Health PEI
One Island Health System

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PEI Pharmacare Bulletin

Issue (2023 - 12) **December 4, 2023**

PRODUCT(S) MOVED TO OPEN BENEFIT STATUS UNDER THE PEI PHARMACARE FORMULARY (EFFECTIVE IMMEDIATELY)

The following DOACs (Direct Oral Anticoagulants) are now available as open benefit (i.e. special authorization not required) within eligible Pharmacare drug programs:

- Apixaban, tablet, 2.5 mg, 5 mg
- Edoxaban, tablet, 15 mg, 30 mg, 60 mg
- Rivaroxaban, tablet, 2.5 mg, 10 mg, 15 mg, 20 mg

Applicable Drug Programs include Family Health Benefit, Generic (generic versions only), Nursing Home, Catastrophic, Seniors and Financial Assistance.

As a reminder regarding reimbursement
- above listed products are eligible for a 90 day's supply
- copayment is $5 in Family Health Benefit, Generic (generic versions only) and Seniors Drug Programs

PEI BIOSIMILAR INITIATIVE – BIOSIMILAR INSULIN REMINDER

- Some patients may require continued access to an originator insulin because their insulin pump has not yet been approved for use with the biosimilar version of their insulin. Coverage of the originator insulin will be extended beyond the end of the switching period if compatibility has not yet been confirmed.
- The Biosimilar Switching Exemption form can be used to identify patients who may require access to the Originator insulin beyond the end of the switching period (June 30, 2024). This form can be completed by the patient or health care professional and is available as an
    - Online Biosimilar Switching Exemption form
    - Paper Biosimilar Switching Exemption form
- Pump and biosimilar insulin compatibility information was previously shared in a PEI Pharmacare Memo which can be found under the "Biosimilars" information on the Resources for Pharmacists page of the Health PEI Staff Resource Centre.

NEW PRODUCT(S) ADDED TO THE PEI PHARMACARE FORMULARY
(EFFECTIVE DATE: December 18, 2023)

Product (Generic name)	Product (Brand name)	Strength	Dosage Form	DIN	MFR
Adalimumab	**Yuflyma**	**80 mg/0.8 ml**	**Prefilled Pen Prefilled Syringe**	**02535084 02535076**	**CLT**
Criteria	See online Formulary for adalimumab criteria				
Program Eligibility	Financial Assistance Drug Program, High Cost Drug Program, Nursing Home Drug Program, Catastrophic Drug Program				

Idelalisib	**Zydelig**	**100 mg 150 mg**	**Tablet Tablet**	**02438798 02438801**	**GIL**
Criteria	In combination with rituximab for the treatment of patients with relapsed chronic lymphocytic leukemia (CLL). Treatment should continue until unacceptable toxicity or disease progression.				
Program Eligibility	Financial Assistance Drug Program, High Cost Drug Program, Nursing Home Drug Program, Catastrophic Drug Program				

Lipase & Protease & Amylase	**Creon 35 Minimicrospheres**	**35,000 & 2,240 & 35,700 units**	**Capsule**	**02494639**	**BGP**
Criteria	Open benefit				
Program Eligibility	Cystic Fibrosis Drug Program, Family Health Benefit Drug Program, Financial Assistance Drug Program, Nursing Home Drug Program, Seniors Drug Program, Catastrophic Drug Program				

Mecasermin	**Increlex**	**10mg/mL**	**Vial**	**02509733**	**IPS**
Criteria	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: o a known genetic mutation recognized as a cause of SPIGFD, AND/OR o has clinical and biochemical features of SPIGFD <u>Renewal Criteria:</u> • Treatment with mecasermin must be discontinued upon the occurrence of any of the following: o Height velocity is less than 1cm per 6 months or less than 2cm per year, OR o Bone age is more than 16 years in boys and 14 years in girls. <u>Claim Notes:</u> • The patient must be under the care of a pediatric endocrinologist. • Mecasermin must not be prescribed concomitantly with recombinant GH treatment. • Approvals: 1 year				
Program Eligibility	Growth Hormone Drug Program				

Methylphenidate	**Foquest**	**25 mg** **35 mg** **45 mg** **55 mg** **70 mg** **85 mg** **100 mg**	**ER Capsule** **ER Capsule** **ER Capsule** **ER Capsule** **ER Capsule** **ER Capsule** **ER Capsule**	**02470292** **02470306** **02470314** **02470322** **02470330** **02470349** **02470357**	**ELV**
Criteria	For treatment of patients with Attention Deficit Hyperactivity Disorder (ADHD) who have tried extended-release methylphenidate with unsatisfactory results. Claim Note: The maximum dose reimbursed is 100mg daily.				
Program Eligibility	Family Health Benefit Drug Program, Financial Assistance Drug Program, Catastrophic Drug Program				

CRITERIA UPDATE

Effective immediately, special authorization criteria for currently listed Dupixent products for the indication atopic dermatitis has been amended and the indication for asthma has been added:

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).

AND
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 period: 6 months.
- Renewal approval period: 1 year**.**

ASTHMA

1. 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) and 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 × 10^9/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:

1. A baseline and annual assessment of asthma symptom control using a validated asthma control questionnaire must be provided.
2. 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.
3. 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.

2. 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 × 10^9/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.

CRITERIA UPDATE

Effective immediately, special authorization criteria for currently listed Upadacitinib (Rinvoq) products has been amended to include the following indication:

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).

AND
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 30 mg daily.
- Initial approval period: 6 months.
- Renewal approval period: 1 year**.**