test (SNOT-22) relative to their baseline score, or
    - a decrease of 1 point or greater on the endoscopic Nasal Polyp Score (NPS) relative to their baseline score.

**Clinical Notes:**

- A baseline and annual SNOT-22 or endoscopic NPS must be provided.
- Patients should be assessed for a response to mepolizumab every 12 months.
- Maximum dose approved: 100mg every 4 weeks
- Renewal Approval: 12 months.

**Claim Notes:**

- Must be prescribed by an otolaryngologist, allergist or respirologist with expertise in managing severe CRSwNP

## *METHADONE *(Metadol 1mg, 5mg, 10mg, 25mg Tablet and generic brands)*

- 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 and generic brands)*

- For the treatment of patients with attention deficit hyperactivity disorder who have tried other forms of extended-release methylphenidate with unsatisfactory results.

**Claim Note:**

- The maximum dose reimbursed is 80mg daily.

## METRELEPTIN *(Myalepta 3mg, 5.8mg and 11.3mg Vial)*

- For the treatment of patients with either of the following:
    - Confirmed congenital generalized lipodystrophy (GL) (Berardinelli-Seip syndrome) or acquired GL (Lawrence syndrome) in adults and children aged 2 years and older with at least 1 metabolic abnormality (diabetes mellitus, insulin resistance, or hypertriglyceridemia).
    - Confirmed familial partial lipodystrophy (PL) or acquired PL (Barraquer-Simons syndrome) in adults and children aged 12 years and older with persistent significant metabolic abnormalities (as defined by baseline hemoglobin A1C ≥ 6.5% and/or fasting TGs ≥ 5.65 mmol/L), for whom standard treatments have failed to achieve adequate metabolic control after at least 12 months since initiating standard treatments.
- Genetic testing must be conducted and:
    - If genetic testing is positive, then diagnosis is confirmed and treatment with metreleptin can be initiated.
    - If after conducting genetic testing lipodystrophy is not confirmed, treatment can be initiated in patients with confirmed clinical diagnosis based on a comprehensive clinician assessment and if fasting leptin levels are < 12.0 ng/mL in females and < 8.0 ng/mL in males older than 5 years of age or < 6 ng/mL in children aged 6 months to 5 years.

**Exclusion Criteria:**

- Patients should not be pregnant or lactating or have HIV-associated LD.

**Initial Renewal Criteria:**

- The prescriber must provide proof of beneficial metabolic effect defined as 1 or both of the following:
    - Actual hemoglobin A1C reduction of at least 0.5% from baseline.
    - Percent fasting TG reduction of at least 15% from baseline.

**Subsequent Renewal Criteria:**

- The prescriber must provide proof of maintenance of reduction in hemoglobin A1C and/or fasting TG from baseline every 12 months for subsequent authorizations.

**Clinical Notes:**

- A1C and/or fasting TG levels must be provided.

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

**Claim Notes:**

- Initial and renewal approval duration: 12 months
- Prescribing should be limited to endocrinologists or pediatric endocrinologists with expertise in treating lipodystrophy.
- Approvals will be for a maximum dose of 0.13 mg/kg daily for patients ≤40kg and 10mg daily for patients >40 kg.

### *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)

### 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.

### MITOTANE *(Lysodren 500mg Tablet)*

- For the treatment of advanced adrenocortical cancer.
- For the treatment of metastatic adrenocortical cancer in combination with doxorubicin, etoposide, cisplatin.

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

- See **OAB Medications**

### MIRIKIZUMAB *(Omvoh 20mg/mL Vial, 100mg/mL Prefilled Syringe and 100mg/mL Prefilled Pen)*

- 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.
- Combination therapy with biologic therapies or JAK inhibitors for UC will not be reimbursed.
- Initial Approval: 6 months
- Renewal Approval: 1 year. Confirmation of continued response is required.
- Initial reimbursement will be 300mg at Weeks 0, 4 and 8. If patients do not have adequate therapeutic response at Week 12, 300mg will be reimbursed at Weeks 12, 16 and 20. Subsequent reimbursement for maintenance dosing is 200mg every 4 weeks.

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

- For the treatment of narcolepsy confirmed by sleep study

### *MOXIFLOXACIN *(400mg Tablet)*

- See **Fluoroquinolones, Respiratory**

### MOXIFLOXACIN *(Vigamox 0.5% Ophthalmic Solution and generic brands)*

- See **Fluoroquinolones, Ophthalmic**

### NARATRIPTAN *(1mg, 2.5mg Tablet)*

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

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

- For the treatment of adult patients with relapsing remitting multiple sclerosis (RRMS) who meet all of the following criteria:
    - Ambulatory with or without aid (i.e. has a recent Expanded Disability Status Scale (EDSS) score of less than or equal to 6.5)
    - Experienced one or more disabling relapses or new MRI activity in the past two years
    - Refractory or intolerant to at least one disease modifying therapy (e.g., interferon, glatiramer, dimethyl fumarate, teriflunomide, ocrelizumab)

**Renewal Criteria:**

- Evidence of continued benefit must be provided (i.e. stability or reduction in the number of relapses in the past year or stability or improvement of EDSS score obtained within the previous 90 days).

**Clinical Note:**

- Treatment should be discontinued for patients with an EDSS score of greater than or equal to 7.
- A relapse is defined as the appearance of new or worsening neurological symptoms in the absence of fever or infection, lasting at least 24 hours yet preceded by stability for at least one month and accompanied by new objective neurological findings observed through evaluation by a neurologist.

**Claim Notes:**

- Must be prescribed by a neurologist with experience in the diagnosis and management of multiple sclerosis.
- Combined use with other disease modifying therapies to treat RRMS will not be reimbursed.
- Initial Approval: 2 years
- Renewal Approval: 5 years

## *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, **[Criteria Code 01]** OR
    - moderately emetogenic chemotherapy who have had inadequate symptom control using a 5-HT3 antagonist and dexamethasone in a previous cycle. **[Criteria Code 02]**

**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 and generic brands)*

**First Line:**

- For the first-line treatment of adult patients with Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase.

**Second Line:**

- For the treatment of chronic phase and accelerated phase Philadelphia chromosome positive (Ph+) chronic myeloid leukemia (CML) in adult patients who:
- Are resistant to imatinib;
- Have progressed to accelerated phase while on imatinib;
- Are intolerant to previous oral tyrosine kinase inhibitors (TKIs) (i.e. imatinib or dasatinib or both). Sequential use of nilotinib and dasatinib is not permitted except in cases of intolerance (i.e. grade 3 or 4 toxicity).

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

### IDIOPATHIC PULMONARY FIBROSIS (IPF)

- **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;

- Patient is under the care of a physician with experience in IPF;
- Initial Approval: 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.

### CHRONIC FIBROSING INTERSTITIAL LUNG DISEASE

**Initiation criteria:**

- For the treatment of chronic fibrosing interstitial lung disease with a progressive phenotype confirmed by a specialist in interstitial lung diseases, if the following criteria are met:
  - the patient has a forced vital capacity greater than or equal to 45% of predicted.

**Renewal criteria:**

- The patient must not experience a more severe progression of disease, defined as an absolute decline in percent predicted forced vital capacity of 10% or greater over the preceding year of treatment with nintedanib.

**Clinical Note:**

- The patient's clinical status should be evaluated every 12 months.

**Claim Notes:**

- The patient is under the care of a physician with experience in interstitial lung diseases.
- Concurrent treatment of nintedanib with pirfenidone should not be reimbursed.
- Approval Period: 12 months

## *NIRAPARIB *(Zejula 100mg Tablet)*

### NEWLY DIAGNOSED ADVANCED EPITHELIAL OVARIAN, FALLOPIAN TUBE OR PRIMARY PERITONEAL CANCER

- As monotherapy maintenance treatment of patients with newly-diagnosed ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) to at least 4 cycles of first-line platinum-based chemotherapy. Eligible patients should have high-grade serous or endometrioid tumours classified as stage III or IV according to the International Federation of Gynecology and Obstetrics (FIGO) criteria.

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

**Clinical Notes:**

- Patients should have a good performance status.
- Maintenance therapy with niraparib should begin within 12 weeks of completion of platinum- based chemotherapy and may continue for up to 3 years, or until disease progression or unacceptable toxicity, whichever occurs first.
- Patients who have stable brain metastases are eligible for treatment with niraparib.
- 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 niraparib.
- Niraparib in combination with bevacizumab is not funded.

**RELAPSED, PLATINUM SENSITIVE ADVANCED EPITHELIAL OVARIAN, FALLOPIAN TUBE OR PRIMARY PERITONEAL CANCER**

- As monotherapy maintenance treatment for patients with relapsed, platinum-sensitive high grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who have completed at least two previous lines of platinum-based chemotherapy, and have achieved a complete or partial response to the most recent platinum-based chemotherapy regimen.

**Clinical Notes:**

- 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.
- Patients must have received at least 4 cycles of the most recent platinum-based chemotherapy before starting treatment with niraparib.
- Maintenance therapy with niraparib should begin within 12 weeks of the last chemotherapy treatment and may continue until disease progression or unacceptable toxicity, whichever occurs first.
- Patients who have stable brain metastases are eligible for treatment with niraparib.
- 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 niraparib.

## *NIRAPARIB AND ABIRATERONE ACETATE *(Akeega 50mg/500mg and 100mg/500mg Tablet)*

- In combination with prednisone for the first-line treatment of adult patients with deleterious or suspected deleterious germline and/or somatic BRCA-mutated metastatic castration-resistant prostate cancer (mCRPC) in whom chemotherapy is not clinically indicated.

**Clinical Notes:**

- Patients should have a good performance status.
- Treatment should continue until disease progression or unacceptable toxicity.
- Eligible patients must have a confirmed germline and/or somatic BRCA1 or BRCA2 gene alteration prior to starting treatment.
- Patients should not have received prior treatment with a poly - (ADP ribose) polymerase (PARP) inhibitor, or with androgen-receptor-axis-targeted (ARAT) therapy (e.g., apalutamide, darolutamide, enzalutamide).
- Patients should not have received prior treatment with abiraterone or are within 4 months of initiating abiraterone in the mCRPC setting with no disease progression.

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

## NIRMATRELVIR/RITONAVIR *(Paxlovid 150mg/100mg and 150mg /100mg (Renal) Tablet)*

For the treatment of adult patients with a diagnosis of mild-to-moderate coronavirus disease 2019 (COVID-19), confirmed with a positive COVID-19 test, and within 5 days of symptom onset in patients who meet any one of the following criteria:

- severely immunosuppressed due to one or more of the following conditions **[Criteria Code 01]**:
    - Solid organ transplant recipients; or
    - Treated for malignant hematologic condition; or
    - Bone marrow, stem cell transplant or transplant-related immunosuppressant use; or
    - Receipt of an AntiCD20 agents or B-cell depleting agents (such as rituximab) in the previous 2 years; or
    - Severe primary immunodeficiencies
- moderately immunosuppressed due to one or more of the following conditions **[Criteria Code 02]**:
    - Treatment for cancer including solid tumors; or
    - Significantly immunosuppressing drugs (e.g., biologic in the last three months, oral immune suppressing medication in the last 1 month, oral steroid [20mg/day of prednisone equivalent taken on an ongoing basis] in the last month, or immune suppressing infusion or injection in the last three months): or
    - Advanced untreated HIV infection or treated HIV[1]; or
    - Moderate primary immunodeficiencies; or
    - Renal conditions (i.e., hemodialysis, peritoneal dialysis, glomerulonephritis treated with steroids, eGFR<15mL/min

[1] Presence of a diagnosis code (2 MSP or 1 DAD/NACRS) for AIDS at any time or presence of 1 MSP diagnosis for AIDS within 2 weeks after a CD4 lab test, or presence of a CD4 lab test result with CD4 count ≤ 200/mm3 or CD4 fraction ≤ 15% at any time.

## 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.

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

- For prevention of recurrent spontaneous bacterial peritonitis. **[Criteria Code 07]**

## 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.
- 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:**

- Coverage for nusinersen will not be provided in combination with other SMA drug therapies or post administration of onasemnogene abeparvovec.

## OAB MEDICATIONS *(Fesoterodine Fumarate and Mirabegron)*

- 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

## OCRELIZUMAB *(Ocrevus 300mg/10mL Vial)*

### PRIMARY PROGRESSIVE MULTIPLE SCLEROSIS

- For the treatment of adult patients with early primary progressive multiple sclerosis (PPMS) who meet all of the following criteria:
  - Recent Expanded Disability Status Scale (EDSS) score equal to or less than 6.5
  - Recent Functional Systems Scale (FSS) score of at least 2 for the pyramidal functions component due to lower extremity findings
  - Disease duration of 10 years for those with an EDSS of less than or equal to 5 or disease duration less than 15 years for those with an EDSS greater than 5
  - Diagnostic imaging features characteristic of inflammatory activity

**Clinical Note:**

- Treatment should be discontinued for patients with an EDSS score of greater than or equal to 7.

**Claim Notes:**

- Must be prescribed by a neurologist with experience in the diagnosis and management of multiple sclerosis.
- Initial Approval: 2 years
- Renewal Approval: 5 years

### RELAPSING REMITTING MULTIPLE SCLEROSIS

- For the treatment of adult patients with relapsing remitting multiple sclerosis (RRMS) who meet all of the following criteria:
  - Experienced one or more disabling relapses or new MRI activity in the last two years
  - Ambulatory with or without aid (i.e. has a recent Expanded Disability Status Scale (EDSS) score of less than or equal to 6.5)

**Clinical Note:**

- Treatment should be discontinued for patients with an EDSS score of greater than or equal to 7.

**Claim Notes:**

- Must be prescribed by a neurologist with experience in the diagnosis and management of multiple sclerosis.
- Combined use with other disease modifying therapies to treat RRMS will not be reimbursed.
- Initial Approval: 2 years
- Renewal Approval: 5 years

## OFATUMUMAB *(Kesimpta 20mg/0.4mL Prefilled Pen)*

- For the treatment of adult patients with relapsing remitting multiple sclerosis (RRMS) who meet all of the following criteria:
    - Ambulatory with or without aid (i.e. has a recent Expanded Disability Status Scale (EDSS) score of less than or equal to 6.5)
    - Experienced one or more disabling relapses or new MRI activity in the past two years

**Clinical Note:**

- Treatment should be discontinued for patients with an EDSS score of greater than or equal to 7.

**Claim Notes:**

- Must be prescribed by a neurologist with experience in the diagnosis and management of multiple sclerosis.
- Combined use with other disease modifying therapies to treat RRMS will not be reimbursed.
- Initial Approval: 2 years
- Renewal Approval: 5 years

## OFLOXACIN, OPHTHALMIC *(Ocuflox 0.3% Ophthalmic Solution)*

- See **Fluoroquinolones, Ophthalmic**

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

### HIGH-RISK EARLY BREAST CANCER

For the treatment of adult patients with germline BRCA-mutated (gBRCAm) HER2-negative high-risk early breast cancer who meet one of the following criteria:

- For patients who underwent upfront surgery followed by adjuvant chemotherapy:
    - If TNBC: must have node-positive disease or pT ≥ 2cm, or
    - If HR-positive, HER2-negative: must have ≥ 4 involved pathologically confirmed lymph nodes

    OR
- For patients who received neoadjuvant chemotherapy followed by surgery:
    - If TNBC: must have residual invasive disease, or
    - If HR-positive, HER2-negative: must have residual invasive disease and deemed high-risk using a risk assessment tool.

**Clinical Notes:**

- Patients should have a good performance status.
- Treatment should continue until disease recurrence, unacceptable toxicity, or to a maximum of one year, whichever occurs first.

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

- Must have confirmed gBRCAm prior to starting therapy.
- Patients must have completed chemotherapy containing anthracyclines and/or taxanes. Patients who stop chemotherapy early for toxicity are eligible.

### NEWLY-DIAGNOSED, ADVANCED, BRCA-MUTATED

- As monotherapy maintenance treatment of patients with newly-diagnosed, advanced, BRCA-mutated (germline or somatic), high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) to at least 4 cycles of first-line platinum-based chemotherapy.

**Clinical Notes:**

- Patients should have a good performance status.
- Maintenance therapy with olaparib should begin within 12 weeks of completion of platinum-based chemotherapy.
- 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.
- Treatment should continue until unacceptable toxicity, disease progression, or to a maximum of 2 years of therapy if no evidence of disease, whichever comes first.[1]
- Imaging is required for patients who are delayed in starting olaparib therapy, i.e. greater than 12 weeks after completion of platinum-based chemotherapy, or who have had a break in therapy for more than 14 days, to rule out progression prior to starting or re-starting olaparib.
- Olaparib in combination with bevacizumab is not funded. Patients already on bevacizumab maintenance at the time of olaparib funding may be switched to olaparib, as long as there is no evidence of progression on imaging and is within 12 weeks of completion of chemotherapy.

1. Patients with a partial response or stable disease at 2 years may continue to receive olaparib at the discretion of the treating physician.

### RELAPSED, BRCA-MUTATED

- 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:**

- Treatment should continue until unacceptable toxicity or disease progression.
- 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.
- 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.

### FIRST-LINE METASTATIC CASTRATE-RESISTANT PROSTATE CANCER

- In combination with abiraterone and prednisone for the first-line treatment of adult patients with deleterious or suspected deleterious germline and/or somatic BRCA-mutated metastatic castration-resistant prostate cancer (mCRPC) in whom chemotherapy is not clinically indicated.

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

**Clinical Notes:**

- Patients should have a good performance status.
- Treatment should continue until disease progression or unacceptable toxicity.
- Eligible patients must have a confirmed germline and/or somatic BRCA1 or BRCA2 gene alteration prior to starting treatment.
- Patients should not have received prior treatment with a poly - (ADP ribose) polymerase (PARP) inhibitor, or with androgen-receptor-axis-targeted (ARAT) therapy (e.g., apalutamide, darolutamide, enzalutamide).
- Patients should not have received prior treatment with abiraterone, or are within 4 months of initiating abiraterone in the mCRPC setting with no disease progression.

**PREVIOUSLY-TREATED METASTATIC CASTRATE-RESISTANT PROSTATE CANCER**

- For the treatment of patients with metastatic castration-resistant prostate cancer (mCRPC) with deleterious or suspected deleterious germline and/or somatic mutations in the homologous recombination repair (HRR) genes BRCA1, BRCA2 or ATM and who have progressed on prior treatment with androgen-receptor-axis-targeted (ARAT) therapy.

**Clinical Note:**

- Patients should have a good performance status and treatment should be continued until disease progression or unacceptable toxicity.

## OMALIZUMAB *(Xolair 150mg Powder for Injection and Prefilled Syringe)*

- 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 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)

## 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.

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

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

- For the treatment of overactive bladder (OAB) with symptoms of urgency, urgency incontinence, and urinary frequency, in adult patients who have an intolerance or insufficient response to an adequate trial of at least two other pharmacologic treatments (e.g. anticholinergics, mirabegron).

**Renewal criteria:**

- Requests for renewal should provide objective evidence of a treatment response, defined as a reduction of at least 50% in the frequency of urinary incontinence episodes.

**Claim Notes:**

- Must be prescribed and administered by a urologist.
- Initial Approval: 12 weeks (one dose).
- Renewal Approval: Maximum of 3 doses per year in responders, at a frequency of no more than once every twelve weeks.

## 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 *(4mg, 8mg Tablet, 4mg/5mL Oral Liquid and ODT Tablet)*

- 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, 6mg/mL Oral Suspension and generic brands)*

**Treatment: [Criteria Code 40]**

- For patients who test negative for COVID-19 and meet one of the following:
    1. have suspected[1] or test confirmed severe, complicated, or progressive[2] influenza OR
    2. are hospitalized[2] with suspected[1] or test confirmed influenza OR
    3. have suspected[1] or test confirmed influenza and are at higher risk of complications, which include the following age groups, chronic medical conditions, and persons:
        - Asthma and other chronic pulmonary disease, including asthma, bronchopulmonary dysplasia, cystic fibrosis, chronic bronchitis, and emphysema
        - Cardiovascular disease (excluding isolated hypertension; including congenital and acquired heart disease, such as congestive heart failure and symptomatic coronary artery disease)
        - Renal disease
        - Chronic liver disease
        - Diabetes mellitus and other metabolic diseases
        - Anemia and hemoglobinopathies, such as sickle cell disease

- Cancer, immunosuppression, or immunodeficiency due to disease (e.g.: HIV infection, especially if CD4 is <200) or management of underlying condition (solid organ transplant or hematopoietic stem cell transplant recipients)
- Neurological disease and neurodevelopmental disorders that compromise handling of respiratory secretions (cognitive dysfunction; spinal cord injury; neuromuscular, neurovascular, neurodegenerative, and seizure disorders; cerebral palsy; metabolic disorders)
- Children aged younger than 5 years[2]
- Individuals aged 65 years or older
- People of any age who are residents of nursing homes or other chronic care facilities
- Pregnancy and up to 4 weeks postpartum regardless of how the pregnancy ended[3]
- Obesity with a BMI ≥40 or a BMI >3 z-scores above the mean for age and gender
- Children and adolescents aged younger than 18 years undergoing treatment for long periods with acetylsalicylic acid because of the potential increase in Reye's syndrome associated with influenza
- Indigenous peoples

- For the treatment of long-term care and eligible[4] residential care residents with clinically suspected or lab confirmed influenza A or B upon advice of the Medical Officer of Health. 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.

**Prophylaxis: [Criteria Code 41]**

- For the prophylaxis of influenza A or B in long-term care and eligible[4] residential care residents where the facility has an outbreak upon advice of the Medical Officer of Health.
- A protocol has been developed by Public Health for the treatment of residents in long-term care facilities and eligible[4] residential care residents. 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.

**Notes:**

1. For suspected cases, discontinue oseltamivir if the lab test is negative
2. Among healthy children aged younger than 5 years, the risk of hospitalization is further increased among those aged younger than 2 years
3. The risk of influenza-related hospitalization increases with length of gestation (i.e., it is higher in the third trimester than in the second)
4. Eligible residents are people of any age who are residents of nursing homes or other chronic care facilities.

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

### STAGE IB-IIIA NON-SMALL CELL LUNG CANCER (NSCLC)

- For adjuvant therapy after tumour resection in patients with Stage IB-IIIA (AJCC 7th edition or equivalent) non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions [exon 19 del] or exon 21 [L858R] substitution mutations.

**Clinical Notes:**

- Patients should have a good performance status.
- Treatment with osimertinib should continue for a total duration of 3 years, or until disease recurrence or unacceptable toxicity.

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

- Osimertinib treatment should be initiated within 10 weeks of complete surgical resection if adjuvant chemotherapy was not administered, or within 26 weeks if adjuvant chemotherapy was administered.
- Retreatment with osimertinib in the metastatic setting will be considered if disease recurrence is at least 6 months following completion of adjuvant therapy.

**LOCALLY ADVANCED OR METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC) MONOTHERAPY**

- For the first-line treatment of patients with locally advanced (not amenable to curative-intent therapy) or metastatic non-small cell lung cancer (NSCLC) whose tumors have the following epidermal growth factor receptor (EGFR) mutations: exon 19 deletions [exon 19 del] or exon 21 [L858R] mutations. Eligible patients should be previously untreated in the locally advanced or metastatic setting and have a good performance status.

**Clinical Notes:**

- Treatment may continue until clinically meaningful disease progression or unacceptable toxicity.
- Retreatment with osimertinib in the metastatic setting will be considered if disease recurrence is at least 6 months following completion of adjuvant therapy.

**LOCALLY ADVANCED OR METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC) IN COMBINATION WITH CHEMOTHERAPY**

- In combination with pemetrexed and platinum-based chemotherapy for the first-line treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) whose tumors have EGFR exon 19 deletions or exon 21 (L858R) substitution mutations.

**Clinical Notes:**

- Patient should have a good performance status.
- Treatment with osimertinib should continue until disease progression or unacceptable toxicity.
- Pemetrexed and platinum-based chemotherapy is given for 4 cycles and pemetrexed maintenance therapy continued.
- Retreatment with osimertinib in the metastatic setting will be considered if recurrence is at least 6 months following completion of adjuvant therapy.

**LOCALLY ADVANCED OR METASTATIC T790M MUTATION-POSITIVE NON-SMALL CELL LUNG CANCER (NSCLC)**

- 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 Notes:**

- Patients currently receiving alternate first-line EGFR TKI's (e.g. erlotinib, gefitinib, afatinib) whose tumors have the noted EGFR mutations (exon 19 del or L858R) may be switched to osimertinib provided they meet all other funding criteria and have not experienced disease progression.
- Patients who have initiated treatment with chemotherapy prior to receiving results of the EGFR mutation status may be switched to osimertinib if otherwise eligible.
- Osimertinib may be continued until there is evidence of disease progression or the development of unacceptable toxicity.
- Retreatment with osimertinib in the metastatic setting will be considered if disease recurrence is at least 6 months following completion of adjuvant therapy.

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

## 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.

## OZANIMOD *(Zeposia 0.23mg & 0.46mg Initiation Pack and 0.92mg Cap)*

- For the treatment of adult patients with moderately to severely active ulcerative colitis (UC) who have a partial Mayo score > 4, and have 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.
- Concurrent use of biologics or Janus kinase inhibitors not approved.
- Maximum dose of 0.92mg daily with no dose escalation permitted.
- Initial Approval: 6 months.
- Renewal Approval: 1 year.

## *PALBOCICLIB *(Ibrance 75mg, 100mg and 125mg Tablet and generic brands)*

### ER POSITIVE, HER2-NEGATIVE ADVANCED BREAST CANCER IN COMBINATION WITH AN AROMATASE INHIBITOR (AI)

- 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 endocrine-based treatment for metastatic disease. Patients may have received up to one prior line of chemotherapy for advanced 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.
- 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. Patients eligible include:

- Pre and peri-menopausal patients (should be treated with a luteinizing hormone- releasing hormone (LHRH) agonist)
- Males
- Patients with bone-only metastases
- Patients who are HER2 equivocal by FISH testing (these patients are HER2 negative)
- Patients currently receiving first line aromatase inhibitor monotherapy for ER positive, HER2-negative metastatic breast cancer may have palbociclib added provided the above criteria is met.

- Patients with prior adjuvant treatment with abemaciclib plus endocrine therapy are eligible if disease progression occurred 6 months or greater after completion of adjuvant abemaciclib.

**HR POSTIVE, HER2-NEGATIVE ADVANCED OR METASTATIC BREAST CANCER IN COMBINATION WITH FULVESTRANT**

- In combination with fulvestrant for the treatment of patients with hormone receptor (HR) positive, HER 2 negative advanced or metastatic breast cancer, as initial endocrine-based therapy or following disease progression on endocrine therapy. Patients may have also received up to one prior line of chemotherapy for advanced disease. Patients should have a good performance status, without active or uncontrolled metastases to the central nervous system and can be of any menopausal status (Perimenopausal and premenopausal women must be treated with an LHRH agonist).

**Clinical Notes:**

- Treatment should continue until unacceptable toxicity or disease progression.
- Patients who progress ≤ 12 months from (neo) adjuvant therapy are eligible for treatment with palbociclib plus fulvestrant.
- Patients who experience disease progression on prior CDK 4/6 inhibitor therapy, fulvestrant or everolimus are not eligible for treatment with palbociclib with fulvestrant.
- Patients currently receiving fulvestrant monotherapy, and who have not progressed may have palbociclib added, provided they are CDK 4/6 inhibitor naïve and otherwise meet funding criteria.
- Patients who previously received everolimus plus exemestane will be eligible for funding of palbociclib plus fulvestrant on progression, provided that treatment was started prior to funding of CDK 4/6 + fulvestrant, patient must be CDK 4/6 naïve and otherwise meet funding criteria.
- Patients with prior adjuvant treatment with abemaciclib plus endocrine therapy are eligible if disease progression occurred 6 months or greater after completion of adjuvant abemaciclib.

## **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.

## PALOVAROTENE *(Sohonos 1mg, 1.5mg, 2.5mg, 5mg and 10mg Capsule)*

- Coverage is for females aged 8 years and above and males aged 10 years and above with a clinical diagnosis of fibrodysplasia ossificans progressiva (FOP) and the R206H ACVR1 mutation as confirmed by genetic testing.

**Clinical Notes:**

- Patients must not have complete ankylosis of the whole body.
- Palovarotene should be discontinued if it is agreed that the perceived balance of benefits and risks is no longer acceptable or if the patient progresses to complete ankylosis of the whole body.

**Claim Note:**

- Palovarotene must be prescribed by an expert in the diagnosis and management of FOP.

## PATISIRAN *(Onpattro 2mg/mL IV Solution)*

- For the treatment of polyneuropathy in adult patients with hereditary transthyretin-mediated amyloidosis (hATTR) who meet all of the following criteria:
    - Confirmed genetic diagnosis of hATTR.
    - Symptomatic with early-stage neuropathy[1].
    - Does not have New York Heart Association class III or IV heart failure.
    - Has not previously undergone a liver transplant.

**Discontinuation Criteria:**

- The patient is permanently bedridden and dependent on assistance for basic activities of daily living.

  **OR**
- The patient is receiving end-of-life care.

**Clinical Note:**

1. Symptomatic early-stage neuropathy is defined as polyneuropathy disability stage I to IIIB or familial amyloidotic polyneuropathy stage I or II.

**Claim Notes:**

- The patient must be under the care of a physician with experience in the diagnosis and management of hATTR.
- Combination therapy with other interfering ribonucleic acid drugs or transthyretin stabilizers used to treat hATTR will not be reimbursed.
- Initial Approval: 9 months.
- Renewal Approval: 12 months. Confirmation of continued response is required.

## *PAZOPANIB *(Votrient 200mg Tablet and generic brands)*

- For patients with advanced or metastatic renal cell carcinoma as either first-line therapy, or second-line therapy after failure of first-line immunotherapy.

**Clinical Notes:**

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

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

- Pazopanib may not be used after another tyrosine kinase inhibitor (i.e., sorafenib, or sunitinib) as sequential therapy.
- In the event of significant toxicity, a switch to another tyrosine kinase inhibitor (i.e., sorafenib or sunitinib) may be allowed.
- Both clear cell and non-clear cell histology are eligible for treatment.

## PDP-AMLODIPINE *(1mg/mL Oral Solution)*

- For patients who require administration through a feeding tube. **[Criteria Code 37]**
- For patients 19 years of age and younger, who cannot use a tablet or capsule. **[Criteria Code 38]**

## PEGCETACOPLAN *(Empaveli 1080mg/20mL (54mg/mL) Vial)*

**Initiation Criteria:**

For the treatment of patients with paroxysmal nocturnal hemoglobinuria (PNH) who meet all the following criteria:

- The diagnosis of PNH has been made based on the following confirmatory results:
    - Flow cytometry/FLAER exam with granulocytes or monocyte clone ≥ 10%; AND
    - LDH > 1.5 ULN; AND
    - At least one of the following:
        - A thrombotic or embolic event which required the institution of therapeutic anticoagulant therapy,
        - Minimum transfusion requirement of 4 units of red blood cells in the previous 12 months,
        - Chronic or recurrent anemia where causes other than hemolysis have been excluded and demonstrated by more than one measure of less than or equal to 70g/L or by more than one measure of less than or equal to 100g/L with concurrent symptoms of anemia,
        - Pulmonary insufficiency: Debilitating shortness of breath and/or chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded,
        - Renal insufficiency: History of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m$^2$, where causes other than PNH have been excluded,
        - Smooth muscle spasm: Recurrent episodes of severe pain requiring hospitalization and/or narcotic analgesia, where causes other than PNH have been excluded.
- Have persistent anemia with hemoglobin levels < 105 g/L, despite an adequate trial of C5 inhibitor treatment and where causes other than extravascular hemolysis have been excluded, or have intolerable adverse events from C5 inhibitor treatment.

**Renewal Criteria:**

- Renewals will be considered for patients who;
    - Demonstrate clinical improvement while on therapy or
    - Where therapy has been shown to stabilize the patient's condition
- Requests for renewal should be accompanied by confirmation of granulocyte clone size (by flow cytometry).

**Exclusion Criteria:**

Exclusion criteria for both initiation and renewal requests:

- Small granulocyte or monocyte clone size - the treatment of patients with a granulocyte and monocyte clone size below 10% will not be eligible for treatment; OR
- Aplastic anemia with two or more of the following: neutrophil count below 0.5 x 10$^9$/L, platelet count below 20 x 10$^9$/L, reticulocytes below 25 x 10$^9$/L, or severe bone marrow hypocellularity; OR
- Patients afflicted with PNH and another life-threatening or severe disease where the long term prognosis is

unlikely to be influenced by therapy (for example acute myeloid leukemia or high-risk myelodysplastic syndrome); OR

- The presence of another medical condition that might reasonably be expected to compromise a response to therapy.

Exclusion criteria for renewal requests:

- The patient or treating physician fails to comply adequately with treatment or measures, including monitoring requirements, taken to evaluate the effectiveness of the therapy; OR
- If therapy fails to relieve the symptoms of disease that originally resulted in the patient being approved for subsidized treatment.

**Claim Notes:**

- Approvals will be for a maximum of 1080mg twice a week (Day 1 and Day 4).
- If lactate dehydrogenase (LDH) levels are greater than 2x the upper limit of normal (ULN) on twice weekly dosing, 1080mg every three days may be approved.
- Initial Approval: 6 months
- Renewal Approval: 1 year
- The patient must be under the care of a pediatric nephrologist, a nephrologist, a pediatric hematologist or a hematologist.
- Pegcetacoplan will not be reimbursed in combination with other complement inhibitors except in the first 4 weeks of treatment.

## *PEGFILGRASTIM *(Fulphila 6mg/0.6mL (10mg/mL) PF Solution for Injection, Lapelga 6mg Prefilled Syringe, & 10mg/mL Prefilled Autoinjector, Nyvepria 10mg/mL Prefilled Syringe and Ziextenzo 10mg/mL Injection)*

- For the prevention of febrile neutropenia in patients with non-myeloid malignancies receiving myelosuppressive chemotherapy with curative intent who:
    - are at high risk of febrile neutropenia due to chemotherapy regimen, co-morbidities or pre-existing severe neutropenia; **[Criteria Code 01]** or
    - have had an episode of febrile neutropenia, neutropenic sepsis or profound neutropenia in a previous cycle of chemotherapy; **[Criteria Code 02]** or
    - have had a dose reduction, or treatment delay greater than one week due to neutropenia **[Criteria Code 03]**

**Clinical Note:**

- Patients with non-curative cancer receiving chemotherapy with palliative intent are not eligible for coverage of pegfilgrastim for prevention of febrile neutropenia.

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

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

**Claim Note:**

- The patient must be under the care of a physician experienced in the treatment of epilepsy.

## *PILOCARPINE, ORAL *(Salagen 5mg Tablet and generic brands)*

- 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.

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

- **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: 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.

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

- 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.

## POSACONAZOLE *(Posanol 100mg DR Tab and generic brands)*

For the prevention of invasive fungal infection (IFI) in allogeneic stem cell transplant recipients with a contraindication or intolerance to voriconazole.

- From time of engraftment until day +90

  OR

- With graft versus host disease (GVHD) taking prednisone 1 mg/kg/day or more, until dose is less than 20 mg/day.

## PROPIVERINE HYDROCHLORIDE *(Mictoryl 5mg Tablet)*

- For the treatment of overactive bladder with symptoms of urgency incontinence and/or urinary frequency and urgency in pediatric patients under 18 years of age.

## PROPRANOLOL *(Hemangiol 3.75mg/mL Solution)*

- For the treatment of patients with proliferating infantile hemangioma that is:
  - Life-or function-threatening OR
  - Ulcerated with pain or not responding to simple wound care measures OR
  - At risk of permanent scarring or disfigurement

## RANIBIZUMAB *(Byooviz 10mg/mL Injection and Ranopto 10mg/mL Injection)*

### ACTIVE (WET) AGE-RELATED MACULAR DEGENERATION

- For the treatment of patients with neovascular (wet) age-related macular degeneration (AMD) who meet all of the following criteria:
  - Best Corrected Visual Acuity (BCVA) is greater than 6/96
  - The lesion size is ≤ 12 disc areas in greatest linear dimension
  - There is evidence of recent (<3 months) presumed disease progression [blood vessel growth, as indicated by fluorescein angiography, optical coherence tomography (OCT), or recent visual acuity changes]
  - There is active disease activity and no permanent structural damage to the central fovea (as defined in the Royal College of Ophthalmologists guidelines)

**Renewal Criteria:**

- Patients must meet all of the following criteria:
  - Evidence of continued disease activity.
  - Maintaining adequate response to therapy.
  - Absolute BCVA maintained above 6/120.
  - Reductions in BCVA of < 6 lines compared to either baseline and/or best recorded level since baseline.

**Claim Notes:**

- Must be prescribed and administered by a retina specialist or an ophthalmologist with experience in administering

intravitreal injections.

- Will not be insured in combination with other anti-VEGF drugs for ophthalmic use.
- Approvals will be for a maximum of 1 vial per eye every 30 days.
- Approval period: 1 year. Confirmation of continued response is required.

### DIABETIC MACULAR EDEMA

- For the treatment of patients with diabetic macular edema (DME) who meet the following criteria:
    - Clinically significant center-involving macular edema
    - Best Corrected Visual Acuity (BCVA) is greater than 6/120

**Renewal Criteria:**

- Patient must meet all of the following criteria:
    - Evidence of continued disease activity.
    - Maintaining adequate response to therapy.
    - Absolute BCVA maintained above 6/120.
    - Reductions in BCVA of < 6 lines compared to either baseline and/or best recorded level since baseline.

**Claim Notes:**

- Must be prescribed and administered by a retina specialist or an ophthalmologist with experience in administering intravitreal injections.
- Will not be insured in combination with other anti-VEGF drugs for ophthalmic use.
- Approvals will be for a maximum of 1 vial per eye every 30 days.
- Approval period: 1 year. Confirmation of continued response is required.

### RETINAL VEIN OCCLUSION

- For the treatment of patients with clinically significant center-involving macular edema secondary to non-ischemic branch retinal vein occlusion (BRVO), or central retinal vein occlusion (CRVO) who meet the following criteria:
    - Best Corrected Visual Acuity (BCVA) is greater than 6/120

**Renewal Criteria:**

- Patient must meet all of the following criteria:
    - Evidence of continued disease activity.
    - Maintaining adequate response to therapy.
    - Absolute BCVA maintained above 6/120.
    - Reductions in BCVA of <6 lines compared to either baseline and/or best recorded level since baseline.

**Claim Notes:**

- Must be prescribed and administered by a retina specialist or an ophthalmologist with experience in administering intravitreal injections.
- Will not be insured in combination with other anti-VEGF drugs for ophthalmic use.
- Approvals will be for a maximum of 1 vial per eye every 30 days.
- Approval period: 1 year. Confirmation of continued response is required.

## RAVULIZUMAB *(Ultomiris 300mg/30mL, 300mg/3mL and 1100mg/11mL Vial)*

### PAROXYSMAL NOCTURNAL HEMOGLOBINURIA

**Initiation Criteria:**

For the treatment of patients with paroxysmal nocturnal hemoglobinuria (PNH) who meet the following criteria:

- The diagnosis of PNH has been made based on the following confirmatory results:
    - Flow cytometry/FLAER exam with granulocytes or monocyte clone ≥ 10%; AND
    - LDH > 1.5 ULN; AND
    - At least one of the following:
        - A thrombotic or embolic event which required the institution of therapeutic anticoagulant therapy,
        - Minimum transfusion requirement of 4 units of red blood cells in the previous 12 months,
        - Chronic or recurrent anemia where causes other than hemolysis have been excluded and demonstrated by more than one measure of less than or equal to 70g/L or by more than one measure of less than or equal to 100g/L with concurrent symptoms of anemia,
        - Pulmonary insufficiency: Debilitating shortness of breath and/or chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded,
        - Renal insufficiency: History of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m$^2$, where causes other than PNH have been excluded,
        - Smooth muscle spasm: Recurrent episodes of severe pain requiring hospitalization and/or narcotic analgesia, where causes other than PNH have been excluded.

**Renewal Criteria:**

- Renewals will be considered for patients who;
    - Demonstrate clinical improvement while on therapy or
    - Where therapy has been shown to stabilize the patient's condition
- Requests for renewal should be accompanied by confirmation of granulocyte clone size (by flow cytometry).

**Exclusion Criteria:**

Exclusion criteria for both initiation and renewal requests:

- Small granulocyte or monocyte clone size - the treatment of patients with a granulocyte and monocyte clone size below 10% will not be eligible for treatment; OR
- Aplastic anemia with two or more of the following: neutrophil count below 0.5 x $10^9$/L, platelet count below 20 x $10^9$/L, reticulocytes below 25 x $10^9$/L, or severe bone marrow hypocellularity; OR
- Patients afflicted with PNH and another life-threatening or severe disease where the long term prognosis is unlikely to be influenced by therapy (for example acute myeloid leukemia or high-risk myelodysplastic syndrome); OR
- The presence of another medical condition that might reasonably be expected to compromise a response to therapy.

Exclusion criteria for renewal requests:

- The patient or treating physician fails to comply adequately with treatment or measures, including monitoring requirements, taken to evaluate the effectiveness of the therapy; OR

- If therapy fails to relieve the symptoms of disease that originally resulted in the patient being approved for subsidized treatment.

**Clinical Notes:**

- Patients with insufficient initial response or who have failed treatment with eculizumab at the Health Canada–recommended dosage are not eligible for reimbursement of ravulizumab.
- All patients must receive meningococcal vaccination with a tetravalent vaccine at least two weeks prior to receiving the first dose of ravulizumab.

**Claim Notes:**

- Approvals will be for a maximum of:

| Body Weight Range (kg) | Loading Dose (mg) | Maintenance Dose (mg) | Dosing Interval |
|---|---|---|---|
| ≥ 5 to < 10 | 600 | 300 | Every 4 weeks |
| ≥ 10 to < 20 | 600 | 600 | Every 4 weeks |
| ≥ 20 to < 30 | 900 | 2,100 | Every 8 weeks |
| ≥ 30 to < 40 | 1,200 | 2,700 | Every 8 weeks |
| ≥ 40 to < 60 | 2,400 | 3,000 | Every 8 weeks |
| ≥ 60 to < 100 | 2,700 | 3,300 | Every 8 weeks |
| ≥ 100 | 3,000 | 3,600 | Every 8 weeks |

- Supplemental dosing following treatment with plasma exchange, plasmapheresis, or intravenous immunoglobulin is approved.
- Initial Approval: 6 months
- Renewal Approval: 1 year
- The patient must be under the care of a pediatric nephrologist, a nephrologist, a pediatric hematologist or a hematologist.

## ATYPICAL HEMOLYTIC UREMIC SYNDROME

**Initiation Criteria:**

- For the treatment of adult and pediatric patients 1 month of age and older with atypical hemolytic uremic syndrome (aHUS) who meet all of the following criteria:
    - Confirmed diagnosis of aHUS at initial presentation, defined by presence of thrombotic microangiopathy (TMA), who meet all the following criteria:
        - A disintegrin and metalloproteinase with a thrombospondin type 1 motif, member 13 (ADAMTS-13) activity ≥ 10% on blood samples taken before plasma exchange or plasma infusion (PE/PI); AND
        - Shiga toxin–producing Escherichia coli (STEC) test negative in patients with a history of bloody diarrhea in the preceding 2 weeks; and
        - TMA must be unexplained (not a secondary TMA).
    - Evidence of ongoing active TMA and progressing, defined by laboratory test abnormalities despite plasmapheresis, if appropriate. Patients must demonstrate:
        - Unexplained (not a secondary TMA) thrombocytopenia (platelet count < 150 × $10^9$/L); and hemolysis as indicated by the documentation of 2 of the following: schistocytes on the blood film;

low or absent haptoglobin; or lactate dehydrogenase (LDH) above normal. OR

- Tissue biopsy confirms TMA in patients who do not have evidence of platelet consumption and hemolysis.

- Evidence of at least 1 of the following documented clinical features of active organ damage or impairment:
  - Kidney impairment, as demonstrated by one of the following:
    - A decline in estimated glomerular filtration rate (eGFR) of > 20% in a patient with pre-existing renal impairment; AND/OR
    - Serum creatinine (SCr) > upper limit of normal (ULN) for age or GFR < 60mL/min and renal function deteriorating despite prior PE/PI in patients who have no history of preexisting renal impairment (i.e., who have no baseline eGFR measurement); OR
    - SCr > the age-appropriate ULN in pediatric patients (as determined by or in consultation with a pediatric nephrologist) OR
  - The onset of neurological impairment related to TMA.
  - Other TMA-related manifestations, such as cardiac ischemia, bowel ischemia, pancreatitis, and retinal vein occlusion.

- For transplant patients with a documented history of aHUS (i.e., history of TMA [not a secondary TMA only] with ADAMTS 13 > 10%) who meet the following criteria:
  - Develop TMA immediately (within hours to 1 month) following a kidney transplant; OR
  - Previously lost a native or transplanted kidney due to the development of TMA; OR
  - Have a history of proven aHUS and require prophylaxis with ravulizumab at the time of a kidney transplant
- Patients should not have a history of ravulizumab treatment failure (i.e., treated with ravulizumab with a previous aHUS recurrence). Treatment failure is defined as:
  - Dialysis-dependent at 6 months, and failed to demonstrate resolution or stabilization of neurological or extrarenal complications if these were originally present; OR
  - On dialysis for ≥ 4 of the previous 6 months while receiving ravulizumab and failed to demonstrate resolution or stabilization of neurological or extrarenal complications if these were originally present; OR
  - Worsening of kidney function with a reduction in eGFR or increase in SCr ≥ 25% from baseline.

**Renewal Criteria:**

- Treatment with ravulizumab can be renewed as long as the patient exhibits a response to treatment or as per physician discretion (e.g., long-term funding based on factors like limited organ reserve or high-risk genetic mutation such as Factor H deficiency).
  - Response to treatment is defined as, but not limited to, hematological normalization (e.g., platelet count, LDH), stabilization of end-organ damage (such as acute kidney injury and brain ischemia), transplant graft survival in susceptible individuals, and dialysis avoidance in patients who are pre- end-stage kidney disease (ESKD).
- Assessment of treatment response should be conducted at 6-months, at 12-months, then annually thereafter.
  - At the 6-month assessment, treatment response and no treatment failure (defined in Initiation Criteria) is required.

- At the 12-month and annual assessments, treatment response, no treatment failure, and the patient has limited organ reserve or high-risk genetic mutation are required.
    - Limited organ reserve is defined as significant cardiomyopathy, neurological, gastrointestinal, or pulmonary impairment related to TMA; or Grade 4 or 5 chronic kidney disease (eGFR < 30mL/min) is required.

- A patient previously diagnosed with aHUS and who responded to treatment with ravulizumab and has not failed ravulizumab is eligible to restart ravulizumab if the patient redevelops a TMA related to aHUS and meets the following clinical conditions:
    - Significant hemolysis as evidenced by presence of schistocytes on the blood film, or low or absent haptoglobin, or LDH above normal; AND
    - EITHER
        - Platelet consumption as measured by either ≥ 25% decline from patient baseline or thrombocytopenia (platelet count < 150,000 × $10^9$/L); OR
        - TMA-related organ impairment (e.g., unexplained rise in serum creatinine with onset of urine dipstick positive for hemoglobin) including on recent biopsy.

**Claim Notes:**

- Approvals will be for a maximum of:

| Body Weight Range (kg) | Loading Dose (mg) | Maintenance Dose (mg) | Dosing Interval |
|---|---|---|---|
| ≥ 5 to < 10 | 600 | 300 | Every 4 weeks |
| ≥ 10 to < 20 | 600 | 600 | Every 4 weeks |
| ≥ 20 to < 30 | 900 | 2,100 | Every 8 weeks |
| ≥ 30 to < 40 | 1,200 | 2,700 | Every 8 weeks |
| ≥ 40 to < 60 | 2,400 | 3,000 | Every 8 weeks |
| ≥ 60 to < 100 | 2,700 | 3,300 | Every 8 weeks |
| ≥ 100 | 3,000 | 3,600 | Every 8 weeks |

- Supplemental dosing following treatment with plasma exchange, plasmapheresis, or intravenous immunoglobulin is approved.
- The patient must be under the care of a pediatric nephrologist, a nephrologist, a pediatric hematologist or a hematologist.
- Initial Approval: 6 months
- Renewal Approval: 1 year

## *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.

### UNRESECTABLE OR METASTATIC HEPATOCELLULAR CARCINOMA (HCC)

- For the treatment of patients with unresectable or metastatic hepatocellular carcinoma (HCC) in the second line setting who have experienced disease progression on sorafenib or lenvatinib and meet all the following criteria:
    - Child-Pugh class status of A
    - Good performance status

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

**Clinical Notes:**

- Treatment should continue until disease progression or unacceptable toxicity.
- Patients with disease progression on sorafenib must have tolerated a minimum dose of 400 mg per day for at least 20 of the last 28 days of treatment.
- Patients who are unable to tolerate cabozantinib may be switched to regorafenib if there is no disease progression and provided all other funding criteria are met.
- Patients with disease progression on cabozantinib are not eligible for reimbursement of regorafenib.
- Patients with disease progression on atezolizumab in combination with bevacizumab or durvalumab in combination with tremelimumab are not eligible for reimbursement of regorafenib.

## *RIBOCICLIB *(Kisqali 200mg Tablet)*

### ER POSITIVE, HER2-NEGATIVE ADVANCED BREAST CANCER IN COMBINATION WITH AN AROMATASE INHIBITOR (AI)

- 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 endocrine-based treatment for metastatic disease. Patients may have received up to one prior line of chemotherapy for advanced 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.
- Patients will be eligible for either ribociclib plus an aromatase inhibitor in the first line setting or everolimus plus exemestane as a subsequent line of therapy, but not both therapies. Patients eligible include:
    - Pre and peri-menopausal patients (should be treated with a luteinizing hormone- releasing hormone (LHRH) agonist)
    - Males
    - Patients with bone only metastases
    - Patients who are HER2 equivocal by FISH testing (these patients are HER2 negative)
    - Patients currently receiving first line aromatase inhibitor monotherapy for ER positive, HER2-negative metastatic breast cancer may have ribociclib added provided the above criteria is met.
    - Patients with prior adjuvant treatment with abemaciclib plus endocrine therapy are eligible if disease progression occurred 6 months or greater after completion of adjuvant abemaciclib.

### HR POSTIVE, HER2-NEGATIVE ADVANCED OR METASTATIC BREAST CANCER IN COMBINATION WITH FULVESTRANT

- In combination with fulvestrant for the treatment of patients with hormone receptor (HR) positive, HER 2 negative advanced or metastatic breast cancer, as initial endocrine-based therapy or following disease progression on endocrine therapy. Patients may have also received up to one prior line of chemotherapy for advanced disease. Patients should have a good performance status, without active or uncontrolled metastases to the central nervous system and can be of any menopausal status (Perimenopausal and premenopausal women must be treated with an LHRH agonist).

**Clinical Notes**:

- Treatment should continue until unacceptable toxicity or disease progression.

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

- Patients who progress ≤ 12 months from (neo) adjuvant therapy are eligible for treatment with ribociclib plus fulvestrant.
- Patients who experience disease progression on prior CDK 4/6 inhibitor therapy, fulvestrant or everolimus are not eligible for treatment with ribociclib with fulvestrant.
- Patients currently receiving fulvestrant monotherapy, and who have not progressed may have ribociclib added, provided they are CDK 4/6 inhibitor naïve and otherwise meet funding criteria.
- Patients who previously received everolimus plus exemestane will be eligible for funding of ribociclib plus fulvestrant on progression, provided that treatment was started prior to funding of CDK 4/6 + fulvestrant, patient must be CDK 4/6 naïve and otherwise meet funding criteria.
- Patients with prior adjuvant treatment with abemaciclib plus endocrine therapy are eligible if disease progression occurred 6 months or greater after completion of adjuvant abemaciclib.

### **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.

### **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 and generic brands)*

- 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.

### ***RIPRETINIB** *(Qinlock 50mg Tablet)*

- For the treatment of adult patients with advanced gastrointestinal stromal tumors (GIST) who have progression on or intolerance to imatinib, sunitinib and regorafenib.

**Clinical Notes:**

- Patients should have a good performance status.
- Treatment should continue until disease progression or unacceptable toxicity.
- Patients must not have active CNS metastases.

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

## **RISANKIZUMAB** (*Skyrizi 75mg/0.83mL Prefilled Injection, 150mg/mL Prefilled Syringe and 150mg/mL Prefilled Pen, 600mg/10ml Vial and 360mg/2.4ml Prefilled Cartridge Injection)*

### PLAQUE PSORIASIS

- For the treatment of patients with chronic moderate to severe plaque psoriasis who meet all of the following:
    - Psoriasis Area Severity Index (PASI) greater than 10 and Dermatology Life Quality Index (DLQI) greater than 10, OR major involvement of visible areas, scalp, genitals, or nails;
    - Refractory, intolerant to or unable to access phototherapy;
    - Refractory, intolerant to or have contraindications to methotrexate (oral or parenteral) at a dose of greater than or equal to 20 mg weekly (greater than or equal to 15 mg if patient is 65 years of age or older) for a minimum of 12 weeks **OR** cyclosporine (6 weeks treatment).
- For continued coverage, patients must meet the following criteria:
    - Greater than or equal to 75% reduction in PASI score, **OR**
    - Greater than or equal to 50% reduction in PASI and greater than or equal to 5 points in the DLQI **OR**
    - Significant reduction in BSA involved, with consideration of specific regions such as face, hands, feet or genital region and situations such as itch and recalcitrant plaques.

**Clinical Notes:**

- For patients who do not demonstrate a clinical response to oral methotrexate, or who experience gastrointestinal intolerance, a trial of parenteral methotrexate may be considered if clinically appropriate.
- 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 dermatologist or prescriber with a specialty in dermatology.
- Combined use of more than one biologic will not be reimbursed.
- Initial Approval: 6 months.
- Renewal Approval: 1 year.

### CROHN'S DISEASE (600MG/10ML VIAL AND 360MG/2.4ML PREFILLED CARTRIDGE INJECTION)

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

**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 to treatments. The nature of intolerance(s) must be clearly documented.

**Claim Notes:**

- Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology.
- Combined use with other biologic drugs or janus kinase (JAK) inhibitors will not be reimbursed.
- Initial reimbursement will be for intravenous doses of 600mg at Weeks 0, 4 and 8, with clinical response to be

assessed prior to Week 12. Subsequent reimbursement for maintenance dosing is 360mg subcutaneously at Week 12, every 8 weeks thereafter.

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

## RISEDRONATE *(30mg Tablet)*

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

## RISDIPLAM *(Evrysdi 0.75mg/mL Powder for Solution)*

### SPINAL MUSCULAR ATROPHY

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 or compound heterozygote, AND
- Patients who:
    - are symptomatic and have genetic documentation of two or three copies of the SMN2 gene, AND
    - aged between 2 months and 7 months (inclusive), OR
    - aged 8 months up to 25 years and are non-ambulatory
- 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 risdiplam treatment.
- 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) after treatment initiation in patients aged between 2 months and 2 years 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) after treatment initiation in patients aged between 2 years and 25 years at the time of treatment initiation; AND
    - Patient does not require permanent invasive ventilation*.

The decision to discontinue reimbursement should be based on 2 assessments separated by no longer than a 12-week interval.

**Claim Notes:**

- Coverage for risdiplam will not be provided in combination with other SMA drug therapies or post administration of onasemnogene abeparvovec.
- Approval: 12 months

* 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.

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

- For the treatment of patients who are:
    - not adherent to an oral antipsychotic, OR
    - currently receiving a long-acting injectable antipsychotic and require an alternative long-acting injectable antipsychotic.

**Claim Note:**

- Requests will not be considered for the treatment of psychotic symptoms related to dementia.

## ROMOSOZUMAB *(Evenity 90mg/mL Prefilled Syringe)*

- For the treatment of osteoporosis in postmenopausal women who meet all the following criteria:
    - Have a history of osteoporotic fracture; and
    - Are at high risk for future fracture, defined as a 10-year fracture risk ≥ 20% as per the Fracture Risk Assessment (FRAX) tool; and
    - Are treatment naive to osteoporosis medications, except for calcium and/or vitamin D.

**Claim Notes:**

- Maximum approval period: 12 months per lifetime.
- Concurrent use with other osteoporosis medications, except for calcium and/or vitamin D, will not be reimbursed.

## 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, 400mg Tablet and generic brands)*

- 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)*

### ACUTE GRAFT-VERSUS-HOST DISEASE

- For the treatment of steroid-refractory or steroid-dependent acute graft-versus-host disease (aGvHD) in adult and pediatric patients aged 12 years and older who meet all the following criteria:
    - Clinically diagnosed grade II to IV aGvHD according to the NIH criteria (Harris et al. [2016]).
    - Confirmed diagnosis of corticosteroid-refractory or corticosteroid-dependent aGvHD.

**Renewal criteria:**

- Achieved an overall response (i.e., CR, VGPR, PR, or stable disease with significant reduction in steroid doses), according to standard NIH criteria at day 28.
- For subsequent renewals, patients should be assessed for treatment response every 2 to 3 months, until the occurrence of any of the discontinuation criteria listed below.

**Clinical Notes:**

- Treatment should be discontinued upon the occurrence of any of the following:
    - progression of aGvHD, defined as worsening of aGvHD symptoms or occurrence of new aGvHD symptoms
    - unacceptable toxicity
    - addition of systemic therapies (other than calcineurin inhibitors) for aGvHD after day 28
    - recurrence or relapse of underlying hematological malignancy.

**Claim Notes:**

- Must be prescribed by clinicians who have experience in the diagnosis and management of patients with aGvHD.
- Must not be added to patients' concurrent treatment of systemic therapies for the treatment of aGvHD other than steroids with or without calcineurin inhibitors.
- Approval: 6 months

**CHRONIC GRAFT-VERSUS-HOST DISEASE**

- For the treatment of chronic graft-versus-host disease (cGvHD) in adults and pediatric patients aged 12 years and older who have inadequate response to corticosteroids or other systemic therapies who meet all the following criteria:
    - Clinically diagnosed cGvHD staging of moderate to severe based on NIH consensus criteria
    - Confirmed diagnosis cGvHD with inadequate response to corticosteroids or other systemic therapies

**Renewal criteria:**

- Achieved an overall response (i.e., CR or PR, or stable disease with significant reduction in steroid doses), according to NIH criteria, after 24 weeks of therapy

**Clinical Notes:**

- Treatment should be discontinued upon the occurrence of any of the following:
    - Progression of cGvHD, defined as worsening of cGvHD symptoms or occurrence of new cGvHD symptoms
    - recurrence or relapse of underlying hematological malignancy

**Claim Notes:**

- Must be prescribed by clinicians who have experience in the diagnosis and management of patients with cGvHD.
- Must not be added to patients' concurrent treatment of systemic therapies other than steroids with or without calcineurin inhibitors.
- Initial Approval: 6 months
- Renewal Approval: 1 year

**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).
    - 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: 6 months
- Renewal Approval: 1 year

## *SACCHARATED IRON OXIDE *(Venofer 20mg/mL Injection and generic brands)*

- 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 Notes:**

- 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 Diskus)*

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

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

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

### SAPROPTERIN DIHYDROCHLORIDE *(Kuvan 100mg Tablet, 100mg and 500mg Sachet and generic brands)*

- Ongoing funding of sapropterin will be considered for nonpregnant patients and patients actively planning pregnancy who have a diagnosis of Phenylketonuria (PKU) and who have demonstrated a response to the initial 6-month trial of sapropterin. [reimbursed through the Supplier's Patient Support Program (PSP)]

**Inclusion Criteria for entry into the 6-month trial period:**

- For the management of patients with the diagnosis of hyperphenylalaninemia (HPA) due to tetrahydrobiopterin (BH4)-responsive phenylketonuria (PKU) who meet ALL of the following criteria:
    - A diagnosis of Phenylketonuria (PKU) confirmed through an approved test.
    - Compliance with a low protein diet and formulas.
    - Baseline blood phenylalanine (Phe) levels > 360 µmol/L despite compliance with a low protein diet (require at least 2 baseline levels during a 3 to 6 month time frame).
    - Baseline protein intake assessment by a dietitian.
    - Ability to comply with medication regimen.
    - Managed by a physician specialized in metabolic/biochemical diseases.
- Modified Criteria for Pregnant Patients during the 6-month trial period:
    - Patient has a diagnosis of PKU confirmed through an approved test
    - Patient's treatment is being managed by a prescriber specialized in metabolic/biochemical diseases; and

- Patient's baseline blood Phe level is greater than 360 µmol/L despite compliance with all recommendations for dietary intervention and monitoring or compliance with a low protein diet.

- Patients will be eligible for funding through the Nova Scotia Pharmacare Programs after demonstrating a response to the 6-month trial period, as per the trial criteria.

**Initial Criteria Post 6 Month Trial:**

- For the management of patients with the diagnosis of hyperphenylalaninemia (HPA) due to tetrahydrobiopterin (BH4)-responsive phenylketonuria (PKU) who meet ALL of the following criteria:
  - Compliance with low protein diet, formulas, and sapropterin; AND
  - During the 6-month trial period under the patient support program patient has achieved a demonstrated response to the sapropterin n responsiveness test or PKU clinical protocol, based on the following information:
    - the clinic's definition for response; and
    - all relevant laboratory results used to determine that the Patient was a responder sapropterin
  - Patient meets one of the following:
    - normal sustained Blood Phe levels [ > 120 µmol/L and < 360 µmol/L] (At least 2 levels measured
    - at least 1 month apart); OR
    - sustained blood Phe reduction of at least 30% (At least 2 levels measured at least 1 month apart)
    - compared to baseline if the Phe baseline level is < 1200 µmol/L; OR
    - sustained blood Phe reduction of at least 50% (At least 2 levels measured at least 1 month apart) compared to baseline if the Phe baseline level is > 1200 µmol/L;
  - Demonstrated an increase in dietary protein tolerance based on targets set between the clinician and patient
  - Managed by a prescriber specialized in metabolic/ biochemical diseases.
- Dosage: Up to a maximum of 20 mg/kg per day
- Approval Duration: 1 year

**Renewal Criteria:**

- Renewals will be considered for patients who demonstrate ongoing response to treatment.
- Renewal Approval Duration: 1 year

## SATRALIZUMAB *(Enspryng 120mg/mL Prefilled Syringe)*

### NEUROMYELITIS OPTICA SPECTRUM DISORDER

- For the treatment of patients 12 years of age and older with neuromyelitis optica spectrum disorder (NMOSD) who meet all of the following criteria:
  - Are anti–aquaporin 4 (AQP4) seropositive
  - Must have had at least one relapse of NMOSD in the previous 12 months:
    - despite an adequate trial of other accessible preventive treatments[1] for NMOSD, OR
    - because the patient cannot tolerate other preventive treatments[1] for NMOSD
- Patients must have an EDSS score of 6.5 points or less.
- Satralizumab should not be initiated during a NMOSD relapse episode.

**Renewal:**

- Requests for renewal will be considered for patients who maintain an EDSS score of less than 8 points.

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

**Clinical Note:**

- Must be prescribed by a neurologist with expertise in treating NMOSD.

**Claim Notes:**

- Approval Period: 1 year
- Combined use of more than one biologic drug will not be reimbursed.
- Approvals will be for a maximum of 120mg at week 0, 2 and 4, then 120 mg every four weeks thereafter.

[1]Other accessible preventative treatments include, but are not limited to, monoclonal antibodies including rituximab and other immunosuppressants.

## **SARILUMAB** *(Kevzara 150mg/1.14mL, 200mg/1.14mL Prefilled Pen &150mg/1.14mL, 200mg/1.14mL Prefilled Syringe)*

- For the treatment of moderately to 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.

## **SAXAGLIPTIN** *(Onglyza 2.5mg and 5mg Tablet and generic brands)*

- 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.

## SEBELIPASE ALFA *(Kanuma 2mg/mL IV Solution)*

- For the treatment of patients diagnosed with lysosomal acid lipase (LAL) deficiency who meet all of the following criteria:
    - Documented biochemical evidence of deficient LAL activity and two documented pathogenic mutations in the LIPA gene

      **AND**
    - Patients who:
        - Have onset of clinical manifestations[1] of LAL deficiency before six months of age.

          **OR**
        - Have at least one of the following clinical manifestations[1] of LAL deficiency at 6 months of age and older:
            - Persistently elevated transaminases (ALT > 1.5 x ULN[2] or AST > 1.5 x ULN[2]) as measured by two assessments three to six months apart.
            - Persistent dyslipidemia (LDL-c and/or TG values in the top 5th percentile based on sex and age) as measured by two assessments three to six months apart.
            - Any documented hepatomegaly or hepatosplenomegaly.
            - Liver fibrosis confirmed by biopsy.
            - Failure to thrive.
            - Growth impairment[3].
            - Evidence of intestinal affection and/or malabsorption.

              **AND**
        - Must not demonstrate evidence of any of the following:
            - Increased portal vein pressures, or de novo evidence of portal hypertension on ultrasound and Doppler, or new clinical presentation of portal hypertension (e.g., esophageal varices).
            - Severe hepatic dysfunction (Child-Pugh Class C).
            - End-stage liver disease.

**Discontinuation Criteria:**

- For patients with onset of clinical manifestations of LAL deficiency at six months of age and older if the patient:
    - Progresses to end-stage liver failure or multi-organ failure.

      **OR**
    - Has at least three out of the following response components compared to baseline values after 12 months of therapy:
        - Less than 10% improvement in ALT or AST.
        - Worsening of liver fibrosis confirmed by biopsy.
        - Persisting growth impairment[3] despite sebelipase alfa therapy and nutritional interventions.

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

- At least a 15% increase in spleen volume and/or a greater than 15% increase in liver volume on ultrasound.
- Increased portal vein pressures, or de novo evidence of portal hypertension on ultrasound and Doppler, or new clinical presentation of portal hypertension (e.g., esophageal varices).

- Regardless of age of onset, for adverse events from sebelipase alfa (particularly hypersensitivity reactions including anaphylaxis, hypotension, or fever), which cannot be managed with standard treatment and/or have a significant impact on the patient's quality of life or are life-threatening.

**Clinical Notes:**

1. The physician must provide baseline values for the clinical manifestation at the time of initial request for reimbursement.
2. Based on age- and- sex-specific normal values for ALT and AST.
3. Growth impairment is defined as decreased body weight across at least two of the major centiles on a WHO weight-for-age chart, or body weight below 10th centile and no weight gain within two weeks and/or decreased height across at least two of the major centiles on a WHO height-for-age chart.

**Claim Notes:**

- The patient must be under the care of a specialist with experience in the diagnosis and management of LAL deficiency.
- Initial Approval: 12 months.
- Renewals: 6 months.

## SECUKINUMAB *(Cosentyx 75mg/0.5mL Prefilled Syringe, 150mg/mL Prefilled Pen, 150mg/mL Prefilled Syringe and 300mg dose Kits (two 150mg/mL Prefilled Pen/Syringe))*

### 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[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 2 weeks each, 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 2 weeks each 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, followed by monthly maintenance dosing. If a patient continues to have active ankylosing spondylitis, a monthly maintenance dosage of 300 mg may be considered.
- Each 300 mg dose is given as two subcutaneous injections of 150 mg.
- Initial Approval: 6 months.
- Renewal Approval: 1 year.

### HIDRADENITIS SUPPURATIVA (150MG PREFILLED PEN, PREFILLED SYRINGE AND 300MG DOSE KITS (TWO 150MG/ML PREFILLED PEN/SYRINGE)

For the treatment of 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 secukinumab).

**Claim Notes:**

- Must be prescribed by a dermatologist or physician with experience in the treatment of HS.
- Combined use of more than one biologic DMARD will not be reimbursed.
- Approvals will be for 300mg given at weeks 0, 1, 2, 3, and 4, followed by monthly maintenance dosing. Based on clinical response, a maintenance dose of 300 mg every 2 weeks can be considered.
- Initial Approval: 6 months
- Renewal Approval: 1 year

### PLAQUE PSORIASIS

For the treatment of patients 6 years of age or older with chronic moderate to severe plaque psoriasis who meet all of the following:

- Psoriasis Area Severity Index (PASI) greater than 10 and Dermatology Life Quality Index (DLQI) greater than 10, OR major involvement of visible areas, scalp, genitals, or nails;
- Refractory, intolerant to or unable to access phototherapy;
- Refractory, intolerant to or have contraindications to methotrexate (oral or parenteral) at a dose of greater than or equal to 20 mg weekly (greater than or equal to 15 mg if patient is 65 years of age or older) 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 may be considered if clinically appropriate.
- 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.
- For patients aged 6 to 16, a Children's Dermatology Life Quality Index (CDLQI) greater than 7 will be considered.
- For pediatric patients an adequate trial of a weight-based appropriate dose of methotrexate will be considered.

**Claim Notes:**

- Must be prescribed by a dermatologist or prescriber with a specialty in dermatology.
- Combined use of more than one biologic will not be reimbursed.
- For pediatric patients weighing less than 50 kg, approvals will be for a maximum of 75mg given at weeks 0, 1, 2, 3, and 4, then monthly.
- Approvals will be for a maximum of 300 mg given at weeks 0, 1, 2, 3, and 4, then monthly.
- Initial Approval: 6 months.
- Renewal Approval:1 year.

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

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

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

### 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 & 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.

**Notes:**

- 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.

## *SELINEXOR *(Xpovio 20mg Tablet)*

- In combination with bortezomib and dexamethasone for the treatment of adult patients with multiple myeloma and who have received at least one prior therapy.

**Clinical Notes:**

1. Prior treatment with bortezomib/proteasome inhibitor is permitted if all the following criteria are met:
    - Best response achieved with bortezomib/proteasome inhibitor was at least a partial response
    - Bortezomib/proteasome inhibitor not discontinued for grade 3 or higher toxicity
    - Bortezomib/proteasome inhibitor treatment-free interval has been at least six months.
2. Treatment should continue until disease progression or unacceptable toxicity.

## *SELPERCATINIB *(Retevmo 40mg and 80mg Capsule)*

### MEDULLARY THYROID CANCER

- For the treatment of patients 12 years and older with unresectable locally advanced or metastatic RET-mutant medullary thyroid cancer (MTC) who have progressed on, are intolerant to, or have a contraindication to first-line therapy.

**Clinical Notes:**

- Discontinuation for unacceptable toxicity or loss of clinical benefit.
- Patients should have a good performance status.
- Monotherapy only.
- Confirm RET mutation prior to initiating therapy.
- Patients with prior progression on a RET inhibitor are ineligible.

### DIFFERENTIATED THYROID CARCINOMA

- For the treatment of adult patients with locally advanced or metastatic RET fusion-positive differentiated thyroid carcinoma (DTC) not amenable to surgery or radioactive iodine therapy following prior Lenvatinib and/or Sorafenib.

**Clinical Notes:**

- Discontinuation for unacceptable toxicity or loss of clinical benefit.
- Patients should have a good performance status.
- Monotherapy only.
- Confirm RET mutation prior to initiating therapy.
- Patients with prior progression on a RET inhibitor are ineligible.

### NON-SMALL CELL LUNG CANCER

- For the treatment of adult patients with metastatic RET fusion-positive non-small cell lung cancer (NSCLC) as first-line treatment or after prior systemic therapy.

**Clinical Notes:**

- Discontinuation for unacceptable toxicity or loss of clinical benefit.
- Patients should have a good performance status.

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

- Monotherapy only.
- Confirm RET mutation prior to initiating therapy.
- Patients with prior progression on a RET inhibitor are ineligible.

## SELUMETINIB *(Koselugo 10mg and 25mg Capsule)*

- For pediatric patients aged 2 to 18 years with neurofibromatosis type 1 (NF1) with symptomatic, inoperable plexiform neurofibromas (PNs).

**Initial renewal:**

- The physician must document the beneficial clinical effect when requesting continuation of reimbursement.
- Patients on therapy should be monitored for response (e.g., a reduction in pain, improved function, reduction in tumour volume, disease stabilization) using clinical judgment and/or standard imaging.

**Second and subsequent renewal criteria (at 18 months after initiation and thereafter):**

- The patient does not have disease worsening or progression (e.g., worsening of motor function or pain).

**Claim Notes:**

- The patient must be under the care of either a neurooncologist or a pediatrician with expertise in neurooncology.
- Initial approval: 18 months
- Renewal Approval: 12 months

## SEMAGLUTIDE *(Ozempic 2mg/1.5mL, 2mg/3mL and 4mg/3mL Prefilled Pen)*

- For the treatment of type 2 diabetes in combination with metformin and a sulfonylurea, when diet and exercise plus dual therapy with metformin and a sulfonylurea do not achieve adequate glycemic control.

**Claim Note:**

- Approvals will be for a maximum of 1 prefilled pen every 4 weeks.

## SEMAGLUTIDE *(Rybelsus 3mg, 7mg and 14mg Tablet)*

- For the treatment of type 2 diabetes in combination with metformin and a sulfonylurea, when diet and exercise plus dual therapy with metformin and a sulfonylurea do not achieve adequate glycemic control.

**Claim Note:**

- Approvals will be for a maximum of one tablet per day.

## SENSOR-BASED GLUCOSE PRODUCT *(Dexcom, Freestyle and Medtronic)*
*(Please see Formulary for insured products)*

- For patients 2 years of age or older with Diabetes Mellitus (DM) AND who require multiple daily injections of insulin or insulin pump therapy as part of intensive insulin therapy. Multiple daily injections of insulin are defined as 1 (or more) injection(s) of basal insulin and 3 (or more) injections of bolus insulin, with a minimum of at least of 4 total insulin injections per day.

## *SEROTONIN (5-$HT_3$) ANTAGONISTS *(Granisetron, Ondansetron)*

### EMESIS (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.

**NAUSEA, VOMITING IN PEDIATRIC PATIENTS (ONDANSETRON)**

- For the treatment of nausea and vomiting in pediatric patients (under 18 years of age) receiving chemotherapy (e.g., methotrexate) for chronic non-oncology conditions who have experienced an episode of nausea/emesis. **[Criteria Code 04]**

## SETMELANOTIDE *(Imcivree 10mg/mL Vial)*

- For weight management in adult and pediatric patients 6 years of age and older with obesity due to clinically or genetically confirmed Bardet-Biedl syndrome (BBS).

**Initial Renewal Criteria:**

- The physician must provide proof of beneficial clinical effect, including:
  - at least a 5% reduction in BMI or total body weight in patients who are at least 12 years of age, OR
  - a reduction in BMI Z score that is considered clinically beneficial by the treating physician as appropriate for patients who are 6 to 11 years of age.

**Subsequent Renewal Criteria:**

- The physician must provide proof that the initial response achieved after the first 26 weeks of therapy with setmelanotide has been maintained, including:
  - maintenance of BMI or total body weight, OR
  - maintenance of BMI Z score.

**Clinical Notes:**

- Obesity is defined as BMI ≥ 30 for patients aged ≥ 16 years, or weight > 97th percentile for age and sex in patients aged < 16 years.
- Clinical diagnosis of BBS is to be based on the Beales criteria.

**Claim Notes:**

- Initial approval: 26 weeks
- Renewal approval: 1 year
- The patient must be under the care of an endocrinologist, pediatric endocrinologist, and/or specialist in weight management or obesity.
- Approvals will be for a maximum of 2.0 mg daily for patients aged 6 to 17 years old and up to 3.0 mg daily for patients aged 18 years and older.

## SEVELAMER *(800mg Tablet and generic brands)*

- 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.

## SIPONIMOD *(Mayzent 0.25mg and 2mg Tab)*

**Initiation Criteria:**

- For the treatment of patients with active secondary progressive multiple sclerosis, who meet all the following criteria:
  - a history of relapsing-remitting multiple sclerosis (RRMS)
  - an Expanded Disability Status Scale (EDSS) score of 3.0 to 6.5
  - documented EDSS progression during the two years prior to initiating treatment with siponimod

**Renewal Criteria:**

- Ongoing funding will be provided for those who continue to benefit from treatment and who have an Expanded Disability Status Scale (EDSS) score of 7.0 or less.

**Claims Notes:**

- The patient is under the care of a neurologist with experience in the diagnosis and management of multiple sclerosis.
- Siponimod should not be used in combination with other disease-modifying treatments (DMTs) used to treat multiple sclerosis.
- Initial approval period: 2 years
- Renewal approval period: 5 years

## SITAGLIPTIN *(Januvia 25mg, 50mg, 100mg Tablet and generic brands)*

- 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, 50mg/500mg XR, 50/1000 XR and 100mg/1000mg XR Tablet and generic brands)*

- 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 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.

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

## 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**<br>▪ Without cirrhosis<br>▪ With compensated cirrhosis | ▪ 12 weeks in combination with ribavirin (RBV) |
| **Genotype 3**<br>▪ Without cirrhosis<br>▪ With compensated cirrhosis | ▪ 24 weeks in combination with RBV |
| **Genotype 3**<br>▪ Without cirrhosis | ▪ 12 weeks in combination with daclatasvir |
| **Genotype 3**<br>▪ With compensated or decompensated cirrhosis<br>▪ 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 Note:**

- Claims will be limited to a 28-day supply.

**** [Criteria Code 34]** has been added to allow payment of a patient's initial 28 day supply only. Criteria code 34 should be provided by the prescribing physician only.

## 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<br>▪ 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 Note:**

- Claims will be limited to a 28-day supply.

**** [Criteria Code 34]** has been added to allow payment of a patient's initial 28 day supply only. Criteria code 34 should be provided by the prescribing physician only.

## 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<br>▪ 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)

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

- 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 Note:**

- Claims will be limited to a 28-day supply.

**** [Criteria Code 34]** has been added to allow payment of a patient's initial 28 day supply only. Criteria code 34 should be provided by the prescribing physician only.

## SOMATROPIN *(Humatrope, Genotropin GoQuick and MiniQuick, Norditropin FlexPro 5mg/1.5mL, 10mg/1.5mL and 15mg/1.5mL Prefilled Pen, 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)*

### HEPATOCELLULAR CARCINOMA (HCC)

- For the treatment of patients with unresectable or metastatic hepatocellular carcinoma as either first-line treatment, or second-line treatment following atezolizumab in combination with bevacizumab or durvalumab in combination with tremelimumab, who meet all the following criteria:
  - Child-Pugh class status of A
  - Good performance status

**Clinical Note:**

- Treatment should be continued until disease progression or unacceptable toxicity.
- Patients who are unable to tolerate lenvatinib may be switched to sorafenib if there is no disease progression and provided all other funding criteria are met.
- Patients with disease progression on lenvatinib are not eligible for reimbursement of sorafenib.

### METASTATIC RENAL CELL CARCINOMA

- For the treatment of patients with advanced or metastatic renal cell carcinoma when used as a second-line therapy following disease progression on cytokine therapy.

**Clinical Notes:**

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

## STIRIPENTOL *(Diacomit 250mg and 500mg Capsule)*

- 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.

## SUCROFERRIC OXYHYDROXIDE *(Velphoro 500mg 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).

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

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

## *SUNITINIB *(Sutent 12.5mg, 25mg, 50mg Capsule and generic brands)*

### METASTATIC RENAL CELL CARCINOMA

- For patients with advanced or metastatic renal cell carcinoma as either first-line therapy, or second-line therapy after failure of first-line immunotherapy.

**Clinical Notes:**

- Patients must have a good performance status.
- Treatment should be discontinued upon disease progression or unacceptable toxicity.
- 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.
- Both clear cell and non-clear cell histology are eligible for treatment.

### ADVANCED GASTROINTESTINAL STROMAL TUMOR (GIST)

- As a single agent for the treatment of advanced gastrointestinal stromal tumor (GIST) patients after failure of imatinib due to intolerance or resistance

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

**ADVANCED OR 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

## 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)

## TAFAMIDIS *(Vyndamax 61mg Capsule)*
## TAFAMIDIS MEGLUMINE *(Vyndaqel 20mg Capsule)*

- For the treatment of cardiomyopathy in adult patients with documented hereditary or wild-type transthyretin-mediated amyloidosis (ATTR) who meet all of the following criteria:
    - New York Heart Association (NYHA) class I to III heart failure
    - At least one prior hospitalization for heart failure or clinical evidence of heart failure that required treatment with a diuretic
    - Has not previously undergone a heart or liver transplant
    - Does not have an implanted cardiac mechanical assist device (CMAD)

**Discontinuation Criteria:**

- The patient has:
    - NYHA class IV heart failure, or
    - received an implanted CMAD, or
    - received a heart or liver transplant.

**Clinical Notes:**

1. Wild-type ATTR-cardiomyopathy (CM) consists of all of the following:
    a. absence of a variant transthyretin (TTR) genotype
    b. TTR precursor protein identification by immunohistochemistry, scintigraphy, or mass spectrometer
    c. evidence of cardiac involvement by echocardiography with end-diastolic interventricular septal wall thickness greater than 12 mm
    d. presence of amyloid deposits in biopsy tissue (fat aspirate, salivary gland, median nerve connection tissue sheath, or cardiac tissue) or positive findings on technetium-99m pyrophosphate (Tc-99m-PYP) scintigraphy with single-photon emission computed tomography (SPECT) scanning
2. Hereditary ATTR-CM consists of all of the following:
    a. presence of a variant TTR genotype associated with CM and presenting with a CM phenotype
    b. evidence of cardiac involvement by echocardiography with end-diastolic interventricular septal wall thickness greater than 12 mm
    c. presence of amyloid deposits in biopsy tissue (fat aspirate, salivary gland, median nerve connective tissue sheath, or cardiac tissue) or positive findings on Tc-99m-PYP scintigraphy with SPECT scanning

**Claim Notes:**

- The patient must be under the care of a physician with experience in the diagnosis and treatment of ATTR-CM.
- Combination therapy with other interfering ribonucleic acid drugs or transthyretin stabilizers used to treat ATTR will not be reimbursed.
- Claims will be limited to a 30-day supply.
- Initial Approval: 9 months.
- Renewal Approval: 1 year.

## TALIGLUCERASE ALFA *(Elelyso 200U Vial)*

- For the treatment of patients with symptomatic Gaucher disease type 1 (GD1) for whom treatment with velaglucerase alfa is not tolerated or contraindicated.

**Clinical Notes:**

- Velaglucerase alfa is the preferred reimbursed enzyme replacement therapy for GD1.
- Requests for patients currently using taliglucerase alfa who do not have a contraindication or intolerance to velaglucerase alfa will be considered for coverage of velaglucerase alfa only.
- Requests for coverage must meet the criteria for diagnosis of GD1, indication for therapy and expected response to enzyme replacement therapy outlined below:

**Initial Coverage**
**Diagnosis:**

- The diagnosis of GD1 must have been established by the demonstration of specific deficiency of glucocerebrosidase (GCase) in tissue or cultured skin fibroblasts, or by demonstration of the presence, in tissue or peripheral blood leukocytes, of mutations in the GCase gene known to result in severe enzyme deficiency.
- Other potentially confounding diagnoses, such as Hodgkin disease or other storage disorders, must have been ruled out. The symptoms experienced by the patient should be shown to be attributable to GD1 and not another condition that might mimic it.
- The patient should not have any GD1-related or other medical condition that might reasonably be expected to compromise their response to treatment. In some patients with GD1, secondary pathologic changes, such as avascular necrosis of bone, may already have occurred that would not be expected to respond to enzyme replacement. In such patients, reversal of the pathology is unlikely.

**Disease Severity**

Evidence of disease severity must be provided, and include at least one of the following:

- **Hematological complications**
  - Hemoglobin <85% of lower limit of age- and sex-appropriate normal after other causes of anemia, such as iron deficiency, have been treated or ruled out.
  - Platelet count <50 x $10^9$/L on two separate occasions at least one month apart. Higher cut offs may be considered in the event the patient is symptomatic with bleeding or bruising.
  - At least two episodes of severely symptomatic splenic infarcts confirmed by CT or other imaging of the abdomen.
- **Skeletal complications**
  - A single acute bone crisis severe enough to require hospitalization or marked incapacitation.
  - Radiographic or MRI evidence of incipient destruction of any major joint (e.g., hips and shoulders) or significant worsening of bony pathology (e.g. marrow infiltration, avascular necrosis, and infarcts).
  - Spontaneous fractures with evidence from imaging studies that recurrence is likely.

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

- Chronic bone pain causing significant loss of time from work or school and not controlled by administration of non-narcotic analgesics or anti-inflammatory drugs.
- Note: Patients who are scheduled for major joint replacement surgery, made necessary by skeletal complications of GD1, should be treated with enzyme therapy at a dosage of at least 30 units/kg every 2 weeks for at least 6 months before the joint replacement surgery and the dose continued until rehabilitation from the surgery is complete.

- **Gastrointestinal complications**
  - Evidence of significant liver dysfunction attributable to GD1, such as portal hypertension or impaired hepatic synthetic function. Elevation of transaminase levels with no evidence of portal hypertension or impairment in synthetic function is not an indication for ERT.
  - Significant discomfort due to enlargement of the spleen or liver.
- **Pulmonary complications**
  - Evidence of clinically significant and/or progressive pulmonary disease due to GD1.
- **Systemic complications**
  - Growth failure in children: significant decrease in percentile linear growth over a 3 - 6 month period.

**Exclusion Criteria:**

- Due to the absence of data demonstrating therapy of asymptomatic patients alters long term outcomes, asymptomatic patients will not be considered for coverage.
- Data does not suggest that ERT is effective in improving central nervous system involvement in patients with Type 2 and 3 disease. Therefore, patients exhibiting primary neurological disease due to GD1 will not be considered for coverage. Treatment for patients at risk of neuronopathic disease should be guided by the non-neurological manifestations of their disease as outlined above and ERT should not be initiated in asymptomatic patients who have a genotype that increases their risk of neuronopathic involvement.

**Continued Coverage:**

- Patients' disease severity must be re-assessed annually.
- A patient may receive approval for further coverage for treatment where there is demonstrated clinical improvement based on the expected response outlined below:

| Indication for therapy | Expected Response |
|---|---|
| Hemoglobin < 85% of lower limit of age and sex-appropriate normal | Increase hemoglobin levels to > 110 for women and children and > 120 for men |
| Platelet count < 50 x $10^9$/L on two separate occasions, or bleeding complications associated with thrombocytopenia irrespective of the platelet count | Increase platelet count to level sufficient to prevent spontaneous bleeding<br>Normalization of platelet count in splenectomized patients<br>In patients with intact spleen, an increase of at least 1.5X baseline value |
| Two episodes of severely symptomatic splenic infarcts | Reduction of spleen volume by 50%<br>Prevention of further splenic infarcts |
| Acute bone crises | Prevent bone crises |
| Radiographic or MRI evidence of incipient destruction of any major joint | Improvement in imaging parameters (either MRI, QCSI[1], or BMD) |
| Spontaneous fractures | Prevention of further fractures |

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

| Indication for therapy | Expected Response |
|---|---|
| Chronic bone pain | Reduce bone pain |
| Major joint replacement surgery | Optimize surgical outcome |
| Significant hepatic dysfunction | Improvement in hepatic function |
| Symptomatic hepatosplenomegaly | Reduction of spleen volume by 50%<br>Reduction in liver volume by 30% |
| Progressive pulmonary disease due to GD1 | Improvement in pulmonary hypertension[2]<br>Improvement in oxygenation<br>Reversal of hepatopulmonary syndrome |
| Growth failure in children | Return to normal range of growth parameters |

1. QCSI- quantitative chemical shift imaging
2. May require adjuvant treatment for pulmonary hypertension

**Discontinuation of Coverage:**

- Renewals will NOT be approved if:
    - The patient or the patient's specialist fails to comply adequately with treatment or measures taken to evaluate the effectiveness of the therapy (e.g. monitoring for expected response).
    - Therapy fails to relieve the symptoms of disease that originally resulted in the patient being approved for treatment.

**Claim Notes:**

- Approvals will be for a maximum of 60 units/kg every 2 weeks.
- Initial Approval: 6 months.
- Renewal Approval: 1 year.

## TAZAROTENE *(Arazlo 0.045% Lotion)*

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

## TEDUGLUTIDE *(Revestive 5mg Powder for Injection)*

### ADULT PATIENTS WITH SHORT BOWEL SYNDROME (SBS)

- **For the 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 or 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.

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

**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 specialist with experience in SBS.
- Approval period: 1 year.

**PEDIATRIC PATIENTS 1 YEAR OF AGE AND OLDER WITH SHORT BOWEL SYNDROME (SBS)**

- **For the treatment of pediatric patients 1 year of age and older with Short Bowel Syndrome (SBS) who have all of the following:**
    - Prior to initiating teduglutide, parenteral support (PS) requirements must be stable or there must have been no improvement in enteral feeding for at least three months.
    - PS must provide more than 30% of caloric and/or fluid/electrolyte needs.
    - The cumulative lifetime duration of PS must be at least 12 months.

**Renewal Criteria:**

- Has maintained at least a 20% reduction in parenteral support volume from baseline.

**Claim Notes:**

- Must be prescribed by a pediatric gastroenterologist or other prescriber currently working within a specialized multi-disciplinary intestinal rehabilitation program with expertise in the diagnosis and management of SBS.
- Initial Approval: 6 months.
- Renewal Approval: 6 months.

**Clinical Note:**

- PS 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.

## *TEMOZOLOMIDE *(Temodal 5mg, 20mg, 100mg, 140mg, 250mg Capsule and generic brands)*

- For the treatment of patients with high grade gliomas as monotherapy or in combination with other therapies such as radiation.

**Clinical Notes:**

- Patients should have a good performance status.
- Treatment should be continued until there is no longer a clinical benefit or unacceptable toxicity.

## TERIFLUNOMIDE *(14mg Tablet)*

- For the treatment of adult patients with relapsing remitting multiple sclerosis (RRMS) who meet all of the following criteria:
    - Ambulatory with or without aid (i.e. has a recent Expanded Disability Status Scale (EDSS) score of less than or equal to 6.5)
    - Experienced one or more disabling relapses or new MRI activity in the past two years

**Clinical Note:**

- Treatment should be discontinued for patients with an EDSS score of greater than or equal to 7.

**Claim Notes:**

- Must be prescribed by a neurologist with experience in the diagnosis and management of multiple sclerosis.
- Combined use with other disease modifying therapies to treat RRMS will not be reimbursed.
- Initial Approval: 2 years
- Renewal Approval: 5 years

## TERIPARATIDE *(Osnuvo 250mcg/mL Prefilled Cartridge Injection)*

- For the treatment of severe osteoporosis in patients who:
    - Have experienced a recent severe vertebral fracture OR
    - Had more than one vertebral fracture and a T-score of -2.5 or less at the total hip or lumbar spine, or femoral neck OR
    - Had failure, intolerance, or contraindication to bisphosphonates (oral and injectable) and denosumab

**Clinical Notes:**

- Recent fracture is defined as a fracture occurring within the past 2 years
- Severe vertebral fracture is defined as a vertebral body height loss of > 40%

**Claim Notes:**

- Requests are to be received from a specialist with expertise in anabolic therapy
- Lifetime exposure to be 24 months.

## *TESTOSTERONE, TOPICAL *(Androgel Gel Packet and 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.

**Notes:**

- Maximum dose approved is 5g per day.
- This will be adjudicated by limiting the quantity payable each quarter (e.g. Jan-Mar) to:
    - 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).

## TESTOSTERONE, TOPICAL *(Androgel Gel Packet and generic brands, and Testim Gel)*

- For use in gender affirming hormone therapy.

**Claim Note:**

- Maximum dose approved is 5g gel per day.

## TEZEPELUMAB *(Tezspire 210mg/1.91mL Prefilled Pen and Syringe)*

- For the treatment of severe asthma in patients 12 years and older who are inadequately controlled with high-dose inhaled corticosteroids (ICS), and one or more additional asthma controller(s) (e.g., long-acting beta-agonist), and have experienced 2 or more clinically significant asthma exacerbations in the past 12 months.

**Initial Discontinuation Criteria:**

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

**Subsequent Discontinuation Criteria:**

- Asthma control questionnaire score achieved after the first 12 months of therapy has not been maintained subsequently, or
- The reduction in the daily maintenance dose of OCS achieved after the first 12 months of treatment is not maintained or improved subsequently, or
- The number of clinically significant asthma exacerbations has increased within the previous 12 months.

**Clinical Notes:**

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

**Claim Notes:**

- Must be prescribed by a respirologist, clinical immunologist, allergist or internist experienced in the treatment of severe asthma.
- Combined us of tezepelumab with other biologics used to treat asthma will not be reimbursed.
- Approvals will be for a maximum of 210mg subcutaneous injection every 4 weeks.
- Approval period: 1 year.

## *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.

## TICAGRELOR *(Brilinta 60mg Tablet and generic brands)*

- In combination with ASA for patients with a history of ST elevation myocardial infarction (STEMI) or non-ST elevation acute coronary syndrome (NSTEACS) in the previous 3 years who are at high risk for subsequent cardiovascular events.

**Clinical Note:**

- High risk for subsequent cardiovascular events is defined as age 65 years or older, diabetes, second prior spontaneous myocardial infarction, multivessel coronary artery disease, or chronic renal dysfunction (creatinine clearance < 60mL/min).

**Claim Notes:**

- Approval period: Up to 3 years.

## TICAGRELOR *(Brilinta 90mg Tablet and generic brands)*

- 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.

## *TIGECYCLINE *(Tygacil 50mg Vial)*

- For the treatment of patients with multi-drug resistant infections when alternative agents are not an option.

**Claim Note:**

- Must be prescribed by, or in consultation with, an infectious disease specialist or medical microbiologist.

## TILDRAKIZUMAB *(Ilumya 100 mg/mL Prefilled Syringe)*

- For the treatment of patients with chronic moderate to severe plaque psoriasis who meet all of the following:
    - Psoriasis Area Severity Index (PASI) greater than 10 and Dermatology Life Quality Index (DLQI) greater than 10, OR major involvement of visible areas, scalp, genitals, or nails;
    - Refractory, intolerant to or unable to access phototherapy;
    - Refractory, intolerant to or have contraindications to methotrexate (oral or parenteral) at a dose of greater than or equal to 20 mg weekly (greater than or equal to 15 mg if patient is 65 years of age or older) for a minimum of 12 weeks **OR** cyclosporine (6 weeks treatment).
- For continued coverage, patients must meet the following criteria:
    - Greater than or equal to 75% reduction in PASI score, **OR**
    - Greater than or equal to 50% reduction in PASI and greater than or equal to 5 points in the DLQI **OR**
    - Significant reduction in BSA involved, with consideration of specific regions such as face, hands, feet or genital region and situations such as itch and recalcitrant plaques.

**Clinical Notes:**

- For patients who do not demonstrate a clinical response to oral methotrexate, or who experience gastrointestinal intolerance, a trial of parenteral methotrexate may be considered if clinically appropriate.
- 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 dermatologist or prescriber with a specialty in dermatology.
- Approvals will be for 100 mg by subcutaneous injection at week 0, week 4, and every 12 weeks thereafter.
- Combined use of more than one biologic will not be reimbursed.

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

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

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

- See **Long-Acting Beta$_2$-Agonists/Long-Acting Muscarinic Antagonists**

## *TRIFLURIDINE AND TIPIRACIL *(Lonsurf 15mg/6.14mg and 20mg/8.19mg Tablet)*

### METASTATIC GASTRIC CANCER OR ADENOCARCINOMA OF THE GASTROESOPHAGEAL JUNCTION

- For the treatment of adult patients with metastatic gastric cancer or adenocarcinoma of the gastroesophageal junction who meet the following criteria:
    - Previously treated with at least two prior lines of chemotherapy including a fluoropyrimidine, a platinum, and either a taxane or irinotecan and if appropriate, with HER2-targeted therapy.
    - Patients should have a good performance status.

**Clinical Notes:**

- Trifluridine/tipiracil should be used in combination with best supportive care.
- Treatment should be discontinued upon disease progression or unacceptable toxicity.
- Requests will be considered for patients who have an intolerance or contraindication to platinum-based therapy.

### UNRESECTABLE OR METASTATIC COLORECTAL CANCER

In combination with bevacizumab for the treatment of adult patients with unresectable or metastatic colorectal cancer who:

- Have previously been treated with, or are not candidates for, available therapies including fluoropyrimidine-, oxaliplatin, and irinotecan-based chemotherapies, anti-VEGF biological agents, and, if RAS wild-type, anti-EGFR agents; and
- Have disease progression or demonstrated intolerance to a maximum of 2 prior chemotherapy regimens for the treatment of unresectable or metastatic colorectal cancer.

**Clinical Notes:**

- Patients should have a good performance status.
- Treatment should continue until disease progression or unacceptable toxicity.
- No active CNS metastases (eligible if treated/stable).
- Patients with small bowel or appendiceal adenocarcinoma are eligible.
- Patients who were unable to receive bevacizumab in a prior line of therapy due to a contraindication will be eligible.
- Patients who have received adjuvant/neoadjuvant chemotherapy and had recurrence during or within 6 months of completion can count the adjuvant/neoadjuvant therapy as 1 of the maximum of 2 required prior chemotherapy regimens. Regimens which contain only targeted therapy or immunotherapy will not be considered as chemotherapy regimens.
- If bevacizumab is discontinued due to intolerance or contraindication, trifluridine-tipiracil can be continued at the discretion of the physician

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

**Effective June 1, 2025, patients currently taking the originator drug product, are required to switch to the biosimilar version by December 1, 2025.**

**For tocilizumab-naïve patients whose therapy is initiated after June 1, 2025, the tocilizumab biosimilar will be the product approved.**

### 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 AND 162MG/0.9ML SC INJECTION AND AUTOINJECTOR)

- 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.
- Subcutaneous injection: Approvals will be for a maximum of 162mg once every three weeks for patients weighing <30kg or 162mg once every two weeks for patients weighing ≥30kg.

**Claim Notes:**

- Initial Approval: 6 months.
- 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 AND AUTOINJECTOR)

- For the treatment of moderately to 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.

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

- 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 AND 162MG/0.9ML SC INJECTION AND AUTOINJECTOR)

- For the treatment of active systemic juvenile idiopathic arthritis (sJIA), in patients 2 years of age or older, who have responded inadequately to non-steroidal anti-inflammatory drugs (NSAIDs) and systemic corticosteroids (with or without methotrexate) due to intolerance or lack of efficacy.

**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 12 mg/kg for patients < 30kg or 8 mg/kg for patients ≥ 30kg, to a maximum of 800mg, administered every two weeks.
- Subcutaneous injection: Approvals will be for a maximum of 162mg once every two weeks for patients weighing <30kg or 162mg once every week for patients weighing ≥30kg.
- Initial Approval: 6 months.
- Renewal Approval: 1 year. Confirmation of continued response is required.

## TOCILIZUMAB *(Tyenne 80mg/4mL, 200mg/10mL and 400mg/20mL Vial, 162mg/ 0.9mL Prefilled Syringe and 162mg /0.9mL Autoinjector)*

**Effective June 1, 2025, patients currently taking the originator drug product, are required to switch to the biosimilar version by December 1, 2025.**

**For tocilizumab-naïve patients whose therapy is initiated after June 1, 2025, the tocilizumab biosimilar will be the product approved.**

### RHEUMATOID ARTHRITIS (TYENNE 80MG/4ML, 200MG/10ML, 400MG/20ML VIAL AND 162MG/0.9ML SC PREFILLED SYRINGE AND AUTOINJECTOR)

- For the treatment of moderately to 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), or use in combination with another DMARD, for a minimum of 12 weeks

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

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: Long term.
- Maximum Dosage Approved:
  - Tocilizumab: 4mg/kg/dose once every 4 weeks followed by an increase to 8 mg/kg/dose based on clinical response

### POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (PJIA) (TYENNE 80MG/4ML, 200MG/10ML, 400MG/20ML VIAL AND 162MG/0.9ML SC PREFILLED SYRINGE AND AUTOINJECTOR)

- 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).

**Clinical 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.
- Subcutaneous injection: Approvals with be for a maximum of 162mg once every three weeks for patients weighing <30kg or 162mg once every two weeks for patients weighing ≥30kg.

**Claim Notes:**

- Initial approval: 6 months
- Renewal Approval: Long term

### SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS (SJIA) (TYENNE 80MG/4ML, 200MG/10ML, 400MG/20ML VIAL AND 162MG/0.9ML SC PREFILLED SYRINGE AND AUTOINJECTOR)

- For the treatment of active systemic juvenile idiopathic arthritis (sJIA), in patients 2 years of age or older, who

have responded inadequately to non-steroidal anti-inflammatory drugs (NSAIDs) and systemic corticosteroids (with or without methotrexate) due to intolerance or lack of efficacy.

**Clinical Notes:**

- 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 12 mg/kg for patients < 30kg or 8 mg/kg for patients ≥ 30kg, to a maximum of 800mg, administered every two weeks.
- Subcutaneous injection: Approvals with be for a maximum of 162mg once every two weeks for patients weighing <30kg or 162mg once every week for patients weighing ≥30kg.

**Claim Notes:**

- Initial approval period: 6 months
- Renewal Approval: Long term

### GIANT CELL ARTERITIS (GCA) (TYENNE 162MG/0.9ML SC PREFILLED SYRINGE AND AUTOINJECTOR)

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

**Clinical 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. If treatment is extended beyond 52 weeks, consideration should be given regarding response to treatment, outcome off therapy and ability to taper glucocorticoids.
- Discontinuation of tocilizumab should be considered at 12 weeks if there is no response to therapy.

**Claim Notes:**

- Initial approval period: 6 months
- Renewal Approval: Long term

## TOFACITINIB *(Xeljanz 5mg, 10mg, Xeljanz XR 11mg Tablet and generic brands)*

### RHEUMATOID ARTHRITIS (5MG TABLET AND XR 11MG TABLET)

- 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.

**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.

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

- 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.

**Claim Notes:**

- Initial Approval: 6 months.
- Renewal Approval: Long term.

**ULCERATIVE COLITIS (5MG AND 10MG TABLET)**

- 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 corticosteroid 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 with one or more biologic DMARD will not be reimbursed.
- Approvals will be for a maximum dose of 10 mg twice daily (Xeljanz).
- Initial Approval: 6 months.
- Renewal Approval: Long term.

## TOPIRAMATE *(Topamax 15mg and 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 *(Retin-A 0.025% Gel and Retin-A 0.05% Cream)*

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

## TRIENTINE HYDROCHLORIDE *(250mg Capsule)*

### WILSON'S DISEASE

- For the treatment of Wilson's disease in patients who have experienced intolerance or have a contraindication to d-penicillamine.

**Clinical Note:**

- Intolerance is defined as demonstrating serious adverse effects to treatments. The nature of intolerance(s) must be clearly documented.

**Claims Notes:**

- Treatment must be initiated by clinicians experienced in the management of Wilson's disease for adult patients 18 years of age or older.
- Treatment must be initiated and renewed by clinicians experienced in the management of Wilson's disease for patients less than 18 years of age.
- Approval: 12 months

## TRIHEPTANOIN *(Dojolvi 100% Oral Liquid)*

- For the treatment of adult and pediatric patients with an acute life-threatening long-chain fatty acid oxidation disorders (LC-FAOD) who meet the following criteria:
    - patients with a confirmed diagnosis of LC-FAOD and acute life-threatening events who require alternative therapy to conventional even-chain medium-chain triglyceride (MCT) supplementation, OR
    - patients without a confirmed diagnosis of LC-FAOD presenting with acute life-threatening events consistent with LC-FAOD who require alternative therapy to conventional even-chain MCT supplementation.

**Claims Notes:**

- Triheptanoin should only be prescribed by clinicians experienced in the management of LC-FAOD.
- Approval: 1 year. Confirmation of continued response required.

## 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

## *TUCATINIB *(Tukysa 50mg and 150mg Tablet)*

### LOCALLY ADVANCED UNRESECTABLE OR METASTATIC HER2-POSITIVE BREAST CANCER

- In combination with trastuzumab and capecitabine for the treatment of patients with locally advanced unresectable or metastatic HER2-positive breast cancer who have received prior treatment with trastuzumab, pertuzumab and a HER2-targeted antibody-drug conjugate (e.g., trastuzumab emtansine or trastuzumab deruxtecan), where at

least one was given in the advanced or metastatic setting.

**Clinical Notes:**

- Patients should have a good performance status.
- Treatment should be discontinued upon disease progression, unacceptable toxicity, or if both trastuzumab and capecitabine are discontinued.

## UMECLIDINIUM (AS BROMIDE) AND VILANTEROL (AS TRIFENATATE) *(Anoro Ellipta 62.5mcg/25mcg Powder for Oral Inhalation)*

- See **Long-Acting Beta$_2$-Agonists/Long-Acting Muscarinic Antagonists**

## UPADACITINIB *(Rinvoq 15mg, 30mg & 45mg Tab)*

### RHEUMATOID ARTHRITIS (15MG TAB)

- For the treatment of severely active rheumatoid arthritis, alone or 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 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.
- Concurrent use of more than one biologic DMARD or janus kinase inhibitors will not be reimbursed.
- Approvals will be for a maximum of 15 mg daily.
- Initial Approval: 6 months
- Renewal Approval: 1 year. Confirmation of continued response required.

### PSORIATIC ARTHRITIS (15MG TAB)

- 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.
- Concurrent use of biologics not approved.
- Approvals will be for a maximum of 15mg daily.
- Initial coverage period: 6 months.
- Renewal Approval: 1 year. Confirmation of continued response required.

**ATOPIC DERMATITIS (15MG & 30MG TAB)**

- For the treatment of moderate to severe atopic dermatitis in patients 12 years of age and older who meet all of the following criteria:
    - Patients must have had an adequate trial (with a documented refractory disease), or were intolerant (with documented intolerance), or are ineligible for each of the following therapies:
        - maximally tolerated medical topical therapies for AD combined with phototherapy (where available), and;
        - maximally tolerated medical topical therapies for AD combined with at least 1 of the 4 systemic immunomodulators (methotrexate, cyclosporine, mycophenolate mofetil, or azathioprine)
    - Baseline Physician Global Assessment score of 3 or greater and Eczema Area and Severity Index (EASI) of 7.1 or greater.

**Renewal Criteria:**

- Requests for renewal must provide proof of beneficial clinical effect when defined as a 75% or greater improvement from baseline in the EASI score (EASI-75) 6 months after treatment initiation.
- Proof of maintenance of EASI-75 response from baseline must be provided for subsequent authorizations.

**Clinical Note:**

- Not to be used in combination with phototherapy, any immunomodulatory agents (including biologics or other janus kinase inhibitor treatment) for moderate to severe AD.

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

**Claim Notes:**

- The patient must be under the care of a dermatologist, allergist, clinical immunologist, or pediatrician who has expertise in the management of moderate to severe AD.
- Approvals will be for a maximum of 30mg once daily.
- Initial Approval: 6 months
- Renewal Approval: 1 year

### CROHN'S DISEASE (15MG, 30MG & 45MG TAB)

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

**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 to treatments. The nature of intolerance(s) must be clearly documented.

**Claim Notes:**

- Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology.
- Combined use with other biologic drugs or janus kinase (JAK) inhibitors will not be reimbursed.
- Approvals will be for a maximum of 45mg daily for 12 weeks followed by a maximum of 30mg daily.
- Initial Approval: 6 months.
- Renewal Approval: 1 year

### ULCERATIVE COLITIS (15MG, 30MG & 45MG TAB)

- 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 with biologic drugs or other JAK inhibitors will not be reimbursed.

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

- Approvals will be for a maximum of 45mg daily for 8 weeks followed by a maximum of 30mg daily.
- Initial Approval: 6 months.
- Renewal Approval: 1 year at a maximum dose of 30mg once daily.

**ANKYLOSING SPONDYLITIS (15MG TAB)**

- For treatment of patients with moderate to severe ankylosing spondylitis (Bath AS Disease Activity Index (BASDAI) score ≥4 on 10 point scale) who are refractory to, intolerant or have contraindications to a biologic disease-modifying antirheumatic drug (bDMARD).

**Renewal Criteria:**

- A decrease of at least 2 points on the BASDAI scale, compared with the pre-treatment score; OR
- Patient and expert opinion of an adequate clinical response as indicated by a significant functional improvement (measured by outcomes such as HAQ or "ability to return to work").

**Clinical Notes:**

- 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 or prescriber with a specialty in rheumatology.
- Combined use with biologic drugs or other JAK inhibitors will not be reimbursed.
- Approvals will be for a maximum of 15 mg daily.
- Initial Approval: 6 months
- Renewal Approval: 1 year.

## USTEKINUMAB *(Jamteki 45mg/0.5mL and 90mg/1.0mL Prefilled Syringe)*

**PLAQUE PSORIASIS**

- For the treatment of patients with chronic moderate to severe plaque psoriasis who meet all of the following:
    - Psoriasis Area Severity Index (PASI) greater than 10 and Dermatology Life Quality Index (DLQI) greater than 10, OR major involvement of visible areas, scalp, genitals, or nails;
    - Refractory, intolerant to or unable to access phototherapy;
    - Refractory, intolerant to or have contraindications to methotrexate (oral or parenteral) at a dose of greater than or equal to 20 mg weekly (greater than or equal to 15 mg if patient is 65 years of age or older) for a minimum of 12 weeks **OR** cyclosporine (6 weeks treatment).
- For continued coverage, patients must meet the following criteria:
    - Greater than or equal to 75% reduction in PASI score, **OR**
    - Greater than or equal to 50% reduction in PASI and greater than or equal to 5 points in the DLQI **OR**
    - Significant reduction in BSA involved, with consideration of specific regions such as face, hands, feet or genital region and situations such as itch and recalcitrant plaques.

**Clinical Notes:**

- For patients who do not demonstrate a clinical response to oral methotrexate, or who experience gastrointestinal intolerance, a trial of parenteral methotrexate may be considered if clinically appropriate.

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

- 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 dermatologist or prescriber with a specialty in dermatology.
- Combined use of more than one biologic will not be reimbursed.
- Approvals will be for a maximum of 45mg subcutaneously at Week 0, 4 and 16 weeks, followed by a maintenance dose of 45mg subcutaneously every 12 weeks. Response must be assessed prior to fourth dose.
- Initial Approval: 6 months.
- Renewal Approval: Long term.

**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.
- Concurrent use of biologics not approved.
- Approvals will be for a maximum of 45mg subcutaneously at Weeks 0 and 4, and maintenance dosing of 45mg subcutaneously every 12 weeks. For patients >100kg, doses of 90mg may be considered.
- Initial period 6 months.
- Renewal Approval: Long term.

## USTEKINUMAB *(Steqeyma 45mg/0.5mL and 90mg/1.0mL Prefilled Syringe and 130mg/26mL Vial)*

**PLAQUE PSORIASIS**

- For the treatment of patients with chronic moderate to severe plaque psoriasis who meet all of the following:
    - Psoriasis Area Severity Index (PASI) greater than 10 and Dermatology Life Quality Index (DLQI) greater

than 10, OR major involvement of visible areas, scalp, genitals, or nails;
    - Refractory, intolerant to or unable to access phototherapy;
    - Refractory, intolerant to or have contraindications to methotrexate (oral or parenteral) at a dose of greater than or equal to 20 mg weekly (greater than or equal to 15 mg if patient is 65 years of age or older) for a minimum of 12 weeks **OR** cyclosporine (6 weeks treatment).
- For continued coverage, patients must meet the following criteria:
    - Greater than or equal to 75% reduction in PASI score, **OR**
    - Greater than or equal to 50% reduction in PASI and greater than or equal to 5 points in the DLQI OR
    - Significant reduction in BSA involved, with consideration of specific regions such as face, hands, feet or genital region and situations such as itch and recalcitrant plaques.

**Clinical Notes:**

- For patients who do not demonstrate a clinical response to oral methotrexate, or who experience gastrointestinal intolerance, a trial of parenteral methotrexate may be considered if clinically appropriate
- 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 dermatologist or prescriber with a specialty in dermatology.
- Combined use of more than one biologic will not be reimbursed.
- Approvals will be for a maximum of 45mg subcutaneously at Week 0, 4 and 16 weeks, followed by a maintenance dose of 45mg subcutaneously every 12 weeks. Response must be assessed prior to fourth dose.
- Initial Approval: 6 months.
- Renewal Approval: Long term.

**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.

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

**Claim Notes:**

- Must be prescribed by a rheumatologist.
- Concurrent use of biologics not approved.
- Approvals will be for a maximum of 45mg subcutaneously at Weeks 0 and 4, and maintenance dosing of 45mg subcutaneously every 12 weeks. For patients >100kg, doses of 90mg may be considered.
- Initial period 6 months.
- Renewal Approval: Long term.

**CROHN'S DISEASE**

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

**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 to treatments. The nature of intolerance(s) must be clearly documented.

**Claim Notes:**

- Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology.
- Combined use of more than one biologic disease-modifying antirheumatic drugs (DMARD) or janus kinase inhibitors (JAK) will not be reimbursed.
- Initial reimbursement will be for a single intravenous dose of up to 520mg at Week 0 and a subcutaneous dose of 90mg at Week 8 and 16. Subsequent reimbursement for maintenance dosing is 90mg subcutaneously every 8 weeks.
- Initial Approval: 6 months.
- Renewal Approval: Long term.

## USTEKINUMAB *(Wezlana 45mg/0.5mL and 90mg/1.0mL Prefilled Syringe and Prefilled Autoinjector and 45mg/0.5mL and 130mg/26mL Vial)*

**PLAQUE PSORIASIS**

- For the treatment of patients with chronic moderate to severe plaque psoriasis who meet all of the following:
    - Psoriasis Area Severity Index (PASI) greater than 10 and Dermatology Life Quality Index (DLQI) greater than 10, OR major involvement of visible areas, scalp, genitals, or nails;
    - Refractory, intolerant to or unable to access phototherapy;
    - Refractory, intolerant to or have contraindications to methotrexate (oral or parenteral) at a dose of greater than or equal to 20 mg weekly (greater than or equal to 15 mg if patient is 65 years of age or older) for a minimum of 12 weeks **OR** cyclosporine (6 weeks treatment).
- For continued coverage, patients must meet the following criteria:
    - Greater than or equal to 75% reduction in PASI score, **OR**
    - Greater than or equal to 50% reduction in PASI and greater than or equal to 5 points in the DLQI **OR**
    - Significant reduction in BSA involved, with consideration of specific regions such as face, hands, feet or genital region and situations such as itch and recalcitrant plaques.

**Clinical Notes:**

- For patients who do not demonstrate a clinical response to oral methotrexate, or who experience gastrointestinal intolerance, a trial of parenteral methotrexate may be considered if clinically appropriate.
- 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 dermatologist or prescriber with a specialty in dermatology.
- Combined use of more than one biologic will not be reimbursed.
- Approvals will be for a maximum of 45mg subcutaneously at Week 0, 4 and 16 weeks, followed by a maintenance dose of 45mg subcutaneously every 12 weeks. Response must be assessed prior to fourth dose.
- Initial Approval: 6 months.
- Renewal Approval: Long term.

**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.
- Concurrent use of biologics not approved.
- Approvals will be for a maximum of 45mg subcutaneously at Weeks 0 and 4, and maintenance dosing of 45mg subcutaneously every 12 weeks. For patients >100kg, doses of 90mg may be considered.
- Initial period 6 months.
- Renewal Approval: Long term.

**ULCERATIVE COLITIS**

- For the treatment of patients with moderately to severely active ulcerative colitis who have a partial Mayo score >

4, and a rectal bleeding subscore ≥ 2 and are:

  - 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 reimbursement will be for a single intravenous dose of up to 520mg at Week 0 and a subcutaneous dose of 90mg at Week 8 and 16. Subsequent reimbursement for maintenance dosing is 90mg subcutaneously every 8 weeks.
- Initial Approval: 6 months.
- Renewal Approval: Long term.

**CROHN'S DISEASE**

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

**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 to treatments. The nature of intolerance(s) must be clearly documented.

**Claim Notes:**

- Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology.
- Combined use with other biologic drugs or janus kinase (JAK) inhibitors will not be reimbursed.
- Initial reimbursement will be for a single intravenous dose of up to 520mg at Week 0 and a subcutaneous dose of 90mg at Week 8 and 16. Subsequent reimbursement for maintenance dosing is 90mg subcutaneously every 8 weeks.
- Initial Approval: 6 months.
- Renewal Approval: Long term.

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

## VALGANCICLOVIR *(Valcyte 50mg/mL Powder for Oral Solution and generic brands)*

- 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.

## *VANDETANIB *(Caprelsa 100mg and 300mg Tablet)*

- For the treatment of symptomatic and/or progressive medullary thyroid cancer (MTC) in patients with unresectable locally advanced or metastatic disease. Treatment should be for patients with a good performance status and should continue until disease progression or unacceptable toxicity.

## VARENICLINE *(0.5mg and 1mg Tablet, 0.5mg/1mg combopack)*

- See **Smoking Cessation Therapies**

## VEDOLIZUMAB *(Entyvio 300mg Vial, 108mg/0.68mL Prefilled Pen and Prefilled Syringe)*

### CROHN'S DISEASE

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

**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 to treatments. The nature of intolerance(s) must be clearly documented.

**Claim Notes:**

- Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology.
- Combined use with other biologic drugs or janus kinase (JAK) inhibitors will not be reimbursed.
- Intravenous infusion: 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.
- Subcutaneous injection: Initial reimbursement is for at least two doses of intravenous infusions of vedolizumab. Clinical response to be assessed prior to the administration of the first subcutaneous dose. Subsequent reimbursement for maintenance dosing is 108mg subcutaneously every 2 weeks.
- Initial Approval: 6 months.
- Renewal Approval: 1 year

### 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.
- Intravenous infusion: 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.
- Subcutaneous injection: Initial reimbursement is for at least two doses of intravenous infusions of vedolizumab. Clinical response to be assessed prior to the administration of the first subcutaneous dose. Subsequent reimbursement for maintenance dosing is 108mg subcutaneously every 2 weeks.
- Initial Approval: 6 months.
- Renewal Approval: 1 year

## VELAGLUCERASE ALFA *(VPRIV 400U Vial)*

- For the treatment of patients with symptomatic Gaucher disease type 1 (GD1) for whom treatment with velaglucerase alfa is tolerated or not contraindicated.

**Clinical Notes:**

- Velaglucerase alfa is the preferred reimbursed enzyme replacement therapy (i.e. first tier) for all new and existing GD1.
- Requests for patients currently using taliglucerase alfa who do not have a contraindication or intolerance to velaglucerase alfa will be switched to velaglucerase alfa only.
- Requests for coverage must meet the criteria for diagnosis of GD1, indication for therapy and expected response to enzyme replacement therapy outlined below:

**Initial Coverage**

**Diagnosis**

- The diagnosis of GD1 must have been established by the demonstration of specific deficiency of glucocerebrosidase (GCase) in tissue or cultured skin fibroblasts, or by demonstration of the presence, in tissue or peripheral blood leukocytes, of mutations in the GCase gene known to result in severe enzyme deficiency.
- Other potentially confounding diagnoses, such as Hodgkin disease or other storage disorders, must have been ruled out. The symptoms experienced by the patient should be shown to be attributable to GD1 and not another condition that might mimic it.

- The patient should not have any GD1-related or other medical condition that might reasonably be expected to compromise their response to treatment. In some patients with GD1, secondary pathologic changes, such as avascular necrosis of bone, may already have occurred that would not be expected to respond to enzyme replacement. In such patients, reversal of the pathology is unlikely.

**Disease Severity**

Evidence of disease severity must be provided, and include at least one of the following:

- **Hematological complications**
  - Hemoglobin <85% of lower limit of age- and sex-appropriate normal after other causes of anemia, such as iron deficiency, have been treated or ruled out.
  - Platelet count <50 x $10^9$/L on two separate occasions at least one month apart. Higher cut offs may be considered in the event the patient is symptomatic with bleeding or bruising.
  - At least two episodes of severely symptomatic splenic infarcts confirmed by CT or other imaging of the abdomen.
- **Skeletal complications**
  - A single acute bone crisis severe enough to require hospitalization or marked incapacitation.
  - Radiographic or MRI evidence of incipient destruction of any major joint (e.g., hips and shoulders) or significant worsening of bony pathology (e.g. marrow infiltration, avascular necrosis, and infarcts).
  - Spontaneous fractures with evidence from imaging studies that recurrence is likely.
  - Chronic bone pain causing significant loss of time from work or school and not controlled by administration of non-narcotic analgesics or anti-inflammatory drugs.
  - Note: Patients who are scheduled for major joint replacement surgery, made necessary by skeletal complications of GD1, should be treated with enzyme therapy at a dosage of at least 30 units/kg every 2 weeks for at least 6 months before the joint replacement surgery and the dose continued until rehabilitation from the surgery is complete.
- **Gastrointestinal complications**
  - Evidence of significant liver dysfunction attributable to GD1, such as portal hypertension or impaired hepatic synthetic function. Elevation of transaminase levels with no evidence of portal hypertension or impairment in synthetic function is not an indication for ERT.
  - Significant discomfort due to enlargement of the spleen or liver.
- **Pulmonary complications**
  - Evidence of clinically significant and/or progressive pulmonary disease due to GD1.
- **Systemic complications**
  - Growth failure in children: significant decrease in percentile linear growth over a 3 - 6 month period.

**Exclusion Criteria:**

- Due to the absence of data demonstrating therapy of asymptomatic patients alters long term outcomes, asymptomatic patients will not be considered for coverage.
- Data does not suggest that ERT is effective in improving central nervous system involvement in patients with Type 2 and 3 disease. Therefore, patients exhibiting primary neurological disease due to GD1 will not be considered for coverage. Treatment for patients at risk of neuronopathic disease should be guided by the non-neurological manifestations of their disease as outlined above and ERT should not be initiated in asymptomatic patients who have a genotype that increases their risk of neuronopathic involvement.

**Continued Coverage:**

- Patients' disease severity must be re-assessed annually.
- A patient may receive approval for further coverage for treatment where there is demonstrated clinical

improvement based on the expected response outlined below:

| Indication for therapy | Expected Response |
|---|---|
| Hemoglobin < 85% of lower limit of age and sex-appropriate normal | Increase hemoglobin levels to > 110 for women and children and > 120 for men |
| Platelet count < 50 x $10^9$/L on two separate occasions, or bleeding complications associated with thrombocytopenia irrespective of the platelet count | Increase platelet count to level sufficient to prevent spontaneous bleeding<br>Normalization of platelet count in splenectomized patients<br>In patients with intact spleen, an increase of at least 1.5X baseline value |
| Two episodes of severely symptomatic splenic infarcts | Reduction of spleen volume by 50%<br>Prevention of further splenic infarcts |
| Acute bone crises | Prevent bone crises |
| Radiographic or MRI evidence of incipient destruction of any major joint | Improvement in imaging parameters (either MRI, QCSI[1], or BMD) |
| Spontaneous fractures | Prevention of further fractures |
| Chronic bone pain | Reduce bone pain |
| Major joint replacement surgery | Optimize surgical outcome |
| Significant hepatic dysfunction | Improvement in hepatic function |
| Symptomatic hepatosplenomegaly | Reduction of spleen volume by 50%<br>Reduction in liver volume by 30% |
| Progressive pulmonary disease due to GD1 | Improvement in pulmonary hypertension[2]<br>Improvement in oxygenation<br>Reversal of hepatopulmonary syndrome |
| Growth failure in children | Return to normal range of growth parameters |

1. QCSI- quantitative chemical shift imaging
2. May require adjuvant treatment for pulmonary hypertension

**Discontinuation of Coverage:**

- Renewals will NOT be approved if:
  - The patient or the patient's specialist fails to comply adequately with treatment or measures taken to evaluate the effectiveness of the therapy (e.g. monitoring for expected response).
  - Therapy fails to relieve the symptoms of disease that originally resulted in the patient being approved for treatment.

**Claim Notes:**

- Approvals will be for a maximum of 60 units/kg every 2 weeks.
- Initial Approval: 6 months.
- Renewal Approval: 1 year.

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

## *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
- For the treatment of patients with BRAF V600 mutation-positive unresectable or metastatic melanoma when used alone or in combination with cobimetinib.

**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 sstatus.
- If brain metastases are present, patients should be asymptomatic or have stable symptoms.
- Treatment should be discontinued upon disease progression or unacceptable toxicity.

**Claim Note:**

- Vemurafenib will not be reimbursed in patients who have progressed on BRAF and/or MEK inhibitor therapy.

## *VENETOCLAX *(Venclexta 10mg, 50mg, 100mg Tablets and Starter Kit)*

### VENETOCLAX WITH OBINUTUZUMAB FOR PREVIOUSLY UNTREATED CHRONIC LYMPHOCYTIC LEUKEMIA (CLL) OR SMALL LYMPHOCYTIC LYMPHOMA (SLL)

- In combination with obinutuzumab for the treatment of adult patients with previously untreated chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) who are fludarabine ineligible.

**Clinical Notes:**

- Treatment should be given for a total of 12 months (six 28-day cycles in combination with obinutuzumab, followed by six months of monotherapy), or until disease progression or unacceptable toxicity, whichever occurs first.
- Retreatment with a venetoclax based regimen is funded if relapse is greater than 12 months from completion of venetoclax in combination with obinutuzumab.
- Either ibrutinib or acalabrutinib is funded as a subsequent treatment option, provided all other funding criteria are met.

### VENETOCLAX WITH AZACITIDINE FOR NEWLY DIAGNOSED ACUTE MYELOID LEUKEMIA (AML)

- In combination with azacitidine for the treatment of patients with newly diagnosed acute myeloid leukemia (AML) who are 75 years of age or older, or who have comorbidities that preclude the use of intensive induction chemotherapy.

**Clinical Notes:**

- Treatment should continue until disease progression or unacceptable toxicity.
- All newly diagnosed AML patients who are ineligible for induction chemotherapy are eligible regardless of cytogenetic risk.,
- On a time-limited need, patients who are currently receiving azacitidine for newly diagnosed AML may have venetoclax added to their treatment provided there is no disease progression and patient otherwise meets criteria.

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

**Claim Notes:**

- Patients who have been previously treated with a hypomethylating agent or chemotherapy for the treatment of myelodysplastic syndromes (MDS) are not eligible for treatment with venetoclax in combination with azacitidine.
- Patients with high risk MDS are not eligible for treatment with venetoclax in combination with azacitidine.

**VENETOCLAX MONOTHERAPY FOR CHRONIC LYMPHOCYTIC LEUKEMIA (CLL) OR SMALL LYMPHOCYTIC LYMPHOMA (SLL) IN PATIENTS WHO HAVE RECEIVED AT LEAST ONE PRIOR THERAPY**

- 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 an 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.

**VENETOCLAX WITH RITUXIMAB FOR CHRONIC LYMPHOCYTIC LEUKEMIA (CLL) OR SMALL LYMPHOCYTIC LYMPHOMA (SLL) IN PATIENTS WHO HAVE RECEIVED AT LEAST ONE PRIOR THERAPY**

- In combination with rituximab for the treatment of adult patients with chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) who have received at least one prior therapy, irrespective of their 17p deletion status. Treatment should be continued until disease progression or unacceptable toxicity up to a maximum of two years, whichever comes first.

**Clinical Notes:**

- Patients who were previously treated with an anti-CD20 therapy (rituximab or obinutuzumab) will be eligible if they had a progression-free interval of 6 months or longer. For patients previously treated with venetoclax, the progression-free interval must be 12 months or longer.
- Patients currently receiving and responding to venetoclax monotherapy, and who have not achieved an adequate response are eligible to have rituximab added to venetoclax. Note: Venetoclax therapy is funded to a maximum of two years from the time rituximab is added.
- Patients will be eligible for treatment with either ibrutinib, or idelalisib with rituximab following progression on venetoclax with rituximab if they have not received before and otherwise meet eligibility criteria.

**VENETOCLAX WITH IBRUTINIB FOR PREVIOUSLY UNTREATED CHRONIC LYMPHOCYTIC LEUKEMIA (CLL) OR SMALL LYMPHOCYTIC LYMPHOMA (SLL)**

- For the treatment of adult patients with previously untreated chronic lymphocytic leukemia (CLL), including those with 17p deletion, in combination with ibrutinib.

**Clinical Notes:**

- Patients should have a good performance status and no evidence of disease transformation.
- Treatment should be discontinued upon disease progression, unacceptable toxicity, or to a maximum of 12 cycles. Note that combination treatment should be initiated following three cycles of ibrutinib monotherapy.
- Patients who have progressed on a BTK inhibitor are not eligible.
- No active CNS involvement (eligible if treated/stable).
- If ibrutinib is discontinued for intolerance, venetoclax monotherapy may be continued.
- Patients with small lymphocytic lymphoma (SLL) are eligible for treatment.

## VERICIGUAT *(Verquvo 2.5mg, 5mg and 10mg Tablet)*

For the treatment of patients with symptomatic chronic heart failure (HF) as an adjunct to standard-of-care (SOC) therapy with reduced ejection fraction who are stabilized after a recent HF decompensation who meet all of the following criteria:

- patients with symptomatic chronic HF with reduced ejection fraction (i.e., left ventricular ejection fraction <45%) AND
- patients must have a recent HF decompensation event requiring hospitalization and/or IV diuretic therapy.

**Clinical Notes:**

- SOC includes beta blockers, angiotensin-converting enzyme inhibitors (ACEis), angiotensin receptor blockers (ARBs), angiotensin receptor-neprilysin inhibitor (ARNI), sodium-glucose co-transporter 2 inhibitor (SGLT2i), and a mineralocorticoid receptor antagonist (MRA) unless these therapies are contraindicated or not tolerated.

## 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 **[Criteria Code 01]**
- For the treatment of culture proven invasive candidiasis with documented resistance to fluconazole **[Criteria Code 02]**

**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.

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

## VUTRISIRAN *(Amvuttra 25mg/0.5mL Prefilled Syringe)*

- For the treatment of polyneuropathy in adult patients with hereditary transthyretin-mediated amyloidosis (hATTR) who meet all of the following criteria:
    - Confirmed genetic diagnosis of hATTR.
    - Symptomatic with early-stage neuropathy[1].
    - Does not have New York Heart Association class III or IV heart failure.
    - Has not previously undergone a liver transplant.

**Discontinuation Criteria:**

- The patient is permanently bedridden and dependent on assistance for basic activities of daily living.

  **OR**

- The patient is receiving end-of-life care.

**Clinical Note:**

- Symptomatic early-stage neuropathy is defined as polyneuropathy disability stage I to IIIB or familial amyloidotic polyneuropathy stage I or II.

**Claim Notes:**

- The patient must be under the care of a physician with experience in the diagnosis and management of hATTR.
- Combination therapy with other interfering ribonucleic acid drugs or transthyretin stabilizers used to treat hATTR will not be reimbursed.
- Initial Approval: 9 months.
- Renewal Approval: 12 months. Confirmation of continued response is required.
- For claim adjudication direction contact Nova Scotia Pharmacare Programs.

## *WET NEBULIZATION SOLUTIONS *(Budesonide, 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.

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

## *ZANUBRUTINIB *(Brukinsa 80mg Capsule and 160mg Tablet)*

### PREVIOUSLY UNTREATED CHRONIC LYMPHOCYTIC LEUKEMIA (CLL) OR SMALL LYMPHOCYTIC LYMPHOMA (SLL)

- As monotherapy for the treatment of adult patients with previously untreated chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) for whom a fludarabine-based regimen is considered inappropriate due to a high risk of relapse or refractory disease based on prognostic biomarkers.

**Clinical Notes:**

- Patients should have a good performance status.
- Treatment should be continued until disease progression or unacceptable toxicity.
- High risk for relapse or refractory disease includes 17p deletion, TP53 mutation, 11q deletion and unmutated IGHV.

**Claim Notes:**

- Patients are not eligible if they have prolymphocytic leukemia or Richter's transformation.
- Requests will not be considered for patients who experience disease progression on a Bruton's tyrosine kinase (BTK) inhibitor or idelalisib.
- Requests will be considered for patients who are not suitable candidates for intravenous therapy.
- Venetoclax with or without rituximab is funded as a subsequent line of therapy in patients who have experienced disease progression during first-line zanubrutinib treatment, provided all other funding eligibility criteria are met.

### RELAPSED/REFRACTORY CHRONIC LYMPHOCYTIC LEUKEMIA (CLL) OR SMALL LYMPHOCYTIC LYMPHOMA (SLL)

- As monotherapy for the treatment of adult patients with relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) who have received at least one prior systemic therapy.

**Clinical Notes:**

- Patients should have a good performance status.
- Treatment should be continued until disease progression or unacceptable toxicity.

**Claim Notes:**

- Patients are not eligible if they have prolymphocytic leukemia or Richter's transformation.
- Requests will not be considered for patients who experience disease progression on a Bruton's tyrosine kinase (BTK) inhibitor or idelalisib.

### RELAPSED OR REFRACTORY WALDENSTRÖM MACROGLOBULINEMIA

- For the treatment of adult patients with relapsed or refractory Waldenström macroglobulinemia who have received at least one prior therapy and have not experienced disease progression on a Bruton's tyrosine kinase inhibitor.

**Clinical Notes:**

- Patients should have a good performance status and no evidence of disease transformation.
- Treatment should be discontinued upon disease progression or unacceptable toxicity.

## 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

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