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P.O. Box 2000
Charlottetown, PE
C1A 7N8
www.healthpei.ca

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PEI Pharmacare Bulletin

Issue (2022 - 3) **March 14, 2022**

NEW PRODUCT(S) ADDED TO THE PEI PHARMACARE FORMULARY (EFFECTIVE DATE: (MARCH 28, 2022)

Product (Generic name)	Product (Brand name)	Strength	Dosage Form	DIN/PDIN	MFR
Deferasirox	Various generics	90 mg 180 mg 360 mg	Tablet Tablet Tablet	Various	Various
Criteria	For the treatment of patients who require iron chelation				
Program Eligibility	Catastrophic Drug Program				

Indacaterol/glycopyrronium/ mometasone	Enerzair Breezhaler	150/50/160 mcg	Inhalation powder hard capsule	02501244	NVR
Criteria	For the maintenance treatment of asthma in adult patients not adequately controlled with a maintenance combination of long-acting-beta$_2$-agonist and a medium or high dose of an inhaled corticosteroid who experienced one or more asthma exacerbations in the previous 12 months				
Program Eligibility	Family Health Benefit Drug Program, Financial Assistance Drug Program, Nursing Home Drug Program, Seniors Drug Program, Catastrophic Drug Program				

Indacaterol/mometasone	Atectura Breezhaler	150/80 mcg 150/160 mcg 150/320 mcg	Inhalation powder hard capsule	02498685 02498707 02498693	NVR
Criteria	For the treatment of asthma in patients who are not well controlled on a regular and adequate course of inhaled steroid therapy prior to the request for combination therapy				
Program Eligibility	Family Health Benefit Drug Program, Financial Assistance Drug Program, Nursing Home Drug Program, Seniors Drug Program, Catastrophic Drug Program				

Product (Generic name)	Product (Brand name)	Strength	Dosage Form	DIN/PDIN	MFR
Lixisenatide	Adlyxine	10 mcg/0.2 ml 20 mcg/0.2 ml	Prefilled pen Prefilled pen	03464276 02464284	AVN
Criteria	For the treatment of type 2 diabetes mellitus when added to: • basal insulin for patients who have inadequate glycemic control on basal insulin; or • basal insulin and metformin for patients who have inadequate glycemic control on metformin and basal insulin				
Program Eligibility	Diabetes Drug Program, Financial Assistance Drug Program, Nursing Home Drug Program, Catastrophic Drug Program				

Nusinersen	Spinraza	2.4 mg/ ml	Intrathecal Vial	02465663 See criteria for list of PDIN's for billing	BGN
Criteria	For patients diagnosed with 5q Spinal Muscular Atrophy (SMA) if the following clinical criteria are met: 1) Genetic documentation of 5q SMA homozygous gene deletion, homozygous mutation, or compound heterozygote, AND 2) 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 3) Patient is not currently requiring permanent invasive ventilation*, AND 4) A baseline assessment using an age-appropriate scale (the Hammersmith Infant Neurological Examination [HINE] Section 2, Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders [CHOP INTEND], or Hammersmith Functional Motor Scale-Expanded [HFMSE] must be completed prior to initiation of nusinersen treatment. Other patients with SMA type 2 or 3 who are over the age of 18 may be considered on a case by case basis. • For continued coverage, the patient must meet the following criteria: 1) 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 2) 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 Notes:** • The patient must be under the care of a specialist experienced in the treatment of SMA. • Approval Period: 1 year. • Claims for Spinraza vials that exceed the maximum claim amount of $9,999.99 must be divided and submitted as separate transactions using the DIN first, and then the following PDINs: 1. 00904366 2. 00904367 3. 00904368 4. 00904369 5. 00904370 6. 00904371 7. 00904372 8. 00904373 9. 00904374 10. 00904375 11. 00904376 12. 00904377
Program Eligibility	High Cost Drug Program, Catastrophic Drug Program

CRITERIA UPDATE

Tofacitinib	Xeljanz	5 mg 10 mg	Tablet Tablet	02423898 02480786	PFI
Criteria	Criteria for currently listed Xeljanz 5 and 10 mg products has been expanded to now include: 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. aminosalicylates for a minimum of four 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. <u>Clinical Notes:</u> • 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 (partial Mayo > 6)do not require a trial of 5-ASA <u>Claim Notes:</u> • Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology. • Combined use of more than one biologic DMARD or another JAK inhibitor will not be reimbursed. Initial Approval: As per induction approval. Renewal Approval: 1 year.
Program Eligibility	High Cost Drug Program, Catastrophic Drug Program

Abiraterone	Various Generics	250 mg 500 mg	Tablet	Various	Various
Criteria	Criteria for currently listed Abiraterone 250 and 500 mg products has been expanded to now include: In combination with androgen deprivation therapy (ADT) for the treatment of patients with metastatic castration sensitive prostate cancer who have had no prior ADT, or are within 6 months of beginning ADT, in the metastatic setting.				
Program Eligibility	High Cost Drug Program, Catastrophic Drug Program				

CRITERIA UPDATE

Methylphenidate	Biphentin	10 mg 15 mg 20 mg 30 mg 40 mg 50 mg 60 mg 80 mg	Controlled Release Capsule	02277166 02277131 02277158 02277174 02277182 02277190 02277204 02277212	ELV
Criteria	Criteria has been updated to the following: For the treatment of patients with Attention Deficit Hyperactivity Disorder who have tried extended-release methylphenidate with unsatisfactory results. Claim Note: The maximum dose reimbursed is 80 mg daily				
Program Eligibility	Family Health Benefit Drug Program, Financial Assistance Drug Program, Catastrophic Drug Program				

REMOVAL OF SPECIAL AUTHORIZATION CRITERIA

Effective immediately, all currently listed Methylphenidate Extended Release tablets (Concerta and various generics) will no longer require special authorization, and will be open benefits in currently listed programs (Financial Assistance, Family Health Benefit, and Catastrophic Drug Programs)