PEI Pharmacare
P.O. Box 2000
Charlottetown, PE
C1A 7N8
www.princeedwardisland.ca

Programmes provinciaux de medicaments
C.P. 2000
Charlottetown, PE
C1A 7N8
www.princeedwardisland.ca

PEI Pharmacare Bulletin

Issue (2024 - 06) **April 23, 2024**

NEW PRODUCT(S) ADDED TO THE PEI PHARMACARE FORMULARY (EFFECTIVE DATE: MAY 7, 2024)

Product (Generic name)	Product (Brand name)	Strength	Dosage Form	DIN	MFR
Adalimumab	**Hyrimoz**	**80mg/0.8mL** **80mg/0.8mL** **40mg/0.4mL** **40mg/0.4mL** **20mg/0.2mL**	**Prefilled Syringe** **Autoinjector** **Prefilled Syringe** **Autoinjector** **Prefilled Syringe**	**02542358** **02542366** **02542323** **02542331** **02542315**	**SDZ**
Criteria	See online Formulary for adalimumab criteria				
Program Eligibility	Financial Assistance Drug Program, High Cost Drug Program, Nursing Home Drug Program, Catastrophic Drug Program				
Risankizumab	**Skyrizi**	**600 mg/10 mL** **360 mg/2.4 mL**	**Vial** **Prefilled cartridge**	**02532107** **02532093**	**ABV**
Criteria	For the treatment of patients with moderate to severe Crohn's disease who have active disease and are refractory, intolerant or have contraindications to: • Prednisone 40mg (or equivalent) daily for ≥ 2 weeks, AND • Azathioprine ≥ 2 mg/kg/day for ≥ 3 months, OR • Mercaptopurine ≥ 1 mg/kg/day for ≥ 3 months, OR • Methotrexate (SC or IM) ≥ 15 mg/week for ≥ 3 months Clinical Notes: • Refractory is defined as lack or loss 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. • Consideration will be given for the approval of a biologic DMARD (disease modifying antirheumatic drug) without a trial of a traditional DMARD for patients who have an aggressive/severe disease course (e.g. extensive disease, a modified Harvey Bradshaw Index score > 16) and are refractory, intolerant or have contraindications to systemic corticosteroids.				

	Claim notes: • Initial approval is for 600mg administered by IV infusion at week 0, week 4 and week 8. Renewal of coverage will require reassessment of the patient and submission of a new Crohn's Disease Special Authorization form. Continued coverage will be approved at a dose of 360mg administered by subcutaneous infusion at week 12, and every 8 weeks thereafter. • Renewal Approval: 1 year. Confirmation of continued response is required. • Combined use of more than one biologic DMARD will not be reimbursed.
Program Eligibility	Financial Assistance Drug Program, High Cost Drug Program, Nursing Home Drug Program, Catastrophic Drug Program

CRITERIA UPDATE

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

Metastatic Castration-Sensitive Prostate Cancer

- In combination with docetaxel and androgen deprivation therapy (ADT) for the treatment of patients with metastatic castration-sensitive prostate cancer (mCSPC). Patients must have had either no prior ADT or are within six months of beginning ADT in the metastatic setting.

Renewal Criteria:

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

Clinical Notes:

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

Claim Notes:

- Requests will not be considered for patients who are within 1 year of completing adjuvant ADT in the nonmetastatic setting.
- Patients who experience disease progression on apalutamide or enzalutamide are not eligible.
- Approval period: 1 year.

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

Breast Cancer

1. For the adjuvant treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated high-risk early breast cancer who have had upfront surgery followed by adjuvant chemotherapy and who meet one of the following criteria:
   - Triple negative breast cancer and either axillary node-positive or axillary node-negative with invasive primary tumor pathological size of at least 2 cm (> pT2 cm)

- Hormone receptor positive, HER2-negative breast cancer with at least 4 pathologically confirmed positive lymph nodes

2. For the adjuvant treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated high-risk early breast cancer who received neoadjuvant chemotherapy followed by surgery and who meet one of the following criteria:

- Triple negative breast cancer with residual invasive disease in the breast and/or resected lymph nodes (nonpCR)
- Hormone receptor positive, HER2-negative breast cancer with residual invasive disease in the breast, and/or the resected lymph nodes, and a CPS + EG score of 3 or higher

Clinical Notes:
1. Patients must have completed neoadjuvant or adjuvant chemotherapy containing an anthracycline and/or taxane.
2. Treatment should be initiated within 12 weeks of completion of the last treatment (i.e., surgery, chemotherapy, or radiation therapy).
3. Patients must have a good performance status.
4. Treatment should be discontinued upon disease recurrence, unacceptable toxicity, or completion of 1 year of therapy, whichever occurs first.

Claim Notes:

- Requests for patients determined to be at high-risk for relapse using a disease scoring system other than CPS + EG will be considered.
- Approval period: 1 year

Pharmacy Plus Update

The age restriction has been removed for UTI assessments as per the College of Pharmacy's updated practice directive. Communication to the public on this change to the Pharmacy Plus program will occur after the CE event has occurred.