

# Health PEI Formulary Drugs: Oncology

updated: June 30, 2025

## ONCOLOGY FORMULARY LEGEND

### Funding Status

There are two Health PEI funding channels for medications listed on the Health PEI Formulary Drugs for Oncology:

- 1) **Pharmacare** – medications covered under one or more PEI Pharmacare programs are routinely dispensed from community pharmacies. Eligible patients must be enrolled in the applicable Pharmacare drug program for which coverage is required. Specific medications may be covered under different Pharmacare drug programs. The formulary code for the corresponding program is listed within the Funding Status field. Coverage of listed medications only applies if the patient meets the funded eligibility criteria provided.
- 2) **CTC Formulary** – medications covered under this program are dispensed and administered at PEI oncology sites (QEH or PCH) or other approved hospital sites. Patients do not need to enroll in this program. All patients with a valid P.E.I Health Card are automatically eligible to receive medications listed under this program at no cost to the patient. Coverage of listed medications only applies if the patient meets the funded eligibility criteria provided.

Medications that are not listed in the Health PEI Formulary Drugs for Oncology or that are prescribed outside of the listed funding eligibility criteria are not routinely covered.

### Funding Eligibility Criteria

Medications are either classified as open-benefit or restricted:

- 1) **Open Benefit** – medications that have “open benefit” listed as their funded eligibility criteria are available to beneficiaries without any restrictions. Open benefit medications are only covered under the program(s) listed in the corresponding Funding Status field.
- 2) **Restricted** – medications that do not have “open benefit” listed as their funded eligibility criteria are only available to beneficiaries if they meet the funded eligibility criteria listed.
  - a. **CTC Formulary with Restrictions**– the adherence to the funded eligibility criteria for these medications will be confirmed by staff at PEI oncology sites.
  - b. **Pharmacare Special Authorization** –the listed Funded Eligibility Criteria for each medication corresponds to the special authorization (SA) criteria required under the P.E.I Pharmacare program. Physicians must ensure patients meet the corresponding criteria. If a SA submission is required, it must be submitted by the prescriber. If a prescription is written by oncologist, select medications do not require the submission of a SA form; this is noted under the Funded Eligibility Criteria. SA coverage will normally only be approved for the treatment of indications and in dosage forms listed. For more information, please refer to the P.E.I Pharmacare Formulary (<http://www.healthpei.ca/pharmacare>).

**\*\*Health PEI is not responsible for medication coverage due to discrepancies within this document.\*\***

**PHARMACARE PROGRAM LEGEND** (Forms are available at <https://www.princeedwardisland.ca/en/information/pei-pharmacare-special-authorization-forms-medical-professionals> )

F = FAMILY HEALTH BENEFIT DRUG PLAN

Q = CATASTROPHIC DRUG PLAN

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Drug Assistance Program (Formulary Code)	Beneficiaries	Benefits (Note: A prescription is required for all benefits)	Fee
<b>(F)</b> - Family Health Benefit Drug Program	Families (parents, guardians, and children under 25 years of age) eligible for PEI Medicare, with at least one child under 25 years of age who is still attending school full time, and a total annual net family income less than \$24,800, plus \$3,000 for each additional child. Families must apply for coverage on an annual basis and provide income information to the program.	Approved prescription medications.	The pharmacy professional fee for each prescription obtained.
<b>(G)</b> - Generic Drug Program	Persons less than 65 years of age with no private drug insurance.	Approved generic prescription medications.	Maximum of \$19.95 per prescription.
<b>(M)</b> - High-Cost Drug Program	Persons eligible for PEI Medicare and approved for coverage for one or more of the medications included in the program. Patients must apply for coverage on an annual basis and provide income information to the program.	Approved high-cost medications.	An income-based portion of the medication cost plus the pharmacy professional fee for each prescription obtained.
<b>(N)</b> - Nursing Home Program or Institutional Pharmacy Program	Residents in private nursing homes eligible for coverage under the Social Assistance Act or residents in government manors.	Approved prescription and non-prescription medications.	No fee.
<b>(Q)</b> - Catastrophic Drug Program	PEI permanent residents with a PEI Health card whose household members have up to date tax filings and are experiencing out of pocket eligible drug expenses that exceed their annual household limit. Eligible drug expenses are expenses incurred for drugs designated as having coverage under the Catastrophic Drug Program- (Q) listed on the PEI formulary.	Out of pocket costs for eligible drug expenses.	An income based program. Once an applicant's out of pocket eligible drug expenses exceed the annual household limit the program will cover any further eligible drug expenses in the program year.
<b>(S)</b> - Seniors Drug Program	Persons eligible for PEI Medicare and 65 years of age or older. Eligibility is effective upon a person becoming 65 years of age.	Approved prescription medications.	Maximum of \$15.94 per prescription.
<b>(W)</b> - Financial Assistance Program	Persons eligible under the Social Assistance Act and Regulations.	Approved prescription and non-prescription medications.	No fee.

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Drug	Dosage Form	Funding Program	Funded Eligibility Criteria
<b>Abemaciclib</b> Verzenio®	Oral (tablet) 50 mg, 100 mg, 150 mg	Pharmacare <b>MQWN</b>	<p><b><u>Breast Cancer</u></b> 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 and a Ki-67 score of at least 20%.</p> <p><b><u>Clinical Notes:</u></b></p> <ul style="list-style-type: none"> <li>• Patients should have a good performance status.</li> <li>• Treatment should continue until disease progression, unacceptable toxicity, or completion of 2 years of adjuvant therapy. ET may be continued after abemaciclib is completed.</li> <li>• Patients are not eligible if they have inflammatory breast cancer, or prior treatment with a cyclin-dependent kinases 4 and 6 (CDK4/6) inhibitor.</li> <li>• 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.</li> </ul> <p><b>Patients must apply for coverage under the High-Cost Drug Program.</b> <b>If written by an oncologist, this medication does <u>not</u> require the submission of a Pharmacare Special Authorization form.</b></p>
<b>Abiraterone</b> Zytiga®, generics	Oral (tablet) 250 mg	Pharmacare <b>MQWN</b>	<p><b><u>Prostate – Metastatic (castration-resistant):</u></b> In combination with prednisone for the treatment of metastatic prostate cancer (castration resistant prostate cancer) in patients who:</p> <ul style="list-style-type: none"> <li>• are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy, OR</li> <li>• have received prior chemotherapy containing docetaxel after failure of androgen deprivation therapy.</li> </ul> <p><b><u>Prostate – Metastatic (castration-sensitive):</u></b> 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.</p> <p><b>Patients must apply for coverage under the High-Cost Drug Program.</b> <b>If written by an oncologist, this medication does <u>not</u> require the submission of a Pharmacare Special Authorization form.</b></p>

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<b>Abraxane®</b> Paclitaxel – nanoparticle albumin-bound (nab) (Tradename used to minimize confusion with paclitaxel)	Injection (vial) 100 mg	CTC Formulary	<b><u>Pancreas Cancer – Locally Advanced or Metastatic</u></b> <ul style="list-style-type: none"> <li>In combination with gemcitabine for the first line treatment of patients with locally advanced unresectable or metastatic adenocarcinoma of the pancreas with an ECOG performance status of 0 to 2, or for patients who are intolerant to first line treatment with FOLFIRINOX.</li> </ul>
<b>Acalabrutinib</b> Calquence®	Oral (tablet & capsule) 100mg	Pharmacare <b>MQWN</b>	<b><u>Chronic Lymphocytic Leukemia (CLL)</u></b> <ol style="list-style-type: none"> <li>As monotherapy for adult patients with previously untreated chronic lymphocytic leukemia (CLL) / small lymphocytic lymphoma (SLL) for whom fludarabine-based treatment is inappropriate due to high-risk cytogenetic markers (i.e., del17p, TP53 mutation, or unmutated IGHV).</li> <li>As monotherapy for adult patients with relapsed or refractory CLL / SLL who have received at least one prior therapy.</li> </ol> <p><b><u>Renewal Criteria:</u></b></p> <ul style="list-style-type: none"> <li>Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.</li> </ul> <p><b><u>Clinical Notes:</u></b></p> <ol style="list-style-type: none"> <li>Patients must have a good performance status.</li> <li>Treatment should be discontinued upon disease progression or unacceptable toxicity.</li> </ol> <p><b><u>Claim Notes:</u></b> Requests will not be considered for patients who experience disease progression on a Bruton's tyrosine kinase (BTK) inhibitor or idelalisib.</p> <p><b>Patients must apply for coverage under the High-Cost Drug Program.</b> <b>If written by an oncologist, this medication does <u>not</u> require the submission of a Pharmacare Special Authorization form.</b></p>
<b>Afatinib</b> Giotrif®	Oral (tablet) 20 mg, 30 mg, 40 mg	Pharmacare <b>MQWN</b>	<b><u>Non-Small Cell Lung Cancer (NSCLC) – Advanced:</u></b> <ul style="list-style-type: none"> <li>First line treatment of patients with EGFR mutation positive advanced or metastatic adenocarcinoma of the lung with an ECOG performance status of 0 or 1.</li> </ul> <p><b><u>Note:</u></b> Use of afatinib precludes the use of any other EGFR inhibitor as a subsequent line of therapy.</p> <p><b>Patients must apply for coverage under the High-Cost Drug Program.</b> <b>If written by an oncologist, this medication does <u>not</u> require the submission of a Pharmacare Special Authorization form.</b></p>

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<b>Aldesleukin</b> (Interleukin-2, IL-2) Proleukin®	Injection (vial) 22 MU	<b>CTC Formulary</b>	Approved for the following indication: <ul style="list-style-type: none"> <li>Intralesional treatment of unresectable in-transit metastatic melanoma (e.g., in patients with rapidly developing in-transit metastases after surgery or patients who present with multiple in-transit metastases unsuitable for surgical resection)</li> </ul>
<b>Alectinib</b> Alecensaro®	Oral (capsule) 150 mg	Pharmacare <b>MQWN</b>	<p><b><u>Non-small Cell Lung Cancer (NSCLC):</u></b></p> <p>For the treatment of patients with anaplastic lymphoma kinase (ALK)-positive locally advanced (not amenable to curative therapy) or metastatic non-small cell lung cancer when used:</p> <ul style="list-style-type: none"> <li>as first-line therapy, or</li> <li>following disease progression on, or intolerance to, crizotinib.</li> </ul> <p><b><u>Renewal Criteria:</u></b></p> <ul style="list-style-type: none"> <li>Confirmation that the patient is responding to treatment.</li> </ul> <p><b><u>Claim Notes:</u></b></p> <ul style="list-style-type: none"> <li>Requests for alectinib will not be considered for patients who experience disease progression on any ALK inhibitor other than crizotinib.</li> <li>No further ALK inhibitor will be reimbursed following disease progression on alectinib.</li> <li>Initial approval period: 1 year.</li> <li>Renewal approval period: 1 year</li> <li>Claims that exceed the maximum claim amount of \$9999.99 must be divided as separate transactions, using DIN first and PDIN* second (see pharmacare formulary).</li> </ul> <p><b>Prescriptions written by PEI oncologists do not require Special Authorization. Patients must apply for coverage by the High-Cost Drug Program.</b></p>
<b>All-trans Retinoic Acid</b> ATRA, retinoin, tretinoin, Vesanoïd®	Oral (capsule) 10 mg	Pharmacare <b>MQWN</b>	Open benefit if written by an oncologist upon notification to Pharmacare.  <b>Patients must apply for coverage under the High-Cost Drug Program.</b>
<b>Anagrelide</b> Agrylin®, generics	Oral (capsule) 0.5 mg	Pharmacare <b>FGNQSW</b>	<p><b><u>Essential thrombocythemia (ET)</u></b> in patients who have:</p> <ul style="list-style-type: none"> <li>failed hydroxyurea therapy (does not provide sufficient platelet reduction) OR</li> <li>have intolerable side effects to hydroxyurea therapy.</li> </ul> <p><b>If written by an oncologist, this medication does <u>not</u> require the submission of a Pharmacare Special Authorization form.</b></p>
<b>Anastrozole</b> Arimidex®, generics	Oral (tablet) 1 mg	Pharmacare <b>FGNQSW</b>	Open benefit

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<b>Apalutamide</b> Erleada®	Oral (tablet) 60mg	Pharmacare <b>MQWN</b>	<p><b><u>Castration-Resistant Prostate Cancer (CRPC)</u></b></p> <p>In combination with androgen deprivation therapy (ADT) for the treatment of patients with castration-resistant prostate cancer (CRPC) who have no detectable distant metastasis (M0) by either CT, MRI or technetium-99m bone scan and who are at high risk of developing metastases<sup>1</sup>.</p> <ul style="list-style-type: none"> <li>• Patients should have a good performance status and no risk factors for seizures.</li> <li>• Treatment should continue until unacceptable toxicity or radiographic disease progression.</li> </ul> <p><b><u>Clinical Notes:</u></b></p> <ul style="list-style-type: none"> <li>• Castration-resistance must be demonstrated during continuous ADT and is defined as 3 PSA rises at least one week apart, with the last PSA &gt; 2 ng/mL.</li> <li>• Castrate levels of testosterone must be maintained.</li> <li>• Patients with N1 disease, pelvic lymph nodes &lt; 2cm in short axis located below the common iliac vessels are eligible for apalutamide.</li> <li>• Apalutamide will not be funded for patients who experience disease progression on enzalutamide.</li> <li>• Patients receiving apalutamide for the treatment of non-metastatic CRPC will be eligible for funding of abiraterone at the time of disease progression to metastatic CRPC. Enzalutamide is not funded for patients who experience disease progression to metastatic CRPC while on apalutamide.</li> <li>• Either abiraterone or enzalutamide may be used to treat metastatic CRPC in patients who discontinued apalutamide in the non-metastatic setting due to intolerance without disease progression.</li> </ul> <p><sup>1</sup> High risk of developing metastases is defined as a prostate-specific antigen (PSA) doubling time of ≤ 10 months during continuous ADT</p> <p><b><u>Metastatic Castration-Sensitive Prostate Cancer (mCSPC)</u></b></p> <p>In combination with 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.</p> <p><b><u>Clinical Notes:</u></b></p> <ul style="list-style-type: none"> <li>• Patients should have a good performance status and no risk factors for seizures.</li> <li>• Treatment should continue until unacceptable toxicity or disease progression.</li> </ul> <p><b><u>Claim Notes:</u></b></p> <ul style="list-style-type: none"> <li>• Patients receiving apalutamide for the treatment of metastatic CSPC will be eligible for funding of abiraterone at the time of disease progression to metastatic CRPC.</li> <li>• Enzalutamide is not funded for patients who experience disease progression to metastatic CRPC while on apalutamide.</li> </ul> <p><b>Patients must apply for coverage under the High-Cost Drug Program.</b>  <b>If written by an oncologist, this medication does <u>not</u> require the submission of a Pharmacare Special Authorization form.</b></p>

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<b>Aprepitant</b> Emend® - also see fosaprepitant (Emend IV)	Oral (tablet) 125 mg, 80 mg	Pharmacare <b>FNQSW</b>	In combination with a 5-HT3 antagonist and dexamethasone for the prevention of acute and delayed nausea and vomiting in patients receiving: <ul style="list-style-type: none"> <li>highly emetogenic chemotherapy, or</li> <li>moderately emetogenic chemotherapy who have had inadequate symptom control using a 5-HT3 antagonist and dexamethasone in a previous cycle.</li> </ul> <b>Clinical notes:</b> <ul style="list-style-type: none"> <li>Highly emetogenic chemotherapy (HEC) includes but is not limited to: cisplatin regimens, anthracycline and cyclophosphamide combination regimens, and regimens containing carmustine, mechlorethamine, streptozocin, dacarbazine and cyclophosphamide &gt; 1500mg/m<sup>2</sup></li> <li>Patients who receive carboplatin-based regimens with AUC ≥ 4 are also eligible to receive aprepitant in combination with a 5-HT3 antagonist and dexamethasone for primary prevention of acute and delayed nausea and vomiting.</li> </ul> <b>If written by an oncologist, this medication does <u>not</u> require the submission of a Pharmacare Special Authorization form.</b>
<b>Arsenic Trioxide</b> Trisenox®	Injection (ampoule) 10 mg/10 mL	CTC Formulary	<b>Acute Promyelocytic Leukemia (APL)</b> <ul style="list-style-type: none"> <li>In combination with all trans-retinoic acid (tretinoin, ATRA, Vesanoid®) in the first-line setting as a treatment for the induction of remission and/or consolidation of low to intermediate risk acute promyelotic leukemia (APL) AND</li> <li>As a consolidation treatment for high risk APL after induction with ATRA plus chemotherapy for patients with the t(15;17) translocation and PML/RAR-alpha gene expression.</li> </ul>
<b>Asciminib</b> Scemblix®	Oral (tablet) 20mg, 40mg	Pharmacare <b>MQWN</b>	<b>Philadelphia Chromosome-Positive Chronic Myeloid Leukemia (Ph+ CML)</b> For the treatment of adult patients with Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in the chronic phase who meet the following criteria: <ul style="list-style-type: none"> <li>Treatment failure on or intolerance to a minimum of two prior tyrosine kinase inhibitor (TKI) therapies.</li> <li>No evidence of a T315I or V299L mutation.</li> </ul> <b>Clinical Notes:</b> <ol style="list-style-type: none"> <li>Patients should have a good performance status.</li> <li>Not for use in the acute phase or blast phase.</li> </ol> <b>Prescriptions written by PEI oncologists do not require Special Authorization. Patients must apply for coverage by the High-Cost Drug Program.</b>
<b>Asparaginase</b> Kidrolase®	Injection (vial) 10,000 units	CTC Formulary	Product discontinued
<b>Asparaginase-PEG</b> Pegaspargase Oncaspar®	Injection (vial) 3,750 units/5 mL	CTC Formulary	IWK criteria (Pediatrics)

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<b>Atezolizumab</b> Tecentriq®	Injection (vial) 1200mg/20mL 840mg/14mL	CTC Formulary	<p><b><u>Non-Small Cell Lung Cancer (NSCLC)</u></b> Monotherapy for adjuvant treatment following complete resection and no progression after platinum-based adjuvant chemotherapy for adult patients with stage II to IIIA (AJCC 7<sup>th</sup> edition) non-small cell lung cancer (NSCLC) whose tumours have PD-L1 expression on 50% or more of tumour cells (TCs) and do not have EGFR or ALK genomic tumour aberrations.</p> <ul style="list-style-type: none"> <li>• Patients must have good performance status upon treatment</li> <li>• Treatment should be discontinued upon disease recurrence, unacceptable toxicity or treatment up to 48 weeks</li> </ul> <p><b><u>Extensive-Stage Small Cell Lung Cancer (ES-SCLC)</u></b> In combination with platinum-based chemotherapy and etoposide for the first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC).</p> <ul style="list-style-type: none"> <li>• Maintenance should be continued until loss of clinical benefit or unacceptable toxicity</li> <li>• Patients must have good performance status upon treatment</li> <li>• Patients must not have received previous treatment for ES-SCLC</li> </ul> <p><b><u>Non-Small Cell Lung Cancer (NSCLC)</u></b> For the treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) and who have disease progression on or after cytotoxic chemotherapy. Patients with genomic tumour driver aberrations (e.g. epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK)) should first be treated with targeted agents followed by cytotoxic chemotherapy prior to receiving atezolizumab. Treatment with atezolizumab should be discontinued upon loss of clinical benefit or unacceptable toxicity.</p> <p><b><u>Hepatocellular (HCC)</u></b> Atezolizumab in combination with bevacizumab for first line treatment of adult patients with unresectable or metastatic hepatocellular carcinoma (HCC) who require systemic therapy. Eligible patients should have no prior systemic treatment, have an Eastern Cooperative Oncology Group Performance Status (ECOG PS) of 0 or 1 and a Child –Pugh class status of A. Treatment with atezolizumab and bevacizumab should continue until loss of clinical benefit or unacceptable toxicity.</p>
	Injection (vial) Subcutaneous 1875 mg/15 mL		

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<b>Axitinib</b> Inlyta®	Oral (tablet) 1 mg, 5 mg	Pharmacare <b>MQWN</b>	<p><b><u>Metastatic renal cell carcinoma (mRCC)</u></b>  For the treatment of patients with advanced or metastatic renal cell carcinoma when used as:</p> <ul style="list-style-type: none"> <li>• As first-line therapy in combination with pembrolizumab; or</li> <li>• Second-line therapy following disease progression on a vascular endothelial growth factor receptor tyrosine kinase inhibitor (i.e., sunitinib or pazopanib); or</li> <li>• third-line therapy following disease progression on first-line nivolumab and ipilimumab combination therapy and a second-line vascular endothelial growth factor receptor tyrosine kinase inhibitor</li> <li>• Patients must have a good performance status.</li> <li>• Treatment should be discontinued upon disease progression or unacceptable toxicity.</li> </ul> <p><b><u>Clinical Notes:</u></b></p> <ul style="list-style-type: none"> <li>• Sequential use of axitinib and everolimus is not permitted except in the case of intolerability or contraindication.</li> <li>• Sequential use of axitinib (as a single agent) and cabozantinib is not permitted for patients following progression on first-line axitinib + pembrolizumab.</li> <li>• For patients treated with nivolumab + ipilimumab first-line and VEGFR TK1 second line, either cabozantinib or axitinib may be used as third-line therapy.</li> <li>• Both clear cell and non-clear cell histology are eligible for treatment.</li> </ul> <p><b>Patients must apply for coverage under the High-Cost Drug Program.</b>  <b>If written by an oncologist, this medication does <u>not</u> require the submission of a Pharmacare Special Authorization form.</b></p>

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<b>Avelumab</b> Bavencio®	Injection (vial) 200 mg/10 mL	CTC Formulary	<p><b><u>Merkel cell carcinoma</u></b> For the treatment of adult patients with metastatic Merkel cell carcinoma who have received prior cytotoxic chemotherapy or who are ineligible (i.e., due to contraindications) to receive first-line cytotoxic chemotherapy.</p> <ul style="list-style-type: none"> <li>• Patients must have a good performance status.</li> <li>• Treatment should be discontinued upon confirmed disease progression or unacceptable toxicity.</li> <li>• For patients who achieve a complete response (CR), treatment should continue for a maximum of 12 months after confirmation of CR.</li> </ul> <p><b><u>Urothelial carcinoma</u></b> For the first-line maintenance treatment of patients with histologically confirmed, unresectable, locally advanced or metastatic urothelial carcinoma whose disease has not progressed with first-line platinum-based induction chemotherapy.</p> <ul style="list-style-type: none"> <li>• Eligible patients should have good performance status with documented locally advanced unresectable or stage IV disease before having received first-line chemotherapy.</li> <li>• First-line chemotherapy should be platinum-based, and patients must have received 4 to 6 cycles of treatment with chemotherapy.</li> <li>• Patients must not have experienced disease progression (i.e., they must have had an ongoing complete response, partial response, or stable disease).</li> <li>• Patients may continue to receive avelumab until confirmed disease progression or unacceptable toxicity, whichever comes first.</li> </ul>
<b>Azacitidine</b> Vidaza®	Injection (vial) 100 mg	CTC Formulary	<p>Approved for the following indications:</p> <ul style="list-style-type: none"> <li>• Treatment of myelodysplastic syndrome (MDS) of intermediate-2 or high risk type according to the International Prognostic Scoring System (IPSS)</li> <li>• Treatment of chronic myelomonocytic leukemia (CMML) with 10-29% blasts</li> <li>• Treatment of acute myeloid leukemia (AML) with 20-30% blasts</li> </ul>

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## Health PEI Formulary Drugs: Oncology

Drug	Dosage Form	Funding Program	Funded Eligibility Criteria
<b>Azacitidine</b> Onureg®	Oral (tablet) 200 mg, 300 mg	Pharmacare <b>MQWN</b>	<p><b><u>Acute Myeloid Leukemia (AML)</u></b> As maintenance therapy for adult patients with acute myeloid leukemia (AML) who meet all of the following criteria:</p> <ul style="list-style-type: none"> <li>Intermediate or poor risk cytogenetics</li> <li>Complete remission (CR) or complete remission with incomplete blood count recovery (CRi) following induction therapy, with or without consolidation treatment.</li> <li>Not eligible for hematopoietic stem cell transplantation (HSCT)</li> </ul> <p><b><u>Clinical Notes:</u></b></p> <ul style="list-style-type: none"> <li>Newly diagnosed includes patients with AML de novo or secondary to prior myelodysplastic syndrome (MDS) or chronic myelomonocytic leukemia (CMML).</li> <li>Last dose of chemotherapy should be within 4 months of starting azacitidine maintenance.</li> <li>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.</li> </ul> <p><b>Patients must apply for coverage under the High-Cost Drug Program.</b> <b>If written by an oncologist, this medication does <u>not</u> require the submission of a Pharmacare Special Authorization form.</b></p>
<b>BCG Vaccine</b> OncoTICE® Verity-BCG®	Intravesical (vial) 50 mg Intravesical (vial) 40 mg	CTC Formulary	<p>Approved for use in the following indication:</p> <ul style="list-style-type: none"> <li>Intravesical treatment of superficial bladder cancer</li> </ul>
<b>Bendamustine</b> Treanda®	Injection (vial) 25 mg, 100 mg	CTC Formulary	<p><b><u>Indolent non-Hodgkin's lymphoma (NHL) and Mantle Cell Lymphoma (MCL):</u></b></p> <ul style="list-style-type: none"> <li>First-line therapy in patients with indolent CD20 positive Non-Hodgkin Lymphoma (iNHL) and Mantle Cell Lymphoma (MCL) with an ECOG performance status of less than or equal to 2, when used in combination with rituximab.</li> <li>In combination with rituximab for <b>relapsed/refractory</b> therapy for bendamustine-naïve patients with Indolent CD20 Non-Hodgkin Lymphoma or Mantle Cell Lymphoma who previously received rituximab-based therapy, sustained a response and had remained treatment free for at least one year's duration following the last dose of rituximab.</li> </ul> <p><b><u>Chronic Lymphocytic Leukemia (CLL):</u></b></p> <ul style="list-style-type: none"> <li>As a single agent or in combination with rituximab for the first line treatment of patients with chronic lymphocytic leukemia with Binet stage B or C and WHO performance status of ≤ 2 and who are not medically fit to tolerate fludarabine-based regimens.</li> </ul>

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<b>Bevacizumab</b> Avastin® Mvasi® Zirabev® Aybintio® Abevmy® Bambevi® Vegzelma®	Injection (vial) 100 mg/4 mL, 400 mg/16 mL	CTC Formulary	<p><b><u>Colorectal Cancer – Metastatic:</u></b></p> <ul style="list-style-type: none"> <li>In one line of therapy and may repeat in patients who did not progress while receiving bevacizumab</li> </ul> <p><b><u>Carcinoma of the Cervix:</u></b></p> <ul style="list-style-type: none"> <li>In combination with chemotherapy for the treatment of patients with metastatic (stage IVB), persistent, or recurrent carcinoma of the cervix of all histologic subtypes (except small cell) and an ECOG performance status of 0 to 1. Retreatment with bevacizumab plus platinum and paclitaxel may be offered to patients following a complete response and a treatment-free period of at least 6 months. The funded dose is bevacizumab 15 mg/kg intravenously every 3 weeks until disease progression, unacceptable toxicity, or complete response, whichever occurs first.</li> </ul> <p><b><u>Ovarian Cancer</u></b></p> <ul style="list-style-type: none"> <li>As a first line treatment of patients with advanced stage ovarian cancer at a high risk of progression (stage II with &gt; 1 cm residual disease, stage III unresectable or stage IV) epithelial ovarian, primary peritoneal or fallopian tube cancer and good performance status. This would include initial treatment in combination with chemotherapy and maintenance therapy for up to 12 additional cycles or until disease progression, whichever occurs first.</li> <li>In combination with paclitaxel, topotecan or pegylated liposomal doxorubicin for the treatment of patients with platinum resistant recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer who have received no more than two prior anticancer regimens, good performance status and whose disease is not primary platinum refractory. Treatment should continue until disease progression or unacceptable toxicity.</li> </ul> <p><b><u>Hepatocellular</u></b></p> <ul style="list-style-type: none"> <li>bevacizumab in combination with atezolizumab for first line treatment of adult patients with unresectable or metastatic hepatocellular carcinoma (HCC) who require systemic therapy. Eligible patients should have no prior systemic treatment, have an Eastern Cooperative Oncology Group Performance Status (ECOG PS) of 0 or 1 and a Child –Pugh class status of A. Treatment with atezolizumab and bevacizumab should continue until loss of clinical benefit or unacceptable toxicity.</li> </ul>
<b>Bicalutamide</b> Casodex®, generics	Oral (tablet) 50 mg	Pharmacare <b>FGNQSW</b>	Open benefit

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Drug	Dosage Form	Funding Program	Funded Eligibility Criteria
<b>Binimetinib</b> Mektovi®	Oral (tablet) 15 mg	Pharmacare <b>MQWN</b>	<p><b><u>Metastatic Melanoma</u></b> For the treatment of patients with BRAF V600 mutation-positive locally advanced unresectable or metastatic melanoma when used in combination with encorafenib.</p> <p><u>Renewal Criteria:</u></p> <ul style="list-style-type: none"> <li>Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.</li> </ul> <p><u>Clinical Notes:</u></p> <ol style="list-style-type: none"> <li>Patients must have a good performance status.</li> <li>If brain metastases are present, patients should be asymptomatic or have stable symptoms.</li> <li>Treatment should be discontinued upon disease progression or unacceptable toxicity.</li> </ol> <p><u>Claim Notes:</u></p> <ul style="list-style-type: none"> <li>Binimetinib will not be reimbursed in patients who have progressed on BRAF targeted therapy.</li> <li>Requests will be considered for patients who received adjuvant BRAF targeted therapy if disease progression occurred at least 6 months following completion of therapy</li> </ul> <p><b>Patients must apply for coverage under the High-Cost Drug Program. If written by an oncologist, this medication does <u>not</u> require the submission of a Pharmacare Special Authorization form.</b></p>
<b>Bleomycin</b>	Injection(vial) 15 units	CTC Formulary	Open benefit

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<b>Blinatumomab</b> Blincyto®	Injection (vial) 38.5 mcg	CTC Formulary	<p><b><u>Acute Lymphoblastic Leukemia</u></b></p> <ul style="list-style-type: none"> <li>Pediatric patients with Philadelphia chromosome-negative (Ph-) relapsed or refractory B precursor acute lymphoblastic leukemia (ALL) who are in second or later relapse, or who relapsed after allogeneic hematopoietic stem cell transplant (alloHSCT), or who have refractory disease. Treatment should be in patients with a good performance status and no active central nervous system disease.</li> <li>Adult patients with Philadelphia chromosome-negative (Ph-) relapsed or refractory B precursor acute lymphoblastic leukemia (ALL). Treatment should be for patients with a good performance status and should be treated for 2 cycles of induction and 3 cycles of consolidation.</li> <li>Adult patients with Philadelphia chromosome-positive B-cell precursor acute lymphoblastic leukemia (Ph+ BCP-ALL) who have been treated with at least two prior tyrosine kinase inhibitors (TKIs) and have relapsed or refractory (R/R) disease.</li> <li>Treatment of Philadelphia chromosome-negative (Ph-), CD19 positive (CD19+), B-cell precursor acute lymphoblastic leukemia (BCP-ALL) adult and pediatric patients with good performance status who are in first or second hematologic complete remission (CR) and are minimal residual disease positive (MRD+)</li> <li>MRD+ disease is defined as MRD detected at a level greater than or equal to 0.1% (i.e., <math>\geq 10^{-3}</math>)</li> <li>Patients should have received over the course of their treatment for BCP-ALL, a minimum of 3 intensive chemotherapy blocks of a treatment regimen that is age-appropriate and given with curative intent before proceeding to blinatumomab therapy</li> <li>Treatment should be continued until unacceptable toxicity, hematologic relapse, MRD relapse, treatment with hematopoietic stem cell transplant (HSCT), or up to the completion of 4 cycles</li> </ul>

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<b>Bortezomib</b> Velcade®	Injection (vial) 3.5 mg	CTC Formulary	<p><b><u>Multiple Myeloma (including amyloidosis)</u></b></p> <ul style="list-style-type: none"> <li>Patients who are refractory to or have relapsed after at least one prior line of therapy <b>OR</b> who have completed at least one full treatment regimen and are experiencing intolerance to their current therapy <b>OR</b></li> <li>First line treatment for multiple myeloma for patient pre-autologous stem cell transplant.</li> </ul>
<b>Bosutinib</b> Bosulif®	Oral (tablet) 100 mg, 500 mg	Pharmacare <b>MQWN</b>	<p><b><u>Chronic Myelogenous Leukemia (CML) - Philadelphia Chromosome Positive (Ph+)</u></b></p> <ul style="list-style-type: none"> <li>For treatment of adult patients with chronic, accelerated, or blast phase Philadelphia chromosome-positive (Ph+) chronic myelogenous leukemia (CML) with resistance or intolerance to prior TKI therapy</li> </ul> <p><b>Patients must apply for coverage under the High-Cost Drug Program.</b>  <b>If written by an oncologist, this medication does <u>not</u> require the submission of a Pharmacare Special Authorization form.</b></p>

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<b>Brentuximab vedotin</b> Adcetris®	Injection (vial) 50 mg	CTC Formulary	<p><b><u>Hodgkin lymphoma (HL)</u></b></p> <ul style="list-style-type: none"> <li>Treatment of patients with Hodgkin lymphoma who have relapsed disease following autologous stem cell transplant and who have an ECOG performance status of 0 or 1</li> <li>For the post-autologous stem cell transplant (ASCT) consolidation treatment of patients with Hodgkin lymphoma (HL) at increased risk of progression. Consolidation treatment should be initiated within four to six weeks post-ASCT or upon recovery from ASCT and continued until a maximum of 16 cycles, disease progression or unacceptable toxicity, whichever comes first.</li> <li><b><u>Notes:</u></b> <ul style="list-style-type: none"> <li>High-risk of progression is defined below: <ul style="list-style-type: none"> <li>Refractory to frontline therapy (e.g., progressed during, or no response to frontline therapy), or</li> <li>Relapsed less than 12 months from completion of frontline therapy, or</li> <li>Relapsed 12 months or later after completion of frontline therapy with extranodal disease</li> </ul> </li> <li>Re-treatment with Brentuximab vedotin is allowed in patients who are not considered refractory to Brentuximab vedotin (e.g., no evidence of disease progression during consolidation Brentuximab vedotin, and a minimum of 6 months since the last dose of consolidation Brentuximab vedotin)</li> </ul> </li> </ul> <p><b><u>First Line Hodgkin Lymphoma</u></b></p> <ul style="list-style-type: none"> <li>Brentuximab vedotin (BV) in combination with doxorubicin, vinblastine, and dacarbazine (AVD) for the treatment of previously untreated patients with stage IV Hodgkin lymphoma (HL).</li> <li>Treatment should be continued until disease progression, unacceptable toxicity, or until a maximum of six cycles, whichever comes first.</li> </ul> <p><b><u>Systemic Anaplastic Large Cell Lymphoma (sALCL)</u></b></p> <ul style="list-style-type: none"> <li>Treatment of patients with systemic anaplastic large cell lymphoma who have failed at least one prior multiagent chemotherapy regimen and who have an ECOG performance status of 0 or 1</li> </ul> <p><b><u>Cutaneous T-cell Lymphoma</u></b></p> <ul style="list-style-type: none"> <li>Brentuximab vedotin (BV) for adult patients with CD30-positive primary cutaneous anaplastic large cell lymphoma (pcALCL) or mycosis fungoides (MF) who have had prior systemic therapy.</li> <li>Eligible patients should have good performance status with confirmation of CD30-positivity (defined as having ≥ 10% CD30-positive malignant cells or lymphoid infiltrate). Patients with MF must have received at least one prior systemic therapy and patients with pcALCL must have at least one prior systemic therapy or prior radiation therapy.</li> <li>Treatment with BV should continue for a maximum of 16 cycles (48 weeks of treatment) or until unacceptable toxicity or disease progression, whichever occurs first.</li> </ul>

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			<p><b><u>Brentuximab vedotin cont'd</u></b></p> <p><b><u>T-Cell Lymphoma</u></b></p> <ul style="list-style-type: none"> <li>For the treatment of previously untreated adult patients with systemic anaplastic large-cell lymphoma (sALCL), peripheral T-cell lymphoma not otherwise specified (PTCL-NOS), or angioimmunoblastic T-cell lymphoma (AITL), whose tumors express CD30, plus cyclophosphamide, doxorubicin, and prednisone (CHP).</li> <li>Patients with anaplastic lymphoma kinase (ALK) positive sALCL should have an International Prognostic Index (IPI) score of <math>\geq 2</math>.</li> <li>Treatment should be continued for six to eight cycles, until disease progression or unacceptable toxicity, whichever comes first.</li> </ul>
<p><b>Brigatinib</b> Alunbrig®</p>	<p>Oral (tablet) 30 mg, 90 mg, 180 mg, Initiation kit</p>	<p>Pharmacare <b>MQWN</b></p>	<p><b><u>Non-small Cell Lung Cancer (NSCLC):</u></b></p> <ul style="list-style-type: none"> <li>For the treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive locally advanced (not amenable to curative therapy) or metastatic non-small cell lung cancer who have not been previously treated with an ALK inhibitor.</li> <li><b><u>Renewal Criteria:</u></b> <ul style="list-style-type: none"> <li>Written confirmation that the patient is responding to treatment.</li> </ul> </li> <li><b><u>Clinical Note:</u></b> <ul style="list-style-type: none"> <li>Treatment should be discontinued upon clinically meaningful disease progression or unacceptable toxicity.</li> </ul> </li> <li><b><u>Claim Notes:</u></b> <ul style="list-style-type: none"> <li>No further ALK inhibitor will be reimbursed following disease progression on brigatinib.</li> <li>Initial approval period: 1 year.</li> <li>Renewal approval period: 1 year</li> </ul> </li> </ul> <p><b>Patients must apply for coverage under the High-Cost Drug Program.</b> <b>If written by an oncologist, this medication does <u>not</u> require the submission of a Pharmacare Special Authorization form.</b></p>
<p><b>Buserelin acetate</b> Suprefact Depot®</p>	<p>Implant 6.3 mg, 9.45 mg</p>	<p>Pharmacare <b>FNQSW</b></p>	<p>Open benefit</p>
<p><b>Busulfan</b> Myleran®</p>	<p>Oral (tablet) 2 mg</p>	<p>Pharmacare <b>FNQSW</b></p>	<p>Open benefit</p>
<p><b>Cabazitaxel</b> generics</p>	<p>Injection (vial) 45 mg/4.5 mL 60 mg/6 mL</p>	<p>CTC Formulary</p>	<p><b><u>Prostate Cancer – metastatic</u></b></p> <ul style="list-style-type: none"> <li>For the treatment of metastatic castration resistant prostate cancer (mCRPC) in combination with prednisone in patients who have received prior docetaxel.</li> </ul>

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<b>Cabozantinib</b> Cabometyx®  (cont'd on next page)	Oral (tablet) 20mg, 40mg, 60mg	Pharmacare <b>MQWN</b>	<p><b><u>metastatic Renal Cell Carcinoma (mRCC):</u></b>                      For the treatment of patients with advanced or metastatic renal cell carcinoma who have received at least one prior vascular endothelial growth factor receptor (VEGFR) tyrosine kinase inhibitor (TKI) therapy when used as:</p> <ul style="list-style-type: none"> <li>second-line therapy following disease progression on sunitinib, pazopanib or pembrolizumab in combination with axitinib; or</li> <li>third-line therapy following disease progression on immunotherapy and VEGFR TKI (i.e., sunitinib or pazopanib), used in any sequence.</li> </ul> <p><b><u>Renewal Criteria:</u></b></p> <ul style="list-style-type: none"> <li>Written confirmation that the patient has responded to treatment and there is no evidence of clinically meaningful disease progression.</li> </ul> <p><b><u>Clinical Note:</u></b></p> <ul style="list-style-type: none"> <li>Treatment should be discontinued upon clinically meaningful disease progression or unacceptable toxicity.</li> </ul> <p><b><u>Claim Notes:</u></b></p> <ul style="list-style-type: none"> <li>Requests for cabozantinib will not be considered for patients who experience disease progression on everolimus or axitinib monotherapy.</li> <li>Initial approval period: 1 year.</li> <li>Renewal approval period: 1 year</li> </ul> <p><b><u>Advanced Hepatocellular Carcinoma</u></b>                      For the second-line treatment of adult patients with unresectable hepatocellular carcinoma who meet all of the following criteria:</p> <ul style="list-style-type: none"> <li>Disease progression on sorafenib or lenvatinib</li> <li>Child-Pugh class status of A</li> <li>ECOG performance status of 0 or 1</li> </ul> <p><b><u>Clinical Note:</u></b></p> <ul style="list-style-type: none"> <li>Treatment should continue until the patient no longer experiences clinical benefit or experiences unacceptable toxicity.</li> </ul> <p><b><u>Claim Notes:</u></b></p> <ul style="list-style-type: none"> <li>Requests for cabozantinib will not be considered for patients who experience disease progression on regorafenib or atezolizumab in combination with bevacizumab.</li> <li>Approval period: 6 months</li> </ul>

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<b>Cabozantinib</b> Cabometyx®	Oral (tablet) 20mg, 40mg, 60mg	Pharmacare <b>MQWN</b>	<p><b><u>Differentiated Thyroid Carcinoma (DTC)</u></b> 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.</p> <p><b><u>Clinical Notes:</u></b></p> <ul style="list-style-type: none"> <li>• Patients should have a good performance status.</li> <li>• Patients should be refractory to radioactive iodine therapy (RAI-R) or not eligible for radioactive iodine therapy.</li> <li>• Treatment should continue until disease progression or unacceptable toxicity.</li> <li>• Patients will be eligible for funding if intolerant to the prior line of VEGFR-targeted TKI therapy.</li> <li>• Cabozantinib may be used in the third line setting for RET fusion positive patients after progression on or intolerance to selpercatinib.</li> </ul> <p><b>Prescriptions written by PEI oncologists do not require Special Authorization. Patients must apply for coverage by the High-Cost Drug Program.</b></p>
<b>Caelyx®</b> Pegylated Liposomal Doxorubicin  (Tradename used to minimize confusion with doxorubicin)	Injection (vial) 20 mg/10 mL	CTC Formulary	Open benefit
<b>Capecitabine</b> Xeloda®, generics	Oral (tablet) 150 mg, 500 mg	Pharmacare <b>FGNQSW</b>	Open benefit
<b>Carboplatin</b>	Injection (vial) 150 mg/15 mL, 600 mg/60 mL	CTC Formulary	Open benefit

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<b>Carfilzomib</b> Kyprolis®	Injection (vial) 10 mg, 30 mg, 60 mg	CTC Formulary	<p><b><u>Multiple Myeloma</u></b></p> <ol style="list-style-type: none"> <li>1. Carfilzomib in combination with lenalidomide and dexamethasone (KRd regimen) for patients with multiple myeloma who have received at least one prior treatment.  <b><u>Notes:</u></b> <ul style="list-style-type: none"> <li>○ Patients must not have had disease progression during treatment with bortezomib or if previously treated with lenalidomide and dexamethasone patients must not have: <ul style="list-style-type: none"> <li>▪ Discontinued therapy because of adverse effects or</li> <li>▪ Disease progression during the first 3 months of treatment, or</li> <li>▪ Progression at any time during treatment if lenalidomide and dexamethasone was their most recent treatment</li> </ul> </li> <li>○ Treatment should be in patients who have good performance status and are deemed to have adequate renal function.</li> <li>○ Treatment with carfilzomib should continue until disease progression or unacceptable toxicity, to a maximum of 18 cycles.</li> </ul> </li> <li>2. Carfilzomib in combination with dexamethasone (Kd regimen) for patients with relapsed multiple myeloma with a good performance status who received one to three prior treatments.</li> </ol>
<b>Carmustine</b> BCNU, BiCNU	Injection (vial) 100 mg	CTC Formulary	Open benefit
<b>Cemiplimab</b> Libtayo®	Injection (vial) 350mg	CTC Formulary	<p><b><u>Cutaneous Squamous Cell Carcinoma</u></b></p> <ul style="list-style-type: none"> <li>• For patients with metastatic or locally advanced cutaneous squamous cell carcinoma (CSCC) who are not candidates for curative surgery or curative radiation.</li> <li>• Treatment should be for previously treated (prior radiation and/or surgery) or treatment naïve patients who are not amenable to curative surgery or curative radiation with good performance status.</li> <li>• Treatment with cemiplimab should continue up to 24 months (96 weeks) or until symptomatic disease progression or unacceptable toxicity, whichever occurs first.</li> </ul>

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<b>Ceritinib</b> Zykadia®	Oral (capsule) 150mg	Pharmacare <b>MQWN</b>	<p><b><u>Non-small Cell Lung Cancer (NSCLC):</u></b></p> <ul style="list-style-type: none"> <li>As monotherapy treatment for patients with anaplastic lymphoma kinase (ALK)-positive locally advanced (not amenable to curative therapy) or metastatic non-small cell lung cancer who experience disease progression on, or intolerance to, crizotinib.</li> <li><b><u>Renewal Criteria</u></b> <ul style="list-style-type: none"> <li>Confirmation that the patient is responding to treatment.</li> </ul> </li> <li><b><u>Clinical Note:</u></b> <ul style="list-style-type: none"> <li>Treatment should be discontinued upon clinically meaningful disease progression or unacceptable toxicity.</li> </ul> </li> </ul> <p><b>Patients must apply for coverage under the High-Cost Drug Program.</b>  <b>If written by an oncologist, this medication does <u>not</u> require the submission of a Pharmacare Special Authorization form.</b></p>
<b>Chlorambucil</b> Leukeran®	Oral (tablet) 2 mg	Pharmacare <b>FNQSW</b>	Open benefit
<b>Cisplatin</b>	Injection (vial) 50 mg/50 mL, 100 mg/100 mL	CTC Formulary	Open benefit
<b>Cladribine</b> 2-CDA	Injection (vial) 10 mg/10 mL	CTC Formulary	Primary treatment of hairy cell leukemia
<b>Cobimetinib</b> Cotellic®	Oral (tablet) 20 mg	Pharmacare <b>MQWN</b>	<p><b><u>Melanoma – Advanced (Unresectable or Metastatic)</u></b></p> <ul style="list-style-type: none"> <li>In combination with vemurafenib, for the treatment of patients with previously untreated BRAF V600 mutation-positive unresectable stage III or stage IV melanoma who have a good performance status. Treatment should continue until unacceptable toxicity or disease progression. If brain metastases are present, patients should be asymptomatic or have stable symptoms.</li> <li>Approvals are for a maximum daily dose of 60 mg during 21 consecutive days per 28 day cycle.</li> </ul> <p><b>Patients must apply for coverage under the High-Cost Drug Program.</b>  <b>If written by an oncologist, this medication does <u>not</u> require the submission of a Pharmacare Special Authorization form.</b></p>
<b>Cortisone acetate</b> Cortisone®	Oral (tablet) 25 mg	Pharmacare <b>FNQSW</b>	Open benefit
<b>Crisantaspase Recombinant</b> Rylaze®	Injection (vial) 10mg/0.5mL	CTC Formulary	Pediatric and adult patients who have acute lymphoblastic leukemia (ALL) or lymphoblastic lymphoma (LBL) with documented hypersensitivity to an E. coli - derived asparaginase.

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**updated: 2025-06-30**

## Health PEI Formulary Drugs: Oncology

Drug	Dosage Form	Funding Program	Funded Eligibility Criteria
<b>Crizotinib</b> Xalkori®	Oral (capsule) 200 mg, 250 mg	Pharmacare <b>MQWN</b>	<p><b><u>Non-Small Cell Lung Cancer (NSCLC)</u></b></p> <p>1. For the treatment of patients with anaplastic lymphoma kinase (ALK)-positive locally advanced non-small cell lung cancer (NSCLC) with an ECOG performance status ≤2 when used as:</p> <p>a) first line therapy or</p> <p>b) second line therapy following chemotherapy</p> <p>2. For the first-line treatment of patients with ROS-1 positive non-small cell lung cancer (NSCLC).</p> <p><b><u>Clinical Notes:</u></b></p> <ul style="list-style-type: none"> <li>• Eligible patients should be previously untreated and have a good performance status.</li> <li>• Treatment may continue until disease progression or unacceptable toxicity.</li> <li>• 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.</li> </ul> <p><b>Patients must apply for coverage under the High-Cost Drug Program.</b>  <b>If written by an oncologist, this medication does <u>not</u> require the submission of a Pharmacare Special Authorization form.</b></p>
<b>Cyclophosphamide</b> Procytox®	Injection (vial) 1 g	CTC Formulary	Open benefit
<b>Cyclophosphamide</b> Procytox®	Oral (tablet) 25 mg, 50 mg	Pharmacare <b>FNQSW</b>	Open benefit (Supplied by and administered at CTC for multiple myeloma patients due to complicated dosing regimen)
<b>Cyproterone acetate</b> CPA, Androcur®, generics	Oral (tablet) 50 mg	Pharmacare <b>FGNQSW</b>	Open benefit
<b>Cytarabine</b> Cytosine Arabinoside ARA-C	Injection (vial) 100 mg/1 mL, 500 mg/5 mL, 1 g/10 mL, 2 g/20 mL	CTC Formulary	Open benefit

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## Health PEI Formulary Drugs: Oncology

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<b>Dabrafenib</b> Tafinlar®	Oral (capsule) 50 mg, 75 mg	Pharmacare <b>MQWN</b>	<p><b><u>Melanoma – Adjuvant</u></b></p> <ul style="list-style-type: none"> <li>In combination with trametinib for the adjuvant treatment of patients with cutaneous melanoma who meet all of the following criteria <ul style="list-style-type: none"> <li>Stage IIIA (limited to lymph node metastases of greater than 1 mm) to stage IIID disease (AJCC 8th edition)</li> <li>BRAF V600-mutation positive</li> <li>Completely resected disease including in-transit metastases</li> </ul> </li> </ul> <p><b><u>Clinical Notes:</u></b></p> <ol style="list-style-type: none"> <li>Patients must have a good performance status.</li> <li>Treatment should continue until disease recurrence, unacceptable toxicity, or up to a maximum of 12 months.</li> </ol> <p><b><u>Claim Notes:</u></b></p> <ol style="list-style-type: none"> <li>Requests will be considered for patients with regional lymph nodes with micrometastases after sentinel lymph node biopsy.</li> <li>Requests will not be considered for patients who received adjuvant immunotherapy for greater than three months. Patients may switch to BRAF targeted therapy within the first three months of initiating immunotherapy to complete a total of 12 months of adjuvant treatment.</li> <li>Approval period: up to 12 months</li> </ol> <p><b><u>Melanoma – Advanced (Unresectable or Metastatic)</u></b></p> <ul style="list-style-type: none"> <li>For the treatment of patients with BRAF V600 mutation-positive unresectable or metastatic melanoma when used alone or in combination with trametinib.</li> </ul> <p><b><u>Clinical Notes:</u></b></p> <ol style="list-style-type: none"> <li>Patients must have an ECOG performance status of 0 or 1.</li> <li>If brain metastases are present, patients should be asymptomatic or have stable symptoms.</li> <li>Treatment should be discontinued upon disease progression or unacceptable toxicity.</li> </ol> <p><b>Patients must apply for coverage under the High-Cost Drug Program.</b>  <b>If written by an oncologist, this medication does <u>not</u> require the submission of a Pharmacare Special Authorization form.</b></p>
<b>Dacarbazine</b> DTIC®	Injection (vial) 600 mg	CTC Formulary	Open benefit
<b>Dactinomycin</b> Actinomycin D, Cosmegen®	Injection (vial) 0.5 mg	CTC Formulary	Open benefit

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Health PEI Formulary Drugs: Oncology

Drug	Dosage Form	Funding Program	Funded Eligibility Criteria
<b>Daunorubicin &amp; Cytarabine Liposome</b> Vyxeos®	Injection (vial) 44 mg & 100 mg	CTC Formulary	<p><b><u>Therapy-Related Acute Myeloid Leukemia (t-AML) or AML with Myelodysplasia-Related Changes (AML-MRC)</u></b></p> <ul style="list-style-type: none"> <li>Adults with newly diagnosed therapy-related acute myeloid leukemia (t-AML) or AML with myelodysplasia-related changes (AML-MRC).</li> <li>Patients must be deemed fit for intensive chemotherapy by the treating physician.</li> <li>Initial reimbursement of liposomal daunorubicin and cytarabine should be limited to 2 cycles of induction therapy.</li> <li>Patients who achieve complete remission (CR) or CR with incomplete neutrophil or platelet recovery (CRi) during induction cycles are eligible for reimbursement of up to an additional 2 cycles of consolidation therapy with liposomal daunorubicin and cytarabine.</li> <li>Vyxeos is not funded in combination with other anti-cancer therapies.</li> <li>Vyxeos is not funded in patients previously treated with azacitidine with or without venetoclax for t-AML or AML-MRC.</li> </ul>

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Health PEI Formulary Drugs: Oncology

Drug	Dosage Form	Funding Program	Funded Eligibility Criteria
<b>Darolutamide</b> Nubeqa®  (cont'd on next page)	Oral (tablet) 300mg	Pharmacare <b>MQWN</b>	<p><b><u>Non-Metastatic Castration-Resistant Prostate Cancer (nmCRPC)</u></b></p> <ul style="list-style-type: none"> <li>In combination with androgen deprivation therapy (ADT) for the treatment of patients with non-metastatic castration-resistant prostate cancer (nmCRPC) who are at high risk of developing metastases.<sup>1</sup></li> <li>Patients should have a good performance status. Treatment should continue until unacceptable toxicity or radiographic disease progression.</li> </ul> <p><b><u>Clinical Notes:</u></b></p> <ul style="list-style-type: none"> <li>Castration-resistance must be demonstrated during continuous ADT and is defined as 3 PSA rises at least one week apart, with the last PSA &gt; 2 ng/mL.</li> <li>Patients should have no detectable distant metastases by either CT, MRI or technetium-99m bone scan.</li> <li>Castrate levels of testosterone must be maintained.</li> <li>Patients with N1 disease, pelvic lymph nodes &lt; 2cm in short axis located below the aortic bifurcation are eligible for darolutamide.</li> <li>Darolutamide will not be funded for patients who experience disease progression on apalutamide or enzalutamide.</li> <li>Patients receiving darolutamide for the treatment of non-metastatic CRPC will be eligible for funding of abiraterone at the time of disease progression to metastatic CRPC. Enzalutamide is not funded for patients who experience disease progression to metastatic CRPC while on darolutamide.</li> <li>Either abiraterone or enzalutamide may be used to treat metastatic CRPC in patients who discontinued darolutamide in the non-metastatic setting due to intolerance without disease progression.</li> </ul> <p>1. High risk of developing metastases is defined as a prostate-specific antigen (PSA) doubling time of ≤ 10 months during continuous ADT.</p> <p><b><u>Metastatic Castration-Sensitive Prostate Cancer (mCSPC)</u></b></p> <ul style="list-style-type: none"> <li>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.</li> </ul> <p><b><u>Renewal Criteria:</u></b></p> <ul style="list-style-type: none"> <li>Confirmation that the patient has responded to treatment and there is no evidence of disease progression.</li> </ul> <p><b><u>Clinical Notes:</u></b></p> <ul style="list-style-type: none"> <li>Patients should have a good performance status.</li> <li>Treatment should continue until unacceptable toxicity or disease progression.</li> </ul>

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<b>Darolutamide</b> Nubeqa®	Oral (tablet) 300mg	Pharmacare <b>MQWN</b>	<p><b><u>Claim Notes:</u></b></p> <ul style="list-style-type: none"> <li>• Requests will not be considered for patients who are within 1 year of completing adjuvant ADT in the nonmetastatic setting.</li> <li>• Patients who experience disease progression on apalutamide or enzalutamide are not eligible.</li> </ul> <p><b>Patients must apply for coverage under the High-Cost Drug Program.</b>  <b>If written by an oncologist, this medication does <u>not</u> require the submission of a Pharmacare Special Authorization form.</b></p>

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## Health PEI Formulary Drugs: Oncology

Drug	Dosage Form	Funding Program	Funded Eligibility Criteria
<b>Daratumumab</b> Darzalex® Darzalex SC®	Injection (vial) 100 mg/5 mL 400 mg/20 mL  Injection (vial) Subcutaneous 1800 mg/15 mL	CTC formulary	<p><b><u>Multiple Myeloma (newly diagnosed – transplant ineligible)</u></b></p> <ul style="list-style-type: none"> <li>In combination with lenalidomide and dexamethasone (DRd) for patients with newly diagnosed multiple myeloma who are not suitable for autologous stem cell transplant <ul style="list-style-type: none"> <li>Eligible patients include those with good performance status</li> <li>Treatment with DRd should continue until unacceptable toxicity or disease progression</li> <li><b>Note:</b> on a time on a time-limited basis, daratumumab may be added to lenalidomide + dexamethasone (Rd) at any time during first-line therapy provided the patient is not experiencing disease progression on Rd</li> </ul> </li> <li>In combination with bortezomib, melphalan and prednisone (DVMP) or cyclophosphamide, bortezomib and dexamethasone (DCyBorD) for patients with newly diagnosed multiple myeloma who are not suitable for autologous stem cell transplant <ul style="list-style-type: none"> <li>Eligible patients include those with good performance status</li> <li>Treatment with the daratumumab component should continue until unacceptable toxicity or disease progression</li> <li><b>Note:</b> on a time-limited basis, daratumumab may be added to a bortezomib-containing regimen (e.g., VMP, CyBorD) in patients who recently initiated treatment provided the patient is not experiencing disease progression on the bortezomib-containing regimen</li> </ul> </li> </ul> <p><b><u>Multiple Myeloma (Relapsed/Refractory)</u></b></p> <ul style="list-style-type: none"> <li>In combination with lenalidomide and dexamethasone (len-dex), or bortezomib and dexamethasone (bor-dex), for the treatment of patients with multiple myeloma with good performance status who have received at least one prior therapy</li> <li><b>Notes:</b> <ul style="list-style-type: none"> <li>Patients have access to only one triplet therapy – either daratumumab (DRd, DVd) or carfilzomib-based (KRd) triplet therapy</li> <li>Patients can access either daratumumab+bortezomib+dexamethasone or daratumumab+lenalidomide+dexamethasone triplet therapy, depending on drug sensitivities.</li> <li>Patients are not allowed access to daratumumab containing regimens when the disease is resistant to both lenalidomide and bortezomib</li> <li>Patients currently receiving either lenalidomide+dexamethasone or bortezomib-based therapy in the second-line setting at the time of daratumumab funding in a jurisdiction will be eligible to add daratumumab provided no disease progression</li> <li>Patients who choose the lenalidomide+dexamethasone doublet in second-line will have the option of accessing daratumumab+bortezomib+dexamethasone in third-line; similarly, patients who choose bortezomib-based chemotherapy in second-line should have access to daratumumab+lenalidomide+dexamethasone or carfilzomib+lenalidomide+dexamethasone in third-line</li> </ul> </li> </ul>

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Health PEI Formulary Drugs: Oncology

Drug	Dosage Form	Funding Program	Funded Eligibility Criteria
<b>Daratumumab</b> Darzalex SC®	Injection (vial) Subcutaneous 1800 mg/15 mL	CTC formulary	<p><b><u>Light chain amyloidosis (newly diagnosed)</u></b></p> <ul style="list-style-type: none"> <li>• In combination with cyclophosphamide, bortezomib, and dexamethasone (DCyBorD) for the treatment of adult patients with newly diagnosed light chain (AL) amyloidosis according to the following clinical pCODR criteria: <ul style="list-style-type: none"> <li>○ Histopathologic diagnosis of systemic AL amyloidosis based on detection by IHC and polarizing light microscopy of green birefringent in Congo red-stained tissue specimens or characteristic electron microscopy appearance</li> <li>○ Measurable disease by serum M protein &gt;0.5 g/dL or abnormal serum free light chain ratio or a difference between involved and uninvolved free light chains (dFLC) &gt;50 mg/L</li> <li>○ Involvement of at least 1 organ system</li> <li>○ Adequate hematologic, hepatic, and renal function (eGFR ≥ 20mL/min/1.73 m<sup>2</sup>)</li> <li>○ Patients should have good performance status</li> <li>○ Patients <b><u>must not</u></b> have any of the following: <ul style="list-style-type: none"> <li>▪ Prior therapy for AL amyloidosis or multiple myeloma, including medications that target CD38</li> <li>▪ Previous or current diagnosis of multiple myeloma including the presence of lytic bone disease, plasmacytomas, &gt;60% plasma cells in the bone marrow, or hypercalcemia</li> <li>▪ Planned autologous stem cell transplant (ASCT) during the first 6 cycles of treatment</li> </ul> </li> <li>○ Treatment with daratumumab should be discontinued upon occurrence of any of the following: <ul style="list-style-type: none"> <li>▪ Evidence of hematologic progression or organ decompensation on treatment</li> <li>▪ Unacceptable toxicity</li> <li>▪ Maximum of 24 months of treatment</li> </ul> </li> <li>○ Daratumumab should be given in combination with CyBorD for 6 months followed by daratumumab monotherapy (starting in week 25) until disease progression or 24 cycles up to a maximum of 2 years <ul style="list-style-type: none"> <li>▪ Patients currently receiving CyBorD for AL amyloidosis who do not demonstrate a response to treatment may have daratumumab added to their CyBorD regimen at the judgement of the treating physician</li> </ul> </li> </ul> </li> </ul>

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## Health PEI Formulary Drugs: Oncology

Drug	Dosage Form	Funding Program	Funded Eligibility Criteria
<b>Dasatinib</b> Sprycel <sup>®</sup> , generics	Oral (tablet) 20 mg, 50 mg, 70 mg, 80 mg, 100 mg, 140 mg	Pharmacare <b>MQWN</b>	<p><b><u>Chronic Myelogenous Leukemia (CML)</u></b></p> <ul style="list-style-type: none"> <li>For use as a single agent for the treatment of adults with chronic, accelerated or blast phase CML with resistance or intolerance to prior therapy including imatinib</li> </ul> <p><b><u>Philadelphia Chromosome Acute Lymphoblastic Leukemia (Ph+ALL)</u></b></p> <ul style="list-style-type: none"> <li>For the treatment of adults with Ph+ALL with resistance or intolerance to prior therapy including imatinib</li> </ul> <p><b>Patients must apply for coverage under the High-Cost Drug Program.</b>  <b>If written by an oncologist, this medication does <u>not</u> require the submission of a Pharmacare Special Authorization form.</b></p>
<b>Daunorubicin</b> Daunomycin, Cerubidine <sup>®</sup>	Injection (vial) 20 mg	CTC Formulary	Open benefit
<b>Decitabine and Cedazuridine</b> Inqovi <sup>®</sup>	Oral (tablet) 35 mg and 100 mg	Pharmacare <b>MQWN</b>	<p><b><u>Myelodysplastic Syndromes (MDS)</u></b></p> <p>For the treatment of patients with myelodysplastic syndromes (MDS), including previously treated and untreated, who meet all of the following criteria:</p> <ul style="list-style-type: none"> <li>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)</li> <li>Intermediate-1, intermediate-2, or high-risk MDS, according to the International Prognostic Scoring System</li> <li>Have not experienced disease progression on a hypomethylating agent</li> </ul> <p><b><u>Clinical Notes:</u></b></p> <ul style="list-style-type: none"> <li>Patients should have a good performance status.</li> <li>Treatment should be discontinued upon disease progression or unacceptable toxicity.</li> </ul> <p><b>Patients must apply for coverage under the High-Cost Drug Program.</b>  <b>If written by an oncologist, this medication does <u>not</u> require the submission of a Pharmacare Special Authorization form.</b></p>
<b>Degarelix</b> Firmagon <sup>®</sup>	Injection (vial) 240 mg (2 x 120 mg), 80 mg	Pharmacare <b>FNQSW</b>	Open benefit

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## Health PEI Formulary Drugs: Oncology

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<b>Denosumab</b> Prolia®	Injection (pre-filled syringe) 60 mg/mL	Pharmacare <b>FNQSW</b>	For the treatment of osteoporosis in postmenopausal women and in men who meet the following criteria: <ul style="list-style-type: none"> <li>• Have a contraindication to oral bisphosphonates; and</li> <li>• High risk for fracture, or refractory or intolerant to other available osteoporosis therapies.</li> </ul> <b>Clinical Notes:</b> <ul style="list-style-type: none"> <li>• 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.</li> <li>• High fracture risk is defined as: <ul style="list-style-type: none"> <li>○ 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</li> <li>○ High 10-year fracture risk (≥ 20%) as defined by the CAROC or FRAX tool.</li> </ul> </li> </ul> <b>Requires submission of a Pharmacare Special Authorization form.</b>
<b>Dexamethasone</b> Decadron®	Injection (vial) 20 mg/5 mL	CTC Formulary	Pre-medication only
<b>Dexamethasone</b>	Oral (tablet) 0.5 mg, 2 mg, 4 mg	Pharmacare <b>FGNQSW</b>	Open benefit
<b>Dexrazoxane</b> Zinecard®	Injection (vial) 250 mg, 500 mg	CTC Formulary	Reducing (preventing) the incidence and severity of cardiotoxicity associated with the use of doxorubicin for the treatment of metastatic breast cancer
<b>Docetaxel</b> Taxotere®	Injection (vial) 20 mg, 80 mg	CTC Formulary	Open benefit
<b>Doxorubicin</b> Myocet®	Injection (vial) 50 mg/25 mL	CTC Formulary	Open benefit
<b>Doxorubicin Pegylated Liposomal</b> Caelyx®	Injection (vial) 20 mg/10 mL	CTC Formulary	See Caelyx®

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<b>Durvalumab</b> Imfinzi®	Injection (vial) 500 mg/10 mL 120 mg/2.4 mL	CTC Formulary	<p><b><u>Extensive-Stage Small Cell Lung Cancer (ES-SCLC)</u></b></p> <ul style="list-style-type: none"> <li>In combination with etoposide and platinum (EP) chemotherapy (cisplatin or carboplatin), for the treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC) who have not received previous treatment for ES-SCLC. Patients must have a good performance status upon treatment initiation with durvalumab.</li> <li>Treatment with durvalumab should continue until confirmed disease progression or unacceptable toxicity.</li> </ul> <p><b><u>Non-Small Cell Lung Cancer (NSCLC) – Locally Advanced</u></b></p> <ul style="list-style-type: none"> <li>Treatment of patients with locally advanced, unresectable stage III non-small cell lung cancer (NSCLC) following curative intent platinum-based concurrent chemoradiation therapy.</li> <li>Eligible patients include those with good performance status who are deemed fit following curative intent platinum-based concurrent chemoradiation therapy</li> <li>Treatment should continue until unacceptable toxicity or disease progression to a maximum of 12 months</li> </ul> <p><b><u>Notes:</u></b></p> <ul style="list-style-type: none"> <li>For patients who have dose interruptions and subsequently resume therapy, durvalumab may continue for up to a maximum of 12 months from the time of treatment initiation</li> <li>Patients will be eligible for PD-1/PD-L1 inhibitor therapy in the metastatic setting only if there has been at least a 6 month progression-free interval between completion of durvalumab and confirmation of disease progression</li> </ul>

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<b>Encorafenib</b> Braftovi®	Oral (capsule) 75 mg	Pharmacare <b>MQWN</b>	<p><b><u>Metastatic Colorectal Cancer</u></b> In combination with panitumumab for the treatment of patients with metastatic colorectal cancer who meet all of the following criteria:</p> <ul style="list-style-type: none"> <li>• Presence of BRAF V600E mutation</li> <li>• Disease progression following at least one prior therapy in the metastatic setting</li> <li>• No previous treatment with an EGFR inhibitor</li> </ul> <p><u>Renewal Criteria:</u></p> <ul style="list-style-type: none"> <li>• Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.</li> </ul> <p><u>Clinical Notes:</u></p> <ol style="list-style-type: none"> <li>1. Patients must have a good performance status.</li> <li>2. Treatment should be discontinued upon disease progression or unacceptable toxicity.</li> </ol> <p><u>Claim Notes:</u></p> <ul style="list-style-type: none"> <li>• Encorafenib will not be reimbursed in patients who have progressed on BRAF targeted therapy.</li> </ul> <p><b><u>Melanoma (BRAF V600 Mutation-Positive Unresectable or Metastatic)</u></b> For the treatment of patients with BRAF V600 mutation-positive unresectable or metastatic melanoma when used in combination with binimetinib.</p> <p><u>Renewal Criteria:</u></p> <ul style="list-style-type: none"> <li>• Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.</li> </ul> <p><u>Clinical Notes:</u></p> <ol style="list-style-type: none"> <li>1. Patients must have a good performance status.</li> <li>2. If brain metastases are present, patients should be asymptomatic or have stable symptoms.</li> <li>3. Treatment should be discontinued upon disease progression or unacceptable toxicity.</li> </ol> <p><u>Claim Notes:</u></p> <ul style="list-style-type: none"> <li>• Encorafenib will not be reimbursed in patients who have progressed on BRAF targeted therapy.</li> <li>• Requests will be considered for patients who received adjuvant BRAF targeted therapy if disease progression occurred at least 6 months following completion of therapy.</li> </ul> <p><b>Patients must apply for coverage under the High-Cost Drug Program.</b> <b>If written by an oncologist, this medication does <u>not</u> require the submission of a Pharmacare Special Authorization form.</b></p>

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Health PEI Formulary Drugs: Oncology

Drug	Dosage Form	Funding Program	Funded Eligibility Criteria
<b>Enfortumab vedotin</b> Padcev®	Injection (vial) 20mg, 30mg	CTC Formulary	<p><b><u>Urothelial Carcinoma</u></b> For the treatment of adult patients with locally advanced or metastatic urothelial carcinoma who have previously received a platinum-containing chemotherapy and PD-1 or PD-L1 inhibitor therapy. Patients must have a good performance status. Treatment may be continued until disease progression or unacceptable toxicity.</p> <ul style="list-style-type: none"> <li>Patients with a contraindication to platinum-based chemotherapy are eligible for enfortumab vedotin provided they have received prior treatment with a PD-1/PD-L1 inhibitor.</li> <li>Patients who permanently discontinued PD-1 or PD-L1 inhibitor therapy for toxicity reasons are eligible at the time of disease progression.</li> </ul>
<b>Entrectinib</b> Rozlytrek®	Oral (capsule) 100mg, 200mg	Pharmacare <b>MQWN</b>	<p><b><u>Non-small cell lung cancer</u></b> 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).</p> <p><b><u>Clinical Notes:</u></b></p> <ul style="list-style-type: none"> <li>Patients should have a good performance status.</li> <li>Treatment should continue until disease progression or unacceptable toxicity.</li> </ul> <p><b><u>Unresectable Locally Advanced or Metastatic Extracranial Solid Tumors with a NTRK Gene Fusion</u></b></p> <ul style="list-style-type: none"> <li>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.</li> </ul> <p><b><u>Clinical Notes:</u></b></p> <ul style="list-style-type: none"> <li>Patients should have a good performance status.</li> <li>Treatment should be discontinued upon disease progression or unacceptable toxicity.</li> <li>CNS metastases are stable if present.</li> <li>Patients with prior progression on an NTRK inhibitor are not eligible.</li> </ul> <p><b>Prescriptions written by PEI oncologists do not require Special Authorization. Patients must apply for coverage by the High-Cost Drug Program.</b></p>

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<b>Enzalutamide</b> Xtandi®	Oral (capsule) 40 mg	Pharmacare <b>MQWN</b>	<p><b><u>Prostate – Metastatic (castration-resistant)</u></b></p> <p>For treatment of patients with metastatic castration resistant prostate cancer, who:</p> <ul style="list-style-type: none"> <li>Are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy with an ECOG performance status <math>\leq 1</math> and have not received prior chemotherapy and would be an alternative to abiraterone for patients and not sequential therapy in this asymptomatic or mildly symptomatic patient population.</li> </ul> <p><b>OR</b></p> <ul style="list-style-type: none"> <li>Have progressed on docetaxel-based chemotherapy with an ECOG performance status <math>\leq 2</math> and no risk factors for seizures and would be an alternative to abiraterone for patients and not sequential therapy in this symptomatic post docetaxel chemotherapy setting.</li> </ul> <p><b><u>Note:</u></b></p> <ul style="list-style-type: none"> <li>Enzalutamide will not be reimbursed in combination with abiraterone</li> <li>Use of enzalutamide in the post docetaxel setting is not permitted if previously used in the prechemotherapy setting</li> </ul> <p><b><u>METASTATIC CASTRATION-SENSITIVE PROSTATE CANCER (mCSPC)</u></b></p> <ul style="list-style-type: none"> <li>In combination with 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.</li> </ul> <p><b><u>Clinical Notes:</u></b></p> <ul style="list-style-type: none"> <li>Patients should have a good performance status and no risk factors for seizures.</li> <li>Treatment should continue until unacceptable toxicity or disease progression.</li> </ul> <p><b><u>NON-METASTATIC CASTRATION-RESISTANT PROSTATE CANCER (nmCRPC)</u></b></p> <ul style="list-style-type: none"> <li>In combination with androgen deprivation therapy (ADT) for the treatment of patients with non-metastatic castration-resistant prostate cancer (nmCRPC) who are at high risk of developing metastases<sup>1</sup>.</li> <li>Patients should have a good performance status and no risk factors for seizures. Treatment should continue until unacceptable toxicity or radiographic disease progression.</li> </ul> <p><b><u>Clinical Notes:</u></b></p> <ul style="list-style-type: none"> <li>Castration-resistance must be demonstrated during continuous ADT and is defined as 3 PSA rises at least one week apart, with the last PSA <math>&gt; 2</math> ng/mL.</li> <li>Castrate levels of testosterone must be maintained.</li> <li>Patients with N1 disease, pelvic lymph nodes <math>&lt; 2</math> cm in short axis located below the common iliac vessels are eligible for enzalutamide.</li> <li>Enzalutamide will not be funded for patients who experience disease progression on apalutamide.</li> <li>Patients receiving enzalutamide for the treatment of non-metastatic CRPC will be eligible for funding of abiraterone at the time of disease progression to metastatic CRPC.</li> </ul> <p><sup>1</sup>High risk of developing metastases is defined as a prostate-specific antigen (PSA) doubling time of <math>\leq 10</math> months during continuous ADT</p> <p><b>Patients must apply for coverage under High-Cost Drug Program. If written by an oncologist, this medication does not require the submission of a Pharmacare Special Authorization form.</b></p>

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<b>Epcoritamab</b> Epkinly®	Injection (vial) 5mg/mL 60mg/mL	CTC Formulary	<p><b><u>Relapsed or Refractory Large B-Cell Lymphoma</u></b> For the treatment of adults with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified, DLBCL transformed from indolent lymphoma, high[1]grade B-cell lymphoma, primary mediastinal B-cell lymphoma, or follicular lymphoma grade 3B who have:</p> <ul style="list-style-type: none"> <li>Received 2 or more lines of systemic therapy; and</li> <li>Received or are ineligible to receive chimeric antigen receptor (CAR) T-cell therapy.</li> </ul> <p><b><u>Clinical Notes:</u></b></p> <ul style="list-style-type: none"> <li>Patients should have a good performance status.</li> <li>Treatment should continue until disease progression or unacceptable toxicity.</li> <li>Patients with CNS lymphoma or CNS involvement are not eligible.</li> <li>Patients who decline or cannot receive CAR T-cell therapy will be eligible for epcoritamab.</li> <li>Sequential usage of epcoritamab and glofitamab is not permitted.</li> </ul>
<b>Epirubicin</b>	Injection (vial) 50 mg/25 mL	CTC Formulary	Open benefit
<b>Eribulin</b> Halaven®	Injection (vial) 1 mg/2 mL	CTC Formulary	<p><b><u>Breast Cancer – metastatic</u></b></p> <ul style="list-style-type: none"> <li>For the treatment of metastatic or incurable locally advanced breast cancer in patients with an ECOG performance status of 0 to 2, who have had previous treatment with a taxane and an anthracycline in either the adjuvant or advanced setting, who have had at least two prior chemotherapy regimens for metastatic or locally advanced disease and who have progressed following their last therapy.</li> </ul>
<b>Erlotinib</b> Tarceva®, generics	Oral (tablet) 25 mg, 100 mg, 150 mg	Pharmacare <b>FGMNQSW</b>	<p><b><u>Non-small cell lung cancer (NSCLC)</u></b></p> <ul style="list-style-type: none"> <li>For use as monotherapy for the treatment of patients with locally advanced or metastatic NSCLC after failure of at least one prior chemotherapy regimen and whose EGFR expression status is positive of unknown.</li> </ul> <p><b>Patients must apply for coverage under the High-Cost Drug Program.</b> <b>If written by an oncologist, this medication does <u>not</u> require the submission of a Pharmacare Special Authorization form.</b></p>
<b>Etoposide</b> VP- 16, Vepesid®	Oral (capsule) 50 mg	Pharmacare <b>MQWN</b>	<p>Open benefit</p> <p><b>Clients accessing this medication through the High Cost and/or Catastrophic Drug Program are required to enroll in the applicable program(s). Applications may be found in the online formulary.</b></p>
<b>Etoposide</b> VP- 16, Vepesid®	Injection (vial) 100 mg/ 5 mL	CTC Formulary	Open benefit

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<b>Everolimus</b> Generics	Oral (tablet) 2.5mg, 5mg, 10mg	Pharmacare <b>MQWN</b>	<p><b><u>Metastatic Renal Cell Carcinoma (RCC)</u></b> For the treatment of patients with advanced or metastatic renal cell carcinoma following disease progression on tyrosine kinase inhibitor therapy. <b>Clinical Notes:</b></p> <ul style="list-style-type: none"> <li>• Patients must have a good performance status.</li> <li>• Treatment should be discontinued upon disease progression or unacceptable toxicity.</li> <li>• Requests for everolimus will not be considered for patients who experience disease progression on axitinib, cabozantinib or nivolumab monotherapy.</li> </ul> <p><b>Claim Notes:</b></p> <ul style="list-style-type: none"> <li>• Initial approval period: 6 months</li> <li>• Renewal approval period: 1 year</li> </ul> <p><b><u>Hormone Receptor Positive, HER2 Negative-Advanced Breast Cancer</u></b> 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). <b>Clinical Notes:</b></p> <ul style="list-style-type: none"> <li>• Patients must have a good performance status.</li> <li>• Treatment should be discontinued upon disease progression or unacceptable toxicity.</li> </ul> <p><b>Claim Notes:</b></p> <ul style="list-style-type: none"> <li>• Requests for everolimus will not be considered for patients who experience disease progression on CDK4/6 inhibitor therapy.</li> <li>• Approval period: 1 year</li> </ul> <p><b><u>Metastatic Pancreatic Neuroendocrine Tumors (pNET)</u></b> 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. <b>Claim Notes:</b></p> <ul style="list-style-type: none"> <li>• Patients whose disease progresses on sunitinib are not eligible for funded treatment with everolimus for pNET</li> <li>• Approval period: 1 year</li> </ul> <p><b><u>Neuroendocrine Tumors of Gastrointestinal or Lung Origin</u></b> As a single agent treatment for patients with unresectable, locally advanced or metastatic; well-differentiated nonfunctional 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.</p> <ul style="list-style-type: none"> <li>• Treatment should continue until confirmed disease progression or unacceptable toxicity.</li> </ul> <p><b>Claim Notes:</b></p> <ul style="list-style-type: none"> <li>• Approval period: 1 year.</li> </ul> <p><b>Prescriptions written by PEI oncologists do not require written Special Authorization. Patients must apply for coverage by the High Cost Drug Program.</b></p>

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<b>Exemestane</b> Aromasin®, generics	Oral (tablet) 25 mg	Pharmacare <b>FGNQSW</b>	Open benefit
<b>Fedratinib</b> Inrebic®	Oral (capsule) 100 mg	Pharmacare <b>MQWN</b>	<p>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.</p> <p><b>Clinical Notes:</b></p> <ul style="list-style-type: none"> <li>Patients should have a good performance status.</li> <li>Treatment should be discontinued upon disease progression or unacceptable toxicity.</li> </ul> <p><b>Patients must apply for coverage under the High-Cost Drug Program.</b> <b>If written by an oncologist, this medication does <u>not</u> require the submission of a Pharmacare Special Authorization form.</b></p>
<b>Filgrastim</b> Grastofil®, Nivestym®, Neupogen®, Nypozi®	<p>Grastofil®: injection (pre-filled syringe) 300 mcg/0.5 mL 480 mcg/0.8 mL</p> <p>Nivestym® injection (pre-filled syringe and vial): 300 mcg/0.5 mL (PFS) 480 mcg/0.8 mL (PFS) 300 mcg/1 mL (vial) 480 mcg/1.6 mL (vial)</p> <p>Neupogen®: injection (vial) 300 mcg/mL</p> <p>Nypozi®: injection (pre-filled syringe) 300 mcg/0.5 mL 480 mcg/0.8 mL</p>	Pharmacare <b>MQWN</b>	<p><b>Chemotherapy support</b> For the prevention of febrile neutropenia in patients receiving myelosuppressive chemotherapy with curative intent who:</p> <ul style="list-style-type: none"> <li>are at high risk of febrile neutropenia due to chemotherapy regimen, co-morbidities or preexisting severe neutropenia; or</li> <li>have had an episode of febrile neutropenia, neutropenic sepsis or profound neutropenia in a previous cycle of chemotherapy; or</li> <li>have had a dose reduction, or treatment delay greater than one week due to neutropenia.</li> </ul> <p><b>Clinical Note:</b></p> <ul style="list-style-type: none"> <li>Patients with non-curative cancer receiving chemotherapy with palliative intent are not eligible for coverage of filgrastim for prevention of febrile neutropenia.</li> </ul> <p><b>High Dose Chemotherapy with Stem Cell Support</b></p> <ul style="list-style-type: none"> <li>For use in mobilizing stem cells in preparation for stem cell collection.</li> </ul> <p>Must be requested and prescribed by a specialist in hematology or medical oncology.</p> <p><b>Claim Notes:</b> All requests for coverage of filgrastim will be approved for the biosimilar version only</p> <p><b>Note: Special Authorization for Neupogen will be considered for patients who have used all biosimilar filgrastim products and have had documented serious intolerance or allergic reactions.</b></p> <p><b>Patients must apply for coverage under the High-Cost Drug Program.</b> <b>If written by an oncologist, this medication does <u>not</u> require the submission of a Pharmacare Special Authorization form.</b></p>

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<b>Fludarabine</b>	Injection (vial) 50 mg	CTC Formulary	Open benefit
<b>Fludarabine</b> Fludara®	Oral (tablet) 10 mg	Pharmacare <b>MQWN</b>	<p><b><u>Chronic Lymphocytic Leukemia (CLL)</u></b></p> <ul style="list-style-type: none"> <li>For the treatment of CLL in patients with an ECOG performance status of 0 to 2 when the patient has failed to respond to, or relapsed during/after previous therapy with an alkylating agent and intravenous administration is not desirable.</li> </ul> <p><b>Patients must apply for coverage under the High-Cost Drug Program.</b>  <b>If written by an oncologist, this medication does <u>not</u> require the submission of a Pharmacare Special Authorization form.</b></p>
<b>Fludrocortisone Acetate</b> Florinef®	Oral (tablet) 0.1 mg	Pharmacare <b>FNQSW</b>	Open benefit
<b>Fluorouracil</b> 5-FU	Injection (vial) 5 g/100 mL	CTC Formulary	Open benefit
<b>Flutamide</b> generics	Oral (tablet) 250 mg	Pharmacare <b>FGNQSW</b>	Open benefit
<b>Fosaprepitant</b> Emend IV® (also see aprepitant)	Injection (vial) 150 mg	CTC Formulary	If unable to swallow aprepitant tablet
<b>Fulvestrant</b> generics	Injection (syringe) 250 mg/5 mL	Pharmacare <b>FGNQSW</b>	<p><b><u>Breast Cancer - metastatic</u></b></p> <ul style="list-style-type: none"> <li>For the treatment of postmenopausal women with non-visceral locally advanced or metastatic estrogen receptor positive, HER2 negative breast cancer, who have not been previously treated with endocrine therapy. <b>OR</b></li> <li>In combination with a CDK4/6 inhibitor (see ribociclib and palbociclib criteria).</li> </ul>
<b>Gemcitabine</b> Gemzar®	Injection (vial) 1g	CTC Formulary	Open benefit

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<b>Gemtuzumab ozogamicin</b> Mylotarg®	Injection (vial) 4.5 mg	CTC Formulary	<p><b><u>Acute Myeloid Leukemia (AML)</u></b></p> <ul style="list-style-type: none"> <li>In combination with daunorubicin and cytarabine for the treatment of adult patients with previously untreated, de novo CD33-positive acute myeloid leukemia (AML), except acute promyelocytic leukemia (APL).</li> <li>Eligible patients include adults with previously untreated, de novo CD33-positive AML, except APL, who have good performance status and favourable, intermediate, or unknown* cytogenetics (using the European LeukemiaNet [ELN] 2017 risk classification). Should a patient's unknown cytogenetic status become known as adverse, then gemtuzumab ozogamicin is discontinued.</li> <li>In combination with daunorubicin (or idarubicin) and cytarabine should consist of one induction cycle; if a second induction cycle is required, gemtuzumab ozogamicin should not be administered during the second induction cycle. For patients with complete remission following induction, gemtuzumab ozogamicin in combination with standard cytarabine consolidation or cytarabine and daunorubicin (or idarubicin) consolidation for up to two cycles is permitted.</li> </ul> <p>*Unknown cytogenetics because the test was unsuccessful or because cytogenetic results are not yet available</p>
<b>Gilteritinib</b> Xospata®	Oral (tablet) 40mg	Pharmacare <b>MQWN</b>	<p><b><u>Acute Myeloid Leukemia</u></b></p> <p>As monotherapy for the treatment of adult patients with relapsed or refractory FMS-like tyrosine kinase 3 (FLT3)-mutated acute myeloid leukemia who meet all of the following criteria:</p> <ul style="list-style-type: none"> <li>Confirmed positive for FLT3 mutation at the time of relapse or determination of refractory disease</li> <li>Presence of FLT3-ITD, FLT3-TKD/D835 or FLT3-TKD/I836 mutation</li> </ul> <p><b><u>Renewal Criteria:</u></b></p> <ul style="list-style-type: none"> <li>Written confirmation that the patient is responding to treatment.</li> </ul> <p><b><u>Clinical Notes:</u></b></p> <ul style="list-style-type: none"> <li>Patients must have a good performance status.</li> <li>Treatment should continue as long as clinical benefit is observed or until unacceptable toxicity occurs.</li> </ul> <p><b>Patients must apply for coverage under the High-Cost Drug Program.</b> <b>If written by an oncologist, this medication does <u>not</u> require the submission of a Pharmacare Special Authorization form.</b></p>
<b>Goserelin acetate</b> Zoladex®	Injection (depot syringe) 3.6 mg, 10.8 mg	Pharmacare <b>FNQSW</b>	Open benefit
<b>Hydroxyurea</b> Hydrea®, generics	Oral (capsule) 500 mg	Pharmacare <b>FGNQSW</b>	Open benefit

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<b>Ibrutinib</b> Imbruvica®	Oral (capsule) 140 mg	Pharmacare <b>MQWN</b>	<p><b><u>Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) – 1st<sup>nd</sup> line</u></b></p> <ul style="list-style-type: none"> <li>For the treatment of 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( includes 17p deletion, TP3 mutation, 11q deletion and unmutated IGHV) based on prognostic biomarkers.</li> </ul> <p><b><u>Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) – 2<sup>nd</sup> line</u></b></p> <ul style="list-style-type: none"> <li>For patients with chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) who have received at least one prior therapy and are considered inappropriate for treatment or re-treatment with a fludarabine-based regimen.</li> </ul> <p><b><u>Mantle Cell Lymphoma (MCL)</u></b></p> <ul style="list-style-type: none"> <li>For the treatment of patients with relapsed/refractory mantle cell lymphoma (MCL)</li> </ul> <p><b><u>Clinical notes:</u></b></p> <ol style="list-style-type: none"> <li>Patients must have a good performance status.</li> <li>Treatment should be discontinued upon disease progression or unacceptable toxicity.</li> </ol> <p><b><u>Claim note:</u></b></p> <ul style="list-style-type: none"> <li>Ibrutinib will not be reimbursed when used in combination with rituximab.</li> </ul> <p><b>Patients must apply for coverage under the High-Cost Drug Program.</b>  <b>If written by an oncologist, this medication does <u>not</u> require the submission of a Pharmacare Special Authorization form.</b></p>
<b>Idarubicin</b>	Injection (vial) 5 mg/5 mL, 10 mg/10 mL	CTC Formulary	Treatment of acute myeloid leukemia (AML)
<b>Idelalisib</b> Zydelig®	Oral (tablet) 100 mg, 150 mg	Pharmacare <b>MQWN</b>	<p><b><u>Chronic Lymphocytic Leukemia (CLL)</u></b></p> <ul style="list-style-type: none"> <li>In combination with rituximab for the treatment of patients with relapsed chronic lymphocytic leukemia (CLL). Treatment should continue until unacceptable toxicity or disease progression.</li> </ul> <p><b>Prescriptions written by PEI oncologists do not require Special Authorization.</b>  <b>Patients must apply for coverage by the High-Cost Drug Program.</b></p>
<b>Ifosfamide</b>	Injection (vial) 1 g	CTC Formulary	Open benefit

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<b>Imatinib</b> Gleevec®, generics	Oral (tablet) 100 mg, 400 mg	Pharmacare <b>FGMNQSW</b>	<p><b><u>Chronic Myeloid Leukemia (CML)</u></b></p> <ul style="list-style-type: none"> <li>For the treatment of patients who have documented evidence of Philadelphia chromosome positive (Ph+) chronic myeloid leukemia (CML), with an ECOG performance status of 0 – 2</li> </ul> <p><b><u>Acute Lymphoblastic Leukemia (ALL)</u></b></p> <ul style="list-style-type: none"> <li>For the treatment of adult patients with newly diagnosed Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ALL) when used as a single agent for induction and maintenance phase therapy.</li> </ul> <p><b><u>Gastrointestinal Stromal Tumor (GIST)</u></b></p> <ul style="list-style-type: none"> <li>For the treatment of patients with C-Kit positive (CD117), metastatic or locally advanced, inoperable gastrointestinal stromal tumors (GIST) and who have an ECOG performance status of 0 - 2.</li> <li>For the adjuvant treatment of adult patients who are at intermediate to high risk of relapse following complete resection of Kit (CD117) positive GIST.</li> </ul> <p><b>Patients requesting coverage under the High-Cost Drug Program must apply to this program. If written by an oncologist, this medication does <u>not</u> require the submission of a Pharmacare Special Authorization form.</b></p>
<b>Imiquimod</b> Aldara®, generics	Topical 5% cream	Pharmacare <b>FGNQSW</b>	Open benefit
<b>Infliximab</b> Remicade®	Injection (vial) 100 mg	CTC Formulary	<p><b><u>Ipilimumab associated enterocolitis:</u></b> Approved for steroid resistant grade 3-4 ipilimumab associated enterocolitis. If no contraindications exist, steroids should have been trialed at a dose not less than 1-2 mg/kg PO per day.</p> <p><b><u>Note:</u></b> future use of ipilimumab is considered contraindicated if infliximab is required as a result of ipilimumab enterocolitis.</p>
<b>Inotuzumab ozogamicin</b> Besponsa®	Injection (vial) 0.9mg	CTC Formulary	<p><b><u>Acute Lymphoblastic Leukemia (ALL)</u></b></p> <ul style="list-style-type: none"> <li>As a single agent treatment option in adult patients with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL).</li> <li>Eligible patients include Philadelphia chromosome (Ph) -positive and (Ph)-negative relapsed or refractory B cell precursor ALL with a good performance status.</li> <li>For patients with (Ph)-positive ALL, failure with at least one second-generation or third-generation tyrosine kinase inhibitor (TKI) and standard multi-drug induction chemotherapy is required before treatment with inotuzumab ozogamicin.</li> <li>Treatment should be continued until unacceptable toxicity or disease progression, up to a maximum of three cycles, for those patients proceeding to hematopoietic stem cell transplant (HSCT).</li> <li>For patients not proceeding to HSCT who achieve a complete response or complete response with incomplete count recovery (CR/Cri) and minimal residual disease negativity, treatment may be continued for a maximum of six cycles.</li> </ul>

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Health PEI Formulary Drugs: Oncology

Drug	Dosage Form	Funding Program	Funded Eligibility Criteria
<b>Ipilimumab</b> Yervoy®  (cont'd on next page)	Injection (vial) 50 mg/10 mL, 200 mg/40 mL	CTC Formulary	<p><b><u>Melanoma – Advanced (unresectable or metastatic)</u></b></p> <ul style="list-style-type: none"> <li>First line treatment of adult patients with stage IIIC or IV melanoma, regardless of BRAF mutation status, who have an ECOG performance status of 0 or 1, and are not currently receiving immunosuppressive therapy                             <ul style="list-style-type: none"> <li>If brain metastases are present, patients should be asymptomatic or stable</li> <li>Ipilimumab induction is funded for four (4) doses at 3 mg/kg administered every 3 weeks</li> <li>Induction therapy is discontinued if 4 doses cannot be administered within 16 weeks</li> </ul> </li> <li>Treatment of patients who have received at least one prior systemic therapy for advanced melanoma (unresectable stage III or metastatic) with good performance status (ECOG 0 or 1).</li> <li>As combination use of ipilimumab plus nivolumab for the treatment of patients with unresectable or metastatic melanoma regardless of BRAF status who are treatment naïve, or may have received prior treatment with BRAF-targeted therapy, with an ECOG performance status of 0-1 and with stable brain metastases, if present. Treatment should continue until unacceptable toxicity or disease progression.</li> </ul> <p><b><u>Notes:</u></b></p> <ul style="list-style-type: none"> <li>Patients receiving anti-PD-1 monotherapy initiated without the combination of Ipilimumab who experience disease progression are eligible for Ipilimumab monotherapy as a subsequent line of therapy, but are not eligible to continue anti-PD-1 therapy with the addition of Ipilimumab</li> <li><b>See nivolumab listing for additional funding details</b></li> </ul> <p><b><u>Renal Cell Carcinoma - Metastatic (mRCC)</u></b></p> <ul style="list-style-type: none"> <li>Combination use of ipilimumab plus nivolumab in patients with intermediate or poor-risk advanced renal-cell carcinoma based on the International Metastatic Renal Cell Carcinoma Database Consortium (IMDC) criteria.</li> </ul> <p><b><u>Notes:</u></b></p> <ul style="list-style-type: none"> <li><b>See nivolumab listing for additional funding details</b></li> </ul>

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<b>Ipilimumab</b> Yervoy®	Injection (vial) 50 mg/10 mL, 200 mg/40 mL	CTC Formulary	<p><b><u>Metastatic or Recurrent Non-Small Cell Lung Cancer (NSCLC) – in combination with nivolumab</u></b></p> <ul style="list-style-type: none"> <li>Nivolumab plus ipilimumab (nivolumab/ipilimumab) and two cycles of platinum doublet chemotherapy (PDC), for the first-line treatment of adult patients with metastatic or recurrent non–small cell lung cancer (NSCLC) with no known epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumour aberrations, and who have good performance status <ul style="list-style-type: none"> <li>Treatment with nivolumab plus ipilimumab should continue until confirmed disease progression or unacceptable toxicity to a maximum of two years, whichever comes first</li> </ul> </li> </ul> <p><b><u>Notes:</u></b></p> <ul style="list-style-type: none"> <li>See nivolumab listing for additional funding details</li> </ul> <p><b><u>Malignant Pleural Mesothelioma (MPM) – in combination with nivolumab</u></b></p> <ul style="list-style-type: none"> <li>Nivolumab, in combination with ipilimumab, for the treatment of adult patients with unresectable malignant pleural mesothelioma (MPM) who have not received prior systemic therapy for malignant pleural mesothelioma, and who have good performance status <ul style="list-style-type: none"> <li>Treatment with nivolumab in combination with ipilimumab should continue until confirmed disease progression or unacceptable toxicity to a maximum of two years, whichever comes first</li> </ul> </li> </ul>
<b>Irinotecan</b> CPT-11	Injection (vial) 100 mg/5 mL, 500 mg/25 mL	CTC Formulary	Open benefit
<b>Isatuximab</b> Sarclisa®	Injection (vial) 100 mg/5 mL 500 mg/25 mL	CTC Formulary	<p><b><u>Multiple Myeloma (MM)</u></b></p> <ul style="list-style-type: none"> <li>In combination with pomalidomide and dexamethasone (IsaPd), for the treatment of adult patients with relapsed or refractory multiple myeloma (MM) who have received at least two prior therapies including lenalidomide and a proteasome inhibitor.</li> </ul> <p>OR</p> <ul style="list-style-type: none"> <li>In combination with carfilzomib and dexamethasone (IsaKd), for the treatment of adult patients with relapsed or refractory multiple myeloma (MM) who have received one to three prior lines of therapy.</li> </ul>

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## Health PEI Formulary Drugs: Oncology

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<b>Kadcyla®</b> Trastuzumab Emtansine (T-DM1) (Tradename used to minimize confusion with trastuzumab)	Injection (vial) 100 mg, 160 mg	CTC Formulary	<p><b><u>Early Breast Cancer:</u></b>  For the adjuvant treatment of patients with human epidermal growth factor receptor 2 (HER2) positive early breast cancer with residual disease, after pre-operative systemic treatment. Treatment should be continued for a maximum of 14 cycles (1 year of therapy) or until disease recurrence or unacceptable toxicity.</p> <p><b><u>Clinical Notes:</u></b></p> <ul style="list-style-type: none"> <li>• Patients with clinical tumor stage T1aN0 or T1bN0 at presentation are not eligible.</li> <li>• Patients that experience intolerance to Kadcyla may be switched to Trastuzumab to complete 1 year of HER2- targeted therapy.</li> <li>• Patients with residual disease who received pertuzumab in addition to trastuzumab + chemotherapy pre-operatively would be eligible for trastuzumab emtansine in the adjuvant setting. <b>Note:</b> Pertuzumab is not a funded in option for early breast cancer.</li> <li>• Patients who have a ≥ 6 month disease free interval following the completion of adjuvant Kadcyla therapy will be eligible for Pertuzumab + Trastuzumab + Taxane in the advanced or metastatic setting.</li> <li>• Patients who have a ≥ 6 month disease free interval following the completion of adjuvant Kadcyla therapy will be eligible for retreatment with Kadcyla in the advanced or metastatic setting.</li> </ul> <p><b><u>Breast Cancer – Metastatic</u></b></p> <ul style="list-style-type: none"> <li>• As a second line treatment for patients with HER-2 positive, unresectable locally advanced or metastatic breast cancer with an ECOG performance status of 0 or 1, who have either received prior treatment with trastuzumab plus chemotherapy in the metastatic setting or had disease recurring within 6 months of completing adjuvant therapy with trastuzumab plus chemotherapy.</li> <li>• <b>Note:</b> For current patients (on an interim basis only) who are receiving a second or later line of anti-HER2 therapy trastuzumab emtansine is approved at time of disease progression (ECOG PS 0-1). In future, once the current patient population has had this treatment option trastuzumab emtansine will be funded as second line therapy only.</li> </ul>
<b>Lanreotide</b> Somatuline Autogel®	Injection (prefilled syringe) 60 mg, 90 mg, 120 mg	Pharmacare <b>MQWN</b>	Open benefit  <b>Clients accessing this medication through the High Cost and/or Catastrophic Drug Program are required to enroll in the applicable program(s). Applications may be found in the online formulary.</b>

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Health PEI Formulary Drugs: Oncology

Drug	Dosage Form	Funding Program	Funded Eligibility Criteria
<b>Larotrectinib</b> Vitrakvi®	Oral (capsule) 25 mg, 100 mg Oral (liquid) 20 mg/mL	Pharmacare <b>MQWN</b>	<p><b><u>Unresectable Locally Advanced or Metastatic Solid Tumors</u></b></p> <p>As monotherapy for the treatment of adult and pediatric patients with unresectable locally advanced or metastatic solid tumors who meet all of the following criteria:</p> <ul style="list-style-type: none"> <li>• Tumors have a NTRK gene fusion without a known acquired resistance mutation</li> <li>• No other satisfactory treatment options</li> <li>• Not a candidate for surgery and/or radiation due to risk of substantial morbidity</li> </ul> <p><u>Clinical Notes:</u></p> <ul style="list-style-type: none"> <li>• Patients must have a good performance status.</li> <li>• If brain metastases are present, patients must be asymptomatic.</li> <li>• Treatment should be discontinued upon radiographic disease progression or unacceptable toxicity.</li> <li>• Patients with prior disease progression on a NTRK inhibitor are not eligible.</li> </ul> <p><b>Prescriptions written by PEI oncologists do not require Special Authorization.</b>  <b>Patients must apply for coverage by the High-Cost Drug Program.</b></p>

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<b>Lenalidomide</b> Revlimid® generics	Oral (capsule) 2.5mg, 5mg, 10mg, 15mg, 20mg, 25mg	Pharmacare <b>MQWN</b>	<p><b><u>Multiple Myeloma</u></b>  For the treatment of newly diagnosed Multiple Myeloma, in combination with daratumumab and dexamethasone, for patients who are not suitable for autologous stem cell transplant and have a good performance status.</p> <p>For the treatment of Multiple Myeloma when used in combination with dexamethasone, in patients who:</p> <ul style="list-style-type: none"> <li>Are <b>NOT</b> candidates for autologous stem cell transplant; <b>AND</b></li> <li>Where the patient is either: <ul style="list-style-type: none"> <li>Refractory to or has relapsed after the conclusion of initial or subsequent treatments and who is suitable for further chemotherapy; <b>OR</b></li> <li>Has completed at least one full treatment regimen therapy and is experiencing intolerance to their current chemotherapy.</li> </ul> </li> </ul> <p>For the <b><u>Maintenance Treatment</u></b> of patients with newly diagnosed multiple myeloma, following autologous stem-cell transplantation (ASCT), in patients who:</p> <ul style="list-style-type: none"> <li>are with stable disease or better, with no evidence of disease progression;</li> <li>treat until progression or development of unacceptable toxicity requiring discontinuation of lenalidomide;</li> <li>initial dose 10 mg lenalidomide PO daily, <b>AND</b></li> <li>dose adjustments (5-15 mg) may be necessary based on individual patient characteristics/responses.</li> </ul> <p><b><u>Myelodysplastic Syndrome (MDS)</u></b>  For the treatment of Myelodysplastic Syndrome (MDS) in patients with:</p> <ul style="list-style-type: none"> <li>Demonstrated diagnosis of MDS on bone marrow aspiration</li> <li>Presence of 5-q31 deletion documented by appropriate genetic testing</li> <li>International Prognostic Scoring System (IPSS) risk category low or intermediate (Calculator available on <a href="http://www.uptodate.com">www.uptodate.com</a> )</li> <li>Presence of symptomatic anemia (defined as transfusion dependent)</li> <li>Initial approval period – 6 months</li> <li><b>Renewal criteria:</b> <ul style="list-style-type: none"> <li>For patients who were transfusion-dependent and have demonstrated a reduction in transfusion requirements of at least 50%.</li> <li>Renewal period – 1 year</li> </ul> </li> </ul> <p><b><u>Clinical Note:</u></b> Due to its structural similarities to thalidomide, lenalidomide is only available through a controlled distribution program to minimize the risk of fetal exposure. Only prescribers and pharmacists registered with this program are able to prescribe and dispense lenalidomide. In addition, patients must be registered and meet all the conditions of the program in order to receive the product.</p> <p><b>Patients must apply for coverage under the High-Cost Drug Program.</b>  <b>If written by an oncologist, this medication does <u>not</u> require the submission of a Pharmacare Special Authorization form.</b></p>

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Health PEI Formulary Drugs: Oncology

Drug	Dosage Form	Funding Program	Funded Eligibility Criteria
<b>Lenvatinib</b> Lenvima®  (cont'd on next page)	Oral (capsule) 4 mg, 8 mg, 10mg, 12 mg, 14mg, 20mg, 24mg	Pharmacare <b>MQWN</b>	<p><b><u>Advanced Endometrial Carcinoma</u></b></p> <ul style="list-style-type: none"> <li>Lenvatinib combined 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, and are not candidates for curative surgery or radiation.</li> </ul> <p><b><u>Advanced and Metastatic Renal Cell Carcinoma</u></b></p> <ul style="list-style-type: none"> <li>Lenvatinib combined with pembrolizumab for the treatment of adult patients with advanced (not amenable to curative surgery or radiation) or metastatic renal cell carcinoma (RCC) who have had no prior systemic therapy for metastatic disease.</li> </ul> <p><b><u>Hepatocellular Carcinoma</u></b></p> <p>For the first-line treatment of adult patients with unresectable or metastatic hepatocellular carcinoma who meet all the following criteria:</p> <ol style="list-style-type: none"> <li>Child-Pugh class status of A.</li> <li>ECOG performance status of 0 or 1.</li> <li>Less than 50% liver involvement and no invasion of the bile duct or main portal vein.</li> <li>No brain metastases or prior liver transplantation</li> </ol> <p><b><u>Clinical Notes:</u></b></p> <ul style="list-style-type: none"> <li>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.</li> <li>Patients with disease progression on lenvatinib are not eligible for reimbursement of sorafenib.</li> </ul> <p><b><u>Differentiated Thyroid Cancer (DTC)</u></b>  <b><u>(Lenvima 10mg,14mg,20mg AND 24mg Compliance Pack)</u></b></p> <p>For the treatment of patients with locally recurrent or metastatic, progressive, differentiated thyroid cancer (DTC) who meet the following criteria:</p> <ol style="list-style-type: none"> <li>Pathologically confirmed papillary or follicular thyroid cancer, and</li> <li>Disease that is refractory or resistant to radioactive iodine therapy, and</li> <li>Radiological evidence of disease progression within the previous 13 months, and</li> <li>Previous treatment with no more than one tyrosine kinase inhibitor (TKI).</li> </ol> <p><b><u>Clinical Notes:</u></b></p> <ul style="list-style-type: none"> <li>Patients must have a good performance status.</li> <li>Treatment should be discontinued upon disease progression or unacceptable toxicity.</li> </ul>

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## Health PEI Formulary Drugs: Oncology

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<b>Lenvatinib</b> Lenvima®	Oral (capsule) 4 mg, 8 mg, 10mg, 12 mg, 14mg, 20mg, 24mg	Pharmacare <b>MQWN</b>	<p><b>Advanced Hepatocellular Carcinoma</b></p> <p>For the treatment of unresectable hepatocellular carcinoma (HCC), as first-line or second-line therapy after progression on immunotherapy (atezolizumab in combination with bevacizumab), for patients who meet all of the following criteria:</p> <ol style="list-style-type: none"> <li>1. Child-Pugh class status of A.</li> <li>2. ECOG performance status of 0 or 1.</li> <li>3. Less than 50% liver involvement and no invasion of the bile duct or main portal vein.</li> <li>4. No brain metastases or prior liver transplantation.</li> </ol> <p><u>Clinical Notes:</u></p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• Patients with disease progression on lenvatinib are not eligible for reimbursement of sorafenib.</li> </ul> <p><b>Patients must apply for coverage under the High-Cost Drug Program.</b> <b>If written by an oncologist, this medication does <u>not</u> require the submission of a Pharmacare Special Authorization form.</b></p>
<b>Letrozole</b> Femera®, generics	Oral (tablet) 2.5 mg	Pharmacare <b>FGNQSW</b>	Open benefit
<b>Leucovorin calcium</b> Folinic acid	Injection (vial) 500 mg/50 mL	CTC Formulary	Open benefit
<b>Leuprolide acetate</b> Lupron Depot® Eligard® Zeulide Depot®	Injection (depot syringe) <b>3.75 mg</b> (Lupron Depot, Zeulide Depot) <b>7.5 mg</b> (Lupron Depot, Zeulide Depot) <b>11.25 mg</b> (Lupron Depot) <b>22.5 mg</b> (Lupron Depot, Eligard, Zeulide Depot) <b>30 mg</b> (Lupron Depot) <b>45 mg</b> (Eligard)	Pharmacare <b>FNQSW</b>	Open benefit
<b>Lomustine</b> CCNU, CeeNU®	Oral (capsule) 10 mg, 40 mg, 100 mg	CTC Formulary	Dispensed through CTC (CTC/PCH) pharmacy

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Health PEI Formulary Drugs: Oncology

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<b>Lorlatinib</b> Lorbrena®	Oral (tablet) 25mg, 100mg	Pharmacare <b>MQWN</b>	<p><b><u>ALK-Positive Locally Advanced or Metastatic Non-Small Cell Lung Cancer</u></b> 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.</p> <p><u>Clinical Note:</u></p> <ul style="list-style-type: none"> <li>Treatment should be discontinued upon clinically meaningful disease progression or unacceptable toxicity.</li> </ul> <p><u>Claim Notes:</u></p> <ul style="list-style-type: none"> <li>Approval period: 1 year.</li> <li>No further ALK inhibitor will be reimbursed following disease progression on lorlatinib.</li> </ul> <p><b>Prescriptions written by PEI oncologists do not require Special Authorization. Patients must apply for coverage by the High-Cost Drug Program.</b></p>
<b>Low Molecular Weight Heparins (LMWH)</b> Dalteparin (Fragmin®) Enoxaparin (Lovenox®, biosimilars) Tinzaparin (Innohep®)	Injection (prefilled syringe) (various strengths) See Health PEI Drug Formulary	Pharmacare <b>FNQSW</b>	<p>Approved for the following indications:</p> <ul style="list-style-type: none"> <li>For the acute treatment of deep vein thrombosis (DVT) and/or pulmonary embolism (PE) for a maximum of 30 days.</li> <li>For prophylaxis in hip replacement and hip fracture surgery, approval is limited to a maximum of 35 days</li> <li>For prophylaxis in knee replacement surgery, approval is limited to a maximum of 10 days.</li> <li>For prophylaxis in high risk surgery, approval is limited to maximum of 10 days.</li> <li>For the extended treatment of recurrent symptomatic venous thromboembolism (VTE) that has occurred while on therapeutic doses of warfarin.</li> <li>For the treatment and secondary prevention of symptomatic venous thromboembolism (VTE) or pulmonary embolism (PE) for a period of up to 6 months in patients with cancer.</li> </ul> <p><b>Enoxaparin biosimilar products are open benefit.</b></p> <p><b>For nursing home program, no special authorization is required.</b></p> <p><b>If written by an orthopedic surgeon, oncologist, or internist this medication does <u>not</u> require the submission of a Pharmacare Special Authorization form.</b></p>
<b>Mechlorethamine</b> Nitrogen Mustard, Mustargen®	Injection (vial) 10 mg	CTC Formulary	Open benefit
<b>Medroxyprogesterone</b> Provera®, generics	Oral (tablet) 5 mg, 10 mg, 100 mg	Pharmacare <b>FGNQSW</b>	Open benefit

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<b>Megestrol acetate</b> generics	Oral (tablet) 40 mg, 160 mg	Pharmacare <b>AFGNQSW</b>	Open benefit
<b>Melphalan</b> Alkeran®	Injection (vial) 50 mg	CTC Formulary	Open benefit
<b>Melphalan</b> Alkeran®	Oral (tablet) 2 mg	Pharmacare <b>FNQSW</b>	Open benefit
<b>Mercaptopurine</b> 6-MP, Purinethol®, generics	Oral (tablet) 50 mg	Pharmacare <b>FGNQSW</b>	Open benefit
<b>Mesna</b> Uromitexan®	Injection (vial) 1 g/10 mL	CTC Formulary	As a uro-protector with and following ifosfamide or high dose cyclophosphamide
<b>Methotrexate</b>	Injection (vial) 50 mg/2 mL, 500 mg/20 mL	CTC Formulary	Open benefit
<b>Methotrexate</b>	Oral (tablet) 2.5 mg	Pharmacare <b>FGNQSW</b>	Open benefit
<b>Midostaurin</b> Rydapt®	Oral (tablet) 25 mg	Pharmacare <b>MQWN</b>	<p><b><u>Acute Myeloid Leukemia</u></b></p> <ul style="list-style-type: none"> <li>For the treatment of adult patients with newly diagnosed FMS-like tyrosine kinase 3 (FLT3)-mutated acute myeloid leukemia (AML) when used in combination with standard cytarabine and daunorubicin (7+3) induction and cytarabine consolidation chemotherapy.</li> </ul> <p><b><u>Claim Notes:</u></b></p> <ul style="list-style-type: none"> <li>Requests for midostaurin will not be considered when used as maintenance therapy, or as part of re-induction and/or re-consolidation.</li> <li>Requests for midostaurin in combination with idarubicin containing 7+3 induction and cytarabine consolidation chemotherapy will be considered.</li> <li>Approval period: Up to 6 cycles (maximum of 2 cycles of induction and 4 cycles of consolidation).</li> </ul> <p><b>Patients must apply for coverage under the High-Cost Drug Program.</b>  <b>If written by an oncologist, this medication does <u>not</u> require the submission of a Pharmacare Special Authorization form.</b></p>
<b>Mitomycin</b> Mitomycin C	Intravesical or Injection (vial) 20 mg	CTC Formulary	Open benefit
<b>Mitoxantrone</b>	Injection (vial) 20 mg/10 mL	CTC Formulary	Open benefit

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<b>Mogamulizumab</b> Poteligeo®	Injection (vial) 20 mg/5 mL	CTC Formulary	<p>For the treatment of adult patients with relapsed or refractory histologically confirmed mycosis fungoides or Sézary syndrome of stage IB-IV who have failed at least one prior systemic therapy.</p> <p>Patients must have a good performance status and no uncontrolled central nervous system metastases.</p> <p>Treatment should continue until disease progression or unacceptable toxicity.</p>
<b>Nabilone</b> Cesamet®	Oral (capsule) 0.5 mg, 1 mg	Pharmacare <b>FNQSW</b>	<p>a) For the treatment of severe nausea and vomiting associated with cancer chemotherapy in patients who have not been well controlled by standard stepwise antiemetic therapy.</p> <p>b) For the treatment of acquired immune deficiency syndrome (AIDS)-related anorexia associated with weight loss.</p> <p><b>Requires submission of a Pharmacare Special Authorization form.</b></p>
<b>Netupitant/palonosetron</b> Akynzeo®	Oral (capsule) 300 mg/0.5 mg	Pharmacare <b>FNQSW</b>	<p>In combination with dexamethasone for the prevention of acute and delayed nausea and vomiting in patients receiving:</p> <ul style="list-style-type: none"> <li>highly emetogenic chemotherapy or</li> <li>moderately emetogenic chemotherapy who have had inadequate symptom control using a 5-HT3 antagonist and dexamethasone in a previous cycle.</li> </ul> <p><b>Clinical notes:</b></p> <ul style="list-style-type: none"> <li>Highly emetogenic chemotherapy (HEC) includes but is not limited to: cisplatin regimens, anthracycline and cyclophosphamide combination regimens, and regimens containing carmustine, mechlorethamine, streptozocin, dacarbazine and cyclophosphamide &gt; 1500mg/m<sup>2</sup></li> <li>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</li> </ul> <p><b>If written by an oncologist, this medication does <u>not</u> require the submission of a Pharmacare Special Authorization form.</b></p>

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Health PEI Formulary Drugs: Oncology

Drug	Dosage Form	Funding Program	Funded Eligibility Criteria
<b>Nilotinib</b> Tasigna®	Oral (capsule) 200 mg	Pharmacare <b>MQWN</b>	<p><b><u>Chronic Myelogenous Leukemia</u></b> For the treatment of leukemia (CML, progressed or intolerant of imatinib)</p> <p>a) As a single second line agent for the treatment of adults with chronic or accelerated phase CML with resistance or intolerance to prior therapy. These second line criteria include:</p> <ul style="list-style-type: none"> <li>• Patients with CML in chronic phase who are intolerant to oral tyrosine kinase inhibitors (TKIs) (i.e. imatinib or dasatinib or both)</li> <li>• Patients with CML in chronic phase who are resistant to imatinib</li> <li>• Patients with CML that have progressed to accelerated phase while on imatinib therapy</li> </ul> <p>b) In any one patient, only two of the TKIs will be funded within these criteria during their lifetime.</p> <p>c) If a patient develops grade 3 or 4 toxicity to one of the TKIs used within 3 months of initiating therapy, access to a third agent will be funded.</p> <p>d) Sequential use of nilotinib and dasatinib is not permitted except in the circumstance described above (i.e. grade 3 or 4 toxicity).</p> <p><b>Patients must apply for coverage under the High-Cost Drug Program.</b> <b>If written by an oncologist, this medication does <u>not</u> require the submission of a Pharmacare Special Authorization form.</b></p>
<b>Nilutamide</b> Anandron®	Oral (tablet) 50 mg, 100 mg	Pharmacare <b>FNQSW</b>	In the treatment of metastatic prostatic carcinoma (Stage D2) in conjunction with surgical or chemical castration.

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<b>Niraparib</b> Zejula®	Oral (100mg) capsule, tablet	Pharmacare <b>MQWN</b>	<p>1. 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.</p> <p><b>Clinical Notes:</b></p> <ul style="list-style-type: none"> <li>• Patients should have a good performance status.</li> <li>• 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.</li> <li>• Patients who have stable brain metastases are eligible for treatment with niraparib.</li> <li>• 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.</li> <li>• Niraparib in combination with bevacizumab is not funded</li> </ul> <p>2. 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.</p> <p><b>Clinical Notes:</b></p> <ul style="list-style-type: none"> <li>• Platinum-sensitive disease is defined as disease progression occurring at least six months after completion of platinum-based chemotherapy.</li> <li>• Patients should have a good performance status.</li> <li>• Patients must have received at least 4 cycles of the most recent platinum-based chemotherapy before starting treatment with niraparib.</li> <li>• 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.</li> <li>• Patients who have stable brain metastases are eligible for treatment with niraparib.</li> <li>• 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.</li> </ul> <p><b>Patients must apply for coverage under the High-Cost Drug Program.</b>  <b>If written by an oncologist, this medication does <u>not</u> require the submission of a Pharmacare Special Authorization form.</b></p>

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Drug	Dosage Form	Funding Program	Funded Eligibility Criteria
<b>Nivolumab</b> Opdivo®  (cont'd on next page)	Injection (vial) 40 mg/4 mL, 100 mg/10 mL	CTC Formulary	<p><b><u>Esophageal or Gastroesophageal Junction</u></b></p> <ul style="list-style-type: none"> <li>For the adjuvant treatment of completely resected esophageal or gastroesophageal junction (GEJ) cancer in patients who have residual pathologic disease following prior neoadjuvant chemoradiotherapy (CRT)</li> <li>In combination with fluoropyrimidine- and platinum-containing chemotherapy for the first-line treatment of adult patients with human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic gastric adenocarcinoma (GAC), gastroesophageal junction adenocarcinoma (GEJAC) or esophageal adenocarcinoma (EAC)</li> </ul> <p><b><u>Squamous Cell Carcinoma of the head and neck</u></b></p> <ul style="list-style-type: none"> <li>As a single agent treatment option for patients with squamous cell cancer of the head and neck (SCCHN) who either have a recurrence within six months of potentially curative platinum-based therapy, or recurrence after receiving platinum-based therapy in a non-curative setting. Patients should have a good performance status. Treatment duration should continue until unacceptable toxicity or disease progression.</li> </ul> <p><b><u>Clinical notes:</u></b></p> <ul style="list-style-type: none"> <li>Patients who received pembrolizumab in the first line are not eligible for nivolumab</li> </ul> <p><b><u>Classical Hodgkin Lymphoma</u></b></p> <ul style="list-style-type: none"> <li>For the treatment of patients with classical Hodgkin lymphoma that has relapsed or progressed after autologous stem cell transplantation (ASCT) and brentuximab vedotin. Treatment should be discontinued upon disease progression or unacceptable toxicity.</li> </ul>

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Drug	Dosage Form	Funding Program	Funded Eligibility Criteria
<b>Nivolumab</b> Opdivo®  (cont'd on next page)	Injection (vial) 40 mg/4 mL, 100 mg/10 mL	CTC Formulary	<p><b><u>Melanoma – Adjuvant</u></b></p> <ul style="list-style-type: none"> <li>For the adjuvant treatment of adult patients with completely resected Stage IIIA (limited to lymph node metastases of <math>\geq 1</math> mm) to Stage IV melanoma (8<sup>th</sup> edition of the American Joint Committee on Cancer [AJCC] melanoma staging system). The disease must be completely resected including in-transit metastases; however, presence of regional lymph nodes with micrometastases after sentinel node biopsy alone is allowed.</li> </ul> <p><b><u>Clinical Notes:</u></b></p> <ul style="list-style-type: none"> <li>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.</li> <li>Patients with ocular melanoma are not eligible for adjuvant treatment with nivolumab.</li> <li>Patients who progress during adjuvant therapy with nivolumab or pembrolizumab, or within 6 months of completion of adjuvant therapy, ipilimumab monotherapy may be funded as a subsequent line of therapy in the metastatic setting.</li> <li>Patients will be eligible for all immunotherapy options in the advanced or metastatic setting (including combination nivolumab with ipilimumab) only if there has been a 6 month progression-free interval between completion of adjuvant immunotherapy and confirmation of disease progression.</li> </ul> <p><b><u>Melanoma – Advanced (Unresectable or Metastatic)</u></b></p> <ul style="list-style-type: none"> <li>As first line monotherapy for the treatment of unresectable or metastatic melanoma (regardless of BRAF status) in patients who are previously untreated, with good performance status and, who have stable brain metastases (if present).</li> </ul> <p><b><u>Notes:</u></b></p> <ul style="list-style-type: none"> <li>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.</li> <li>Eligible patients may receive nivolumab or pembrolizumab for this indication but not the sequential use of these agents.</li> </ul> <ul style="list-style-type: none"> <li>As combination use of nivolumab plus ipilimumab for the treatment of patients with unresectable or metastatic melanoma regardless of BRAF status who are treatment naïve, or may have received prior treatment with BRAF-targeted therapy, with an ECOG performance status of 0-1 and with stable brain metastases, if present. Treatment should continue until unacceptable toxicity or disease progression.</li> </ul> <p><b><u>Notes (cont'd on next page):</u></b></p> <ul style="list-style-type: none"> <li>Patients receiving Nivolumab monotherapy initiated as maintenance therapy following combination Ipilimumab and Nivolumab who experience disease progression are not eligible for Ipilimumab as a subsequent line of therapy</li> </ul>

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Drug	Dosage Form	Funding Program	Funded Eligibility Criteria
<b>Nivolumab</b> Opdivo®  (cont'd on next page)	Injection (vial) 40 mg/4 mL, 100 mg/10 mL	CTC Formulary	<p><b><u>Notes (cont'd):</u></b></p> <ul style="list-style-type: none"> <li>○ Patients receiving anti-PD-1 monotherapy initiated without the combination of Ipilimumab who experience disease progression are eligible for Ipilimumab monotherapy as a subsequent line of therapy, but are not eligible to continue anti-PD-1 therapy with the addition of Ipilimumab</li> <li>○ Patients who have completed or stopped anti-PD-1 monotherapy, initiated as either a single agent or maintenance after combination immunotherapy, without disease progression, are eligible to re-initiate antiPD-1 monotherapy at time of subsequent disease progression</li> <li>○ Combination dosing for melanoma is Nivolumab 1 mg/kg plus Ipilimumab 3 mg/kg every 3 weeks for up to 4 doses, followed by Nivolumab maintenance 3 mg/kg (up to a maximum of 240 mg) every 2 weeks or 6 mg/kg (up to a maximum of 480 mg) every 4 weeks</li> </ul> <p><b><u>Non-Small Cell Lung Cancer (NSCLC) – 2<sup>nd</sup> line and beyond</u></b></p> <ul style="list-style-type: none"> <li>• For the treatment of patients with advanced or metastatic non-small cell lung cancer (NSCLC) with disease progression on or after cytotoxic chemotherapy for advanced disease who have a good performance status.</li> </ul> <p><b><u>Notes:</u></b></p> <ul style="list-style-type: none"> <li>○ Patients cannot have received pembrolizumab in either first line or second line lung cancer setting.</li> <li>○ Patients will be eligible for Nivolumab in the advanced setting only if there has been at least a 6 month progression-free interval between completion of Durvalumab if used for stage III NSCLC and confirmation of disease progression</li> </ul> <p><b><u>Metastatic or Recurrent Non-Small Cell Lung Cancer (NSCLC) – in combination with ipilimumab</u></b></p> <ul style="list-style-type: none"> <li>• Nivolumab plus ipilimumab (nivolumab/ipilimumab) and two cycles of platinum doublet chemotherapy (PDC), for the first-line treatment of adult patients with metastatic or recurrent non–small cell lung cancer (NSCLC) with no known epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumour aberrations, and who have good performance status                         <ul style="list-style-type: none"> <li>○ Treatment with nivolumab plus ipilimumab should continue until confirmed disease progression or unacceptable toxicity to a maximum of two years, whichever comes first</li> </ul> </li> </ul> <p><b><u>Notes:</u></b></p> <ul style="list-style-type: none"> <li>○ Patients will be eligible for Nivolumab in the advanced setting only if there has been at least a 6 month progression-free interval between completion of Durvalumab if used for stage III NSCLC and confirmation of disease progression</li> </ul>

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<b>Nivolumab</b> Opdivo®  (cont'd on next page)	Injection (vial) 40 mg/4 mL, 100 mg/10 mL	CTC Formulary	<p><b><u>Malignant Pleural Mesothelioma (MPM) – in combination with ipilimumab</u></b></p> <ul style="list-style-type: none"> <li>Nivolumab, in combination with ipilimumab, for the treatment of adult patients with unresectable malignant pleural mesothelioma (MPM) who have not received prior systemic therapy for malignant pleural mesothelioma, and who have good performance status</li> <li>Treatment with nivolumab in combination with ipilimumab should continue until confirmed disease progression or unacceptable toxicity to a maximum of two years, whichever comes first</li> </ul> <p><b><u>Renal Cell Carcinoma - Metastatic (mRCC)</u></b></p> <ul style="list-style-type: none"> <li>As monotherapy for the treatment of patients with advanced or metastatic renal cell carcinoma with disease progression after at least one prior antiangiogenic systemic therapy and who have a good performance status.</li> <li>Combination use of nivolumab plus ipilimumab in patients with intermediate or poor-risk advanced renal-cell carcinoma based on the International Metastatic Renal Cell Carcinoma Database Consortium (IMDC) criteria.</li> </ul> <p><b><u>Notes:</u></b></p> <ul style="list-style-type: none"> <li>Eligible patients should be previously untreated in the metastatic setting and have a good performance status (KPS ≥ 70). Treatment should continue until disease progression or unacceptable toxicity</li> <li>Patients who have stopped Nivolumab maintenance therapy without disease progression (e.g., on a treatment break) are eligible to re-initiate Nivolumab monotherapy at time of subsequent disease progression (Note: repeat treatment with combination Nivolumab and Ipilimumab is not funded)</li> <li>Combination dosing for renal cell carcinoma is Nivolumab 3 mg/kg plus Ipilimumab 1 mg/kg every 3 weeks for up to 4 doses, followed by Nivolumab maintenance 3 mg/kg (up to a maximum of 240 mg) every 2 weeks or 6 mg/kg (up to a maximum of 480 mg) every 4 weeks</li> </ul> <p><b><u>Urothelial Carcinoma</u></b></p> <ul style="list-style-type: none"> <li>As monotherapy for the adjuvant treatment of adult patients with urothelial carcinoma (UC) who are at high risk of recurrence after undergoing radical resection of UC</li> <li>Nivolumab should be initiated within 120 days following completion of local therapy; evidence of no recurrence must be confirmed before initiating therapy.</li> <li>Treatment with nivolumab may continue for up to 1 year of adjuvant therapy, or until confirmed disease progression or unacceptable toxicity, whichever comes first.</li> </ul>

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<b>Nivolumab</b> Opdivo®	Injection (vial) 40 mg/4 mL, 100 mg/10 mL	CTC Formulary	<b><u>Non-Small Cell Lung Cancer (NSCLC)</u></b> <ul style="list-style-type: none"> <li>• Neoadjuvant treatment of adult patients with resectable non–small cell lung cancer (NSCLC) (tumors <math>\geq</math> 4 cm or node positive), in combination with platinum-doublet chemotherapy</li> <li>• Treatment with nivolumab in combination with platinum-doublet chemotherapy may continue for up to 3 cycles, until confirmed disease progression or unacceptable toxicity, whichever comes first</li> </ul>

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<b>Obinutuzumab</b> Gazyva®	Injection (vial) 100 mg/40 mL	CTC Formulary	<p><b><u>Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL)</u></b></p> <ul style="list-style-type: none"> <li>In combination with chlorambucil for patients with previously untreated chronic lymphocytic leukemia (CLL) or small lymphocytic leukemia (SLL) for whom fludarabine based treatment is considered inappropriate. Patients who have initiated single agent chlorambucil as first line therapy (fludarabine ineligible) within the 3 months prior to August 1, 2018 are eligible to receive obinutuzumab in combination with chlorambucil.</li> <li>Obinutuzumab in combination with chlorambucil may be considered as an option for CLL/SLL patients previously treated with single agent chlorambucil and have been disease free for 2 years or more and have not received prior CD20 antibody therapy and are considered fludarabine ineligible</li> <li>Obinutuzumab in combination with chlorambucil is not funded in patients who have received prior treatment with ibrutinib, idelalisib or venetoclax</li> </ul> <p><b><u>Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL)</u></b></p> <ul style="list-style-type: none"> <li>In combination with venetoclax for the treatment of adult patients with previously untreated chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) who are fludarabine ineligible.</li> </ul> <p>Clinical Notes:</p> <ul style="list-style-type: none"> <li>Fludarabine ineligibility is defined by either a cumulative illness rating scale (CIRS) score greater than 6 or a creatinine clearance (CrCl) less than 70 mL/min</li> <li>Treatment should be given for a total of 12 months (six 28-day cycles in combination with venetoclax, followed by six months of venetoclax as a single agent), or until disease progression or unacceptable toxicity, whichever occurs first.</li> <li>Retreatment with a venetoclax based regimen is funded if relapse is greater than 12 months from completion of venetoclax in combination with obinutuzumab.</li> <li>Either ibrutinib or acalabrutinib is funded as a subsequent treatment option, provided all other funding criteria are met.</li> </ul> <p><b><u>Follicular Lymphoma</u></b></p> <ul style="list-style-type: none"> <li>In adults with follicular lymphoma with disease that is refractory to a rituximab containing regimen as defined in the GADOLIN trial, and with good performance status.</li> <li>Patients with disease response to induction treatment with obinutuzumab plus chemotherapy (i.e. the initial 6 treatment cycles) or who have stable disease should continue to obinutuzumab maintenance.</li> <li>Obinutuzumab maintenance treatment should not be for patients who have progressive disease while on obinutuzumab induction treatment (i.e. obinutuzumab plus chemotherapy for 6 cycles).</li> <li>Maintenance treatment should continue until disease progression or for up to two years, whichever occurs first.</li> </ul>
<b>Octreotide</b> Sandostatin®, generic	Injection 200 mcg/mL (5 mL)	Pharmacare <b>FGNQSW</b>	Open benefit
<b>Octreotide</b> Sandostatin LAR®	Injection (PFS) 10mg,20mg,30mg	Pharmacare <b>MQWN</b>	Open benefit <b>Patients must apply for coverage by the High-Cost Drug Program.</b>

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## Health PEI Formulary Drugs: Oncology

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<b>Olaparib</b> Lynparza®  (cont'd on next page)	Oral (tablet) 100mg, 150mg	Pharmacare <b>MQWN</b>	<p>1. 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.</p> <p><b>Clinical Notes:</b></p> <ul style="list-style-type: none"> <li>• Patients should have a good performance status.</li> <li>• Maintenance therapy with olaparib should begin within 12 weeks of completion of platinum-based chemotherapy.</li> <li>• 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.</li> <li>• 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.<sup>1</sup></li> <li>• 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 restarting olaparib.</li> <li>• 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.</li> </ul> <p><sup>1</sup>Patients with a partial response or stable disease at 2 years may continue to receive olaparib at the discretion of the treating physician.</p> <p>2. 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.</p> <p><b>Clinical Notes:</b></p> <ul style="list-style-type: none"> <li>• Treatment should continue until unacceptable toxicity or disease progression.</li> <li>• Maintenance therapy with olaparib should begin within eight weeks of the last dose of platinum-based chemotherapy.</li> <li>• Platinum-sensitive disease is defined as disease progression occurring at least six months after completion of platinum-based chemotherapy.</li> <li>• Patients should have a good performance status.</li> <li>• 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.</li> </ul>

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Health PEI Formulary Drugs: Oncology

Drug	Dosage Form	Funding Program	Funded Eligibility Criteria
<b>Olaparib</b> Lynparza®  (cont'd on next page)	Oral (tablet) 100mg, 150mg	Pharmacare <b>MQWN</b>	<p>3. For the treatment of patients with metastatic castration-resistant prostate cancer (mCRPC) who meet all of the following criteria:</p> <ul style="list-style-type: none"> <li>• deleterious or suspected deleterious germline and/or somatic mutations in the homologous recombination repair (HRR) genes BRCA1, BRCA2 or ATM; and</li> <li>• Disease progression on prior treatment with androgen-receptor-axis-targeted (ARAT) therapy.</li> </ul> <p><b>Renewal Criteria:</b> Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.</p> <p><b>Clinical Notes:</b></p> <ul style="list-style-type: none"> <li>• Patients must have a good performance status.</li> <li>• Treatment should be discontinued upon disease progression or unacceptable toxicity.</li> </ul> <p><b>Breast Cancer</b></p> <ol style="list-style-type: none"> <li>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: <ul style="list-style-type: none"> <li>• Triple negative breast cancer and either axillary node-positive or axillary node-negative with invasive primary tumor pathological size of at least 2 cm (&gt; pT2 cm)</li> <li>• Hormone receptor positive, HER2-negative breast cancer with at least 4 pathologically confirmed positive lymph nodes</li> </ul> </li> <li>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: <ul style="list-style-type: none"> <li>• Triple negative breast cancer with residual invasive disease in the breast and/or resected lymph nodes (nonpCR)</li> <li>• 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</li> </ul> </li> </ol> <p><b>Clinical Notes:</b></p> <ol style="list-style-type: none"> <li>1. Patients must have completed neoadjuvant or adjuvant chemotherapy containing an anthracycline and/or taxane.</li> <li>2. Treatment should be initiated within 12 weeks of completion of the last treatment (i.e., surgery, chemotherapy, or radiation therapy).</li> <li>3. Patients must have a good performance status.</li> <li>4. Treatment should be discontinued upon disease recurrence, unacceptable toxicity, or completion of 1 year of therapy, whichever occurs first.</li> </ol>

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<b>Olaparib</b> Lynparza®	Oral (tablet) 100mg, 150mg	Pharmacare <b>MQWN</b>	<p><b>Claim Notes:</b></p> <ul style="list-style-type: none"> <li>Requests for patients determined to be at high-risk for relapse using a disease scoring system other than CPS + EG will be considered.</li> </ul> <p><b>Patients must apply for coverage under the High-Cost Drug Program.</b>  <b>If written by an oncologist, this medication does <u>not</u> require the submission of a Pharmacare Special Authorization form.</b></p>
<b>Ondansetron</b> Zofran®, generics	Oral (tablet) 4 mg, 8 mg  Oral (tablets, oral disintegrating) 4 mg, 8 mg	Pharmacare <b>FGNQSW</b>	<p>For the treatment of emesis in cancer patients receiving highly emetogenic chemotherapy (i.e. containing cisplatin); receiving moderately emetogenic chemotherapy (i.e. containing cyclophosphamide, doxorubicin, epirubicin, or melphalan); <b>OR</b> receiving radiation therapy and who have:</p> <ol style="list-style-type: none"> <li>Experienced adverse effects to metoclopramide, prochlorperazine, or dexamethasone or have a specific contraindication which does not allow use of these drugs as antiemetics <b>OR</b>,</li> <li>Continued episodes of nausea and vomiting related to chemotherapy which have not responded to therapeutic doses of metoclopramide, prochlorperazine, or dexamethasone.</li> </ol> <p><b>Note: a maximum of 10 tablets per cycle of chemotherapy will be approved.</b>  <b>Only requests for the oral dosage forms are eligible for consideration.</b></p> <p><b>If written by an oncologist, this medication does <u>not</u> require the submission of a Pharmacare Special Authorization form.</b></p>
<b>Ondansetron</b> Ondissolve®	Oral (medicated film) 4 mg, 8 mg	Pharmacare <b>FNQSW</b>	<p>For the treatment of emesis in cancer patients receiving highly emetogenic chemotherapy (i.e. containing cisplatin); receiving moderately emetogenic chemotherapy (i.e. containing cyclophosphamide, doxorubicin, epirubicin, or melphalan); <b>OR</b> receiving radiation therapy and who have:</p> <ol style="list-style-type: none"> <li>Experienced adverse effects to metoclopramide, prochlorperazine, or dexamethasone or have a specific contraindication which does not allow use of these drugs as antiemetics <b>OR</b>,</li> <li>Continued episodes of nausea and vomiting related to chemotherapy which have not responded to therapeutic doses of metoclopramide, prochlorperazine, or dexamethasone.</li> </ol> <p><b>Note: a maximum of 10 films per cycle of chemotherapy will be approved.</b></p> <p><b>If written by an oncologist, this medication does <u>not</u> require the submission of a Pharmacare Special Authorization form.</b></p>

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<b>Osimertinib</b> Tagrisso®	Oral (tablet) 40 mg, 80 mg	Pharmacare <b>MQWN</b>	<p><b><u>Adjuvant Non-Small Cell Lung Cancer</u></b></p> <p>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.</p> <p><u>Clinical Notes:</u></p> <ul style="list-style-type: none"> <li>• Patients should have a good performance status.</li> <li>• Treatment with osimertinib should continue for a total duration of 3 years, or until disease recurrence or unacceptable toxicity.</li> <li>• 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.</li> <li>• Retreatment with osimertinib in the metastatic setting will be considered if disease recurrence is at least 6 months following completion of adjuvant therapy.</li> </ul> <p><b><u>Advanced Non-Small Cell Lung Cancer</u></b></p> <ol style="list-style-type: none"> <li>1. 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 epidermal growth factor receptor (EGFR) mutations (exon 19 deletions [exon 19 del] or exon 21 [L858R]). Eligible patients should be previously untreated in the locally advanced or metastatic setting and have a good performance status.</li> <li>2. In 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.</li> </ol> <p><u>Clinical Notes:</u></p> <ol style="list-style-type: none"> <li>1. Treatment should be discontinued upon clinically meaningful disease progression or unacceptable toxicity.</li> <li>2. Prior treatment with EGFR TKI therapy is not required in patients with de novo T790M mutation-positive NSCLC.</li> </ol> <p><b>Patients must apply for coverage under the High-Cost Drug Program.</b>  <b>If written by an oncologist, this medication does <u>not</u> require the submission of a Pharmacare Special Authorization form.</b></p>
<b>Oxaliplatin</b> Eloxatin®	Injection (vial) 50 mg/10 mL	CTC Formulary	Open benefit

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Health PEI Formulary Drugs: Oncology

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<b>Paclitaxel</b>	Injection (vial) 100 mg/ 6.7mL, 300 mg/50 mL	CTC Formulary	<p><b><u>Breast Cancer- Adjuvant</u></b></p> <ul style="list-style-type: none"> <li>Treatment with the AC -&gt; Paclitaxel regimen</li> </ul> <p><b><u>Breast Cancer- Metastatic</u></b></p> <ul style="list-style-type: none"> <li>One line of therapy as a single agent or as part of combination chemotherapy in patients who are taxane naïve or have recurrent disease greater than 1 year after receiving a taxane in the adjuvant setting</li> </ul> <p><b><u>Gastro-Esophageal Cancer</u></b></p> <ul style="list-style-type: none"> <li>As part of neoadjuvant therapy</li> <li>Second line treatment for locally advanced, locally recurrent, or metastatic gastric or esophageal adenocarcinoma not curable with surgery or radiation</li> </ul> <p><b><u>Gynecology</u></b></p> <ul style="list-style-type: none"> <li>Treatment of epithelial ovarian, fallopian tube and primary peritoneal cancer</li> <li>Treatment of advanced or recurrent endometrial cancer</li> <li>Treatment of high risk early stage endometrial cancer</li> <li>Management of gynecologic small-cell cancer as part of a combined modality regimen</li> <li>Treatment of advanced or recurrent small cell or non-small cell cancer of the cervix</li> </ul> <p><b><u>Non-Small Cell Lung Cancer (NSCLC)</u></b></p> <ul style="list-style-type: none"> <li>First line treatment In combination with Carboplatin for advanced NSCLC</li> <li>Adjuvant treatment for resected Stage IB, II or III NSCLC in patients who are not candidates for cisplatin combination therapy</li> <li>As part of combined modality therapy in combination with RT for locally advanced NSCLC</li> </ul> <p><b><u>Unknown Primary</u></b></p> <ul style="list-style-type: none"> <li>First line treatment in combination with Carboplatin with or without Etoposide</li> </ul> <p><b><u>Urothelial Cancer – Advanced</u></b></p> <ul style="list-style-type: none"> <li>Second line treatment after progression on or after a platinum containing regimen</li> </ul>
<b><i>Paclitaxel – nanoparticle albumin-bound (nab)</i></b> <b>Abraxane®</b> (Tradename used to minimize confusion with doxorubicin)	Injection (vial) 100 mg	CTC Formulary	See Abraxane®

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<b>Palbociclib</b> Ibrance®	Oral (tablet) 75 mg, 100 mg, 125 mg	Pharmacare <b>MQWN</b>	<p><b><u>Breast Cancer – Metastatic</u></b></p> <ol style="list-style-type: none"> <li>In combination with an aromatase inhibitor for the treatment of estrogen receptor positive, HER2 negative advanced breast cancer in postmenopausal women who: <ul style="list-style-type: none"> <li>have not received prior therapy for metastatic disease and</li> <li>are not resistant to (neo)adjuvant non-steroidal aromatase inhibitor (NSAI) therapy and</li> <li>do not have active or uncontrolled metastases to the central nervous system.</li> </ul> </li> </ol> <p><b>Renewal Criteria:</b> Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.</p> <p><b><u>Clinical Notes:</u></b></p> <ul style="list-style-type: none"> <li>Patients must have a good performance status.</li> <li>Resistance is defined as disease progression occurring during or within 12 months following NSAI therapy</li> <li>Treatment should be discontinued upon disease progression or unacceptable toxicity.</li> </ul> <p><b><u>Claim Notes:</u></b></p> <ul style="list-style-type: none"> <li>Initial approval period: 1 year</li> <li>Renewal approval period: 1 year</li> </ul> <ol style="list-style-type: none"> <li>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 in the case of women can be of any menopausal status (Perimenopausal and premenopausal women must be treated with an LHRH agonist).</li> </ol> <p><b><u>Clinical Notes:</u></b></p> <ul style="list-style-type: none"> <li>Treatment should continue until unacceptable toxicity or disease progression.</li> <li>Patients who progress ≤ 12 months from (neo) adjuvant therapy are eligible for treatment with palbociclib plus fulvestrant.</li> <li>Patients who experience disease progression on prior CDK 4/6 inhibitor therapy, fulvestrant or everolimus are not eligible for treatment with palbociclib with fulvestrant.</li> <li>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.</li> <li>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.</li> </ul> <p><b>Patients must apply for coverage under the High-Cost Drug Program.</b>  <b>If written by an oncologist, this medication does <u>not</u> require the submission of a Pharmacare Special Authorization form.</b></p>
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## Health PEI Formulary Drugs: Oncology

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<b>Palonosetron</b>	Injection (vial) 0.25 mg/5 mL	CTC Formulary	For failure of first line anti-emetic therapies with treatment of moderately or highly emetogenic chemotherapy regimens in pediatric patients as per APPHON guidelines.
<b>Pamidronate</b> Aredia®	Injection (vial) 90 mg/10 mL	CTC Formulary (in CTC use only)	<p><b><u>Breast Cancer – Metastatic</u></b></p> <ul style="list-style-type: none"> <li>Use in patients with documented bone metastases in conjunction with standard care in order to prevent or delay potential complications from bone lesions</li> </ul> <p><b><u>Multiple Myeloma</u></b></p> <ul style="list-style-type: none"> <li>For a maximum duration of 24 months</li> </ul> <p><b><u>Supportive</u></b></p> <ul style="list-style-type: none"> <li>For acute management of hypercalcemia related to malignancy</li> </ul> <p><b>Note:</b> NOT approved for Prevention or treatment of osteopenia or osteoporosis</p>
<b>Panitumumab</b> Vectibix®	Injection (vial) 100 mg/5 mL 400 mg/20 mL	CTC Formulary	<p><b><u>Colorectal Cancer – Metastatic (1<sup>st</sup> line in combination with chemotherapy – bevacizumab contraindication or intolerance):</u></b></p> <ul style="list-style-type: none"> <li>In addition to combination chemotherapy for the treatment of patients with WT RAS mCRC in the first-line treatment setting who have a contraindication or intolerance to bevacizumab and who would otherwise be treated only with combination therapy. Patients should have a good performance status. Treatment should continue until unacceptable toxicity or disease progression.</li> </ul> <p><b><u>Clinical note:</u></b></p> <ul style="list-style-type: none"> <li>A contraindication or intolerance to bevacizumab may defined as: <ul style="list-style-type: none"> <li>High risk of bleeding or wound healing issues due to temporal proximity to surgery – recently received or planned for resectable/potentially resectable liver metastases</li> <li>A history of cardiovascular disease, or established class-specific side effects to bevacizumab such as hypertension, thromboembolic events, atrial fibrillation, as well as, proteinuria, risk of or presence of fistulae, risk of or current GI perforation, primary tumour in place, active bleeding, non-healing wound ulcer, recent trauma, etc.</li> </ul> </li> </ul> <p><b><u>Colorectal Cancer – Metastatic (single agent)</u></b></p> <ul style="list-style-type: none"> <li>As monotherapy for treatment of patients with non-mutated (wild type) RAS (KRAS or NRAS) after failure of at least 2 prior lines of therapy, including regimens containing a fluoropyrimidine, oxaliplatin and irinotecan</li> </ul> <p><b><u>Colorectal Cancer – Locally Advanced Unresectable or Metastatic, BRAF V600E Mutation-Positive</u></b></p> <ul style="list-style-type: none"> <li>In combination with encorafenib in patients who have been previously treated with systemic therapy.</li> </ul>

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<b>Pazopanib</b> Votrient®	Oral (tablet) 200 mg	Pharmacare <b>MQWN</b>	<p><b><u>Renal Cell Carcinoma – Metastatic</u></b></p> <ul style="list-style-type: none"> <li>As a first-line treatment for patients with advanced or metastatic clear cell renal carcinoma and good performance status.</li> <li>For the treatment of advanced or metastatic renal cell (clear cell) carcinoma (mRCC) in patients who are unable to tolerate sunitinib and who have an ECOG performance status of 0 or 1.</li> </ul> <p><b>Renewal criteria:</b> Written confirmation that the patient has benefited from therapy and is expected to continue to do so.</p> <p><b>Patients must apply for coverage under the High-Cost Drug Program.</b>  <b>If written by an oncologist, this medication does <u>not</u> require the submission of a Pharmacare Special Authorization form.</b></p>
<b>Pegfilgrastim</b> Fulphila® Lapelga® Nyvepria® Ziextenzo®	Injectable (pre-filled syringe) 6 mg/0.6 mL	Pharmacare <b>MQWN</b>	<p><b><u>Chemotherapy support</u></b></p> <p>For the prevention of febrile neutropenia in patients receiving myelosuppressive chemotherapy with curative intent who:</p> <ul style="list-style-type: none"> <li>are at high risk of febrile neutropenia due to chemotherapy regimen, co-morbidities or preexisting severe neutropenia; or</li> <li>have had an episode of febrile neutropenia, neutropenic sepsis or profound neutropenia in a previous cycle of chemotherapy; or</li> <li>have had a dose reduction, or treatment delay greater than one week due to neutropenia.</li> </ul> <p><b><u>Clinical Note:</u></b></p> <ul style="list-style-type: none"> <li>Patients with non-curative cancer receiving chemotherapy with palliative intent are not eligible for coverage of pegfilgrastim for prevention of febrile neutropenia.</li> </ul> <p><b>Must be requested and prescribed by a specialist in hematology or medical oncology.</b>  <b>Patients must apply for coverage under the High-Cost Drug Program.</b>  <b>Prescriptions written by a PEI oncologist do not require a Special Authorization.</b></p>

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<b>Pembrolizumab</b> Keytruda®  (cont'd on next page)	Injectable (vial) 100 mg	CTC Formulary	<p><b><u>Colorectal Cancer</u></b></p> <ul style="list-style-type: none"> <li>As monotherapy for the first-line treatment of metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) colorectal cancer.                             <ul style="list-style-type: none"> <li>Eligible patients include those who have not received prior treatment for metastatic MSI-H/dMMR colorectal cancer and have a good performance status at the start of treatment with pembrolizumab.</li> <li>Treatment should continue until confirmed disease progression or unacceptable toxicity to a maximum of 2 years or 35 doses, whichever comes first.</li> </ul> </li> </ul> <p><b><u>Head and Neck Cancer</u></b></p> <ul style="list-style-type: none"> <li>For the first-line treatment of metastatic or unresectable recurrent Head &amp; Neck Squamous Cell Carcinoma (HNSCC) as monotherapy for patients whose tumours have PD-L1 expression Combined Positive Score (CPS) <math>\geq 1</math>, or in combination with platinum and 5-FU chemotherapy regardless of PD-L1 expression level.                             <ul style="list-style-type: none"> <li>Pembrolizumab treatment should continue until confirmed disease progression or unacceptable toxicity to a maximum of 35 cycles (approximately two years), whichever occurs first.</li> </ul> </li> </ul> <p><b><u>Hodgkin Lymphoma</u></b></p> <ul style="list-style-type: none"> <li>As monotherapy for the treatment of adult patients with refractory or relapsed classical Hodgkin lymphoma (cHL) who have failed autologous stem cell transplantation (ASCT) and brentuximab vedotin (BV) or, are not candidates for ASCT and have failed BV. Treatment should be discontinued upon confirmed disease progression, unacceptable toxicity or a maximum of 2 years, whichever occurs first.</li> </ul> <p><b><u>Classical Hodgkin Lymphoma (cHL)</u></b></p> <ul style="list-style-type: none"> <li>As monotherapy, for the treatment of adult and pediatric patients with refractory or relapsed classical Hodgkin Lymphoma (cHL) who have failed autologous stem cell transplant (ASCT) or who are not candidates for multiagent salvage chemotherapy and ASCT.</li> <li><b><u>Clinical Notes</u></b> <ul style="list-style-type: none"> <li>Eligible patients include those who (1) have failed to achieve a response or progressed after ASCT, or (2) are not eligible to receive ASCT due to chemotherapy-resistant disease, advanced age, or any significant coexisting medical condition that may have a negative impact on tolerability of ASCT.</li> <li>Patients must have good performance status upon treatment initiation with pembrolizumab.</li> <li>Pembrolizumab treatment should continue until confirmed disease progression as per the International Working Group (IWG) response criteria or unacceptable toxicity to a maximum of 2 years or 35 cycles, whichever occurs first.</li> </ul> </li> </ul>

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<b>Pembrolizumab</b> Keytruda®  (cont'd on next page)	Injectable (vial) 100 mg	CTC Formulary	<p><b><u>Melanoma – Adjuvant</u></b></p> <ul style="list-style-type: none"> <li>For the adjuvant treatment of patients with cutaneous melanoma with completely resected Stage IIIA (limited to lymph node metastases of <math>\geq 1</math> mm) to Stage IV (8<sup>th</sup> edition of the American Joint Committee on Cancer [AJCC] melanoma staging system), regardless of BRAF status. 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. Patients must have a good performance status). Treatment should be discontinued upon disease progression, unacceptable toxicity or a maximum of 1 year if adjuvant treatment, whichever comes first.</li> </ul> <p><b><u>Clinical Notes:</u></b></p> <ul style="list-style-type: none"> <li>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.</li> <li>Patients with mucosal melanoma will be eligible for adjuvant treatment with pembrolizumab.</li> <li>Patients with ocular melanoma are not eligible for adjuvant treatment with pembrolizumab.</li> <li>Patients who progress during adjuvant therapy with nivolumab or pembrolizumab, or within 6 months of completion of adjuvant therapy, ipilimumab monotherapy may be funded as a subsequent line of therapy in the metastatic setting.</li> <li>Patients will be eligible for all immunotherapy options in the advanced or metastatic setting (including combination nivolumab with ipilimumab) only if there has been a 6 month progression-free interval between completion of adjuvant immunotherapy and confirmation of disease progression.</li> </ul> <p><b><u>Melanoma – Advanced (Unresectable or Metastatic)</u></b></p> <p>Treatment of patients with advanced (unresectable or metastatic) melanoma as a single agent at a dose of 2 mg/kg every 3 weeks for 24 months or until disease progression, whichever occurs first, with the following criteria:</p> <ul style="list-style-type: none"> <li>First line checkpoint inhibitor immunotherapy in patients naïve to Ipilimumab treatment (patients with BRAF mutation positive tumors may or may not have received BRAF targeted therapy)</li> <li>Treatment in either setting if for patients with an ECOG performance status of 0 or 1 and who have stable brain metastases (if present)</li> </ul> <p><b><u>Note:</u></b> Pembrolizumab is not funded in the following settings</p> <ul style="list-style-type: none"> <li>in patients who have experienced disease progression on, or after receiving nivolumab as a single agent or in combination with ipilimumab</li> <li>in patients who have experienced disease recurrence either during or within 6 months from the last dose of PD-1 inhibitor therapy (nivolumab or pembrolizumab) in the adjuvant setting</li> <li>in patients who stopped nivolumab due to significant intolerance or toxicity</li> </ul>
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## Health PEI Formulary Drugs: Oncology

Drug	Dosage Form	Funding Program	Funded Eligibility Criteria
<b>Pembrolizumab</b> Keytruda®  (cont'd on next page)	Injectable (vial) 100 mg	CTC Formulary	<p><b><u>Non-Small Cell Lung Cancer (NSCLC) – First Line</u></b></p> <ul style="list-style-type: none"> <li>Treatment of locally advanced (Stage IIIB, not eligible for potentially curative concurrent chemoradiotherapy) or previously untreated metastatic non-small cell lung cancer (NSCLC) in patients whose tumors express PD-L1 Tumor Proportion Score (TPS) ≥50% as determined by a validated test and who have a good performance status, and who do not harbour a sensitizing epidermal growth factor receptor (EGFR) mutation or anaplastic lymphoma kinase (ALK) translocation</li> </ul> <p><b><u>Non-squamous Non-small Cell Lung Cancer (NSCLC) in combination with chemotherapy</u></b></p> <ul style="list-style-type: none"> <li>In combination with pemetrexed and platinum chemotherapy for the treatment of metastatic non-squamous non-small cell lung cancer (NSCLC), in patients with no EGFR or ALK genomic tumor aberrations, and no prior systemic chemotherapy treatment for metastatic NSCLC. Patients must have a good performance status. Treatment should be discontinued upon confirmed disease progression, unacceptable toxicity or after completing 2 years of therapy, whichever occurs first.</li> </ul> <p><b><u>Clinical Notes:</u></b></p> <ul style="list-style-type: none"> <li>Patients who complete 2 years of therapy (35 cycles), or less than 2 years in the setting of maximum response, may receive up to an additional 12 months (17 cycles) at the point of confirmed disease progression if the treating physician deems the patient eligible for treatment.</li> <li>Funding is limited to one line of PD-1 inhibitor therapy for patients with advanced or metastatic non-small cell lung cancer (ie: one of Pembrolizumab 1<sup>st</sup> line, Pembrolizumab 2<sup>nd</sup> line or beyond, or Nivolumab).</li> <li>Patients who have been treated with curative intent durvalumab will be eligible for treatment with combination pembrolizumab with chemotherapy in the metastatic setting, provided that there has been a 6 month interval between the completion of durvalumab treatment and metastatic disease.</li> </ul> <p><b><u>Squamous Non-small Cell Lung Cancer (NSCLC) in combination with chemotherapy</u></b></p> <ul style="list-style-type: none"> <li>In combination with platinum-doublet chemotherapy for the treatment of metastatic squamous non-small cell lung cancer (NSCLC), in patients with no prior systemic chemotherapy treatment for metastatic NSCLC. Patients must have a good performance status. Treatment should be discontinued upon confirmed disease progression, unacceptable toxicity or after completing 2 years of therapy, whichever occurs first.</li> </ul> <p><b><u>Clinical Notes:</u></b></p> <ul style="list-style-type: none"> <li>Patients who complete 2 years of therapy (35 cycles), or less than 2 years in the setting of maximum response, may receive up to an additional 12 months (17 cycles) at the point of confirmed disease progression if the treating physician deems the patient eligible for treatment.</li> <li>Funding is limited to one line of PD-1 inhibitor therapy for patients with advanced or metastatic non-small cell lung cancer (ie: one of Pembrolizumab 1<sup>st</sup> line, Pembrolizumab 2<sup>nd</sup> line or beyond, or Nivolumab).</li> </ul>

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<b>Pembrolizumab</b> Keytruda®  (cont'd on next page)	Injectable (vial) 100 mg	CTC Formulary	<ul style="list-style-type: none"> <li>Patients who have been treated with curative intent durvalumab will be eligible for treatment with combination pembrolizumab with carboplatin and paclitaxel chemotherapy in the metastatic setting, provided that there has been a 6 month interval between the completion of durvalumab treatment and metastatic disease.</li> </ul> <p><b><u>Non-Small Cell Lung Cancer (NSCLC) – Second or Subsequent Line</u></b></p> <ul style="list-style-type: none"> <li>Treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors express PD-L1 Tumor Proportion Score (TPS) ≥1% as determined by a validated test and who have a good performance status, and who have disease progression on or after cytotoxic chemotherapy and targeted therapy for mutations of either epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) for those patients who tumors express these genomic aberrations</li> </ul> <p><b><u>NSCLC Funding Notes (First and Second Line):</u></b></p> <ul style="list-style-type: none"> <li>Treatment should continue until confirmed disease progression or unacceptable toxicity, or to a maximum of two years (35 cycles), whichever comes first</li> <li>Pembrolizumab may be re-started and continued for up to 12 additional months at the time of confirmed radiographic disease progression (according to immune-related response criteria) after initial Pembrolizumab therapy was stopped due to either completion of two years of therapy (35 cycles) or at physician discretion before 2 years in the setting of maximum response</li> <li>Patients who have received prior treatment with any other PD-1/PD-L1 inhibitor (e.g., Nivolumab) for advanced disease will not be eligible for Pembrolizumab.</li> <li>Patients will be eligible for Pembrolizumab in the advanced setting only if there has been at least a 6 month progression-free interval between completion of Durvalumab if used for stage III NSCLC and confirmation of disease progression</li> </ul> <p><b><u>Renal Cell Carcinoma</u></b></p> <ul style="list-style-type: none"> <li>In combination with axitinib for the treatment of patients with advanced renal cell carcinoma (RCC) as first-line treatment.                         <ul style="list-style-type: none"> <li>Eligible patients should be previously untreated in the advanced or metastatic setting and have a good performance status.</li> <li>Treatment should continue until confirmed disease progression or unacceptable toxicity to a maximum of 35 cycles (approximately two years), whichever comes first.</li> <li>Treatment with axitinib should continue until disease progression or unacceptable toxicity.</li> </ul> </li> </ul>

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<b>Pembrolizumab</b> Keytruda®  (cont'd on next page)	Injectable (vial) 100 mg	CTC Formulary	<p><b><u>Urothelial Carcinoma</u></b></p> <ul style="list-style-type: none"> <li>For the treatment of patients with locally advanced or metastatic urothelial carcinoma who have disease progression during or following platinum-containing chemotherapy or within 12 months of completing neoadjuvant or adjuvant platinum-containing chemotherapy. Patients must have a good performance status. Treatment should be discontinued upon confirmed disease progression, unacceptable toxicity or after completing 2 years of therapy, whichever occurs first.</li> </ul> <p><b><u>Clinical Notes:</u></b></p> <ul style="list-style-type: none"> <li>Patients that are ineligible for platinum-based chemotherapy, i.e. have a contraindication to platinum, and who would receive an alternative chemotherapy, will be eligible for pembrolizumab in the second-line setting.</li> <li>Patients who complete 2 years of therapy, or less than 2 years in the setting of maximum response, may receive up to an additional 12 months (17 cycles) at the point of confirmed disease progression if the treating physician deems the patient eligible for treatment.</li> </ul> <p><b><u>Esophageal Carcinoma - Gastroesophageal Junction Adenocarcinoma (EC-GEJ)</u></b></p> <ul style="list-style-type: none"> <li>In combination with platinum and fluoropyrimidine-based chemotherapy, for the first-line treatment of adult patients with locally advanced unresectable or metastatic carcinoma of the esophagus or human epidermal growth factor receptor 2 (HER2)-negative adenocarcinoma of the esophagogastric junction (EGJ) (tumour centre 1 cm to 5 cm above the gastric cardia).</li> </ul> <p><b><u>Clinical Notes:</u></b></p> <ul style="list-style-type: none"> <li>Eligible patients include those who have (1) histologically or cytologically confirmed locally advanced unresectable or metastatic adenocarcinoma or squamous cell carcinoma of the esophagus, or advanced or metastatic Siewert type I adenocarcinoma of the esophagogastric junction, and (2) an ECOG PS of 0 or 1.</li> <li>Patients must have no history of receiving anti-PD-1, anti-PD-L1, or anti-PD-L2 therapies, or an agent directed to another co-inhibitory Tcell receptor upon treatment initiation with pembrolizumab.</li> <li>Pembrolizumab treatment should continue until confirmed disease progression as per RECIST (version 1.1) or unacceptable toxicity to a maximum of 2 years or 35 cycles, whichever occurs first.</li> </ul> <p><b><u>Early Triple Negative Breast Cancer (TNBC)</u></b>                      For the treatment of adult patients with high-risk early-stage triple-negative breast cancer (TNBC) in combination with chemotherapy as neoadjuvant treatment, and then continued as monotherapy as adjuvant treatment after surgery.</p>

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<b>Pembrolizumab</b> Keytruda®	Injectable (vial) 100 mg	CTC Formulary	<p><b><u>Adjuvant Renal Cell Carcinoma</u></b></p> <ul style="list-style-type: none"> <li>For the adjuvant treatment of adult patients with renal cell carcinoma (RCC) at intermediate-high or high risk of recurrence following nephrectomy, or following nephrectomy and resection of metastatic lesions.</li> </ul> <p><b><u>Recurrent or Metastatic Cervical Cancer</u></b></p> <ul style="list-style-type: none"> <li>For the treatment of adult patients with persistent, recurrent, or metastatic cervical cancer whose tumours express PD-L1 (CPS≥1) as determined by a validated test, in combination with chemotherapy with or without bevacizumab.</li> </ul> <p><b><u>Advanced Endometrial Cancer (dMMR/MSI-H)</u></b></p> <ul style="list-style-type: none"> <li>For the treatment of adult patients with unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) endometrial cancer whose tumours have progressed following prior therapy and who have no satisfactory alternative treatment options, as monotherapy.</li> </ul> <p><b><u>Advanced or Metastatic Renal Cell Carcinoma</u></b></p> <ul style="list-style-type: none"> <li>In combination with lenvatinib, for the treatment of adult patients with advanced or metastatic renal cell carcinoma (RCC) with no prior systemic therapy for metastatic RCC.</li> </ul> <p><b><u>Advanced Endometrial Cancer (non dMMR/MSI-H)</u></b></p> <ul style="list-style-type: none"> <li>In combination with lenvatinib 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, and are not candidates for curative surgery or radiation.</li> </ul> <p><b><u>Melanoma Adjuvant Treatment (Stage IIb or IIc)</u></b></p> <ul style="list-style-type: none"> <li>Adjuvant treatment of adult and pediatric (12 years and older) patients with stage IIb or IIC melanoma following complete resection.</li> </ul> <p><b><u>Metastatic Triple-Negative Breast Cancer (TNBC)</u></b></p> <ul style="list-style-type: none"> <li>In combination with chemotherapy for the treatment of adult patients with locally recurrent unresectable or metastatic TNBC who have not received prior chemotherapy for metastatic disease and whose tumors express PD-L1 (CPS ≥ 10) as determined by a validated test.</li> </ul>

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<b>Pemetrexed</b> Alimta®	Injectable (vial) 100 mg, 500 mg	CTC Formulary	<p>Approved for the following indications:</p> <p><b><u>Non-Small Cell Lung Cancer (NSCLC) – Advanced, Non-Squamous Histology</u></b></p> <ul style="list-style-type: none"> <li>First line (or Induction) chemotherapy treatment option in combination with platinum for 4-6 cycles; patients who received either EGFR or ALK targeted therapy as their initial treatment for advanced disease may be considered for this treatment as a next line chemotherapy option</li> <li>Maintenance single agent treatment following 4-6 cycles of platinum doublet induction treatment, which may include pemetrexed, for patients who achieved stable disease or better and who have an ECOG performance status of 0 or 1; treatment may be continued until disease progression</li> <li>Second (or subsequent) line single agent treatment for patients who have disease progression following any non-pemetrexed treatment option; treatment may be continued until disease progression</li> </ul> <p><b><u>Malignant Mesothelioma</u></b></p> <ul style="list-style-type: none"> <li>First line therapy in combination with Cisplatin</li> </ul>
<b>Pertuzumab</b> Perjeta®	Injectable (vial) 420 mg/14 mL	CTC Formulary	<p><b><u>Breast Cancer- Metastatic</u></b></p> <ul style="list-style-type: none"> <li>In combination with a taxane and trastuzumab (Herceptin) for the treatment of patients with HER-2 positive unresectable locally recurrent or metastatic (advanced) breast cancer who have not received prior anti-HER-2 therapy or chemotherapy for advanced disease, or who have had a relapse-free interval of at least 6 months from anti-HER-2 therapy given in the neoadjuvant or adjuvant setting</li> <li>Patients must be fit for therapy with an ECOG performance status of 0 or 1 and no clinically significant cardiac disease with a LVEF of greater than or equal to 50%</li> </ul>
<b>Plerixafor</b> Mozobil®	Injectable (vial) 24 mg/ 1.2 mL	CTC Formulary	Administered to select patients in Halifax prior to bone marrow harvest. Charged to approved out of province services and sent to attention of the Out-of-Province Physician Referral Coordinator, Health PEI
<b>Polatuzumab vedotin</b> Polivy®	Injectable (vial) 30mg/6mL 140mg/20mL	CTC Formulary	<p><b><u>Lymphoma</u></b></p> <ul style="list-style-type: none"> <li>In combination with bendamustine and rituximab (pola-BR) for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma, not otherwise specified, who are not eligible for autologous stem cell transplant and have received at least 1 prior therapy</li> <li>Eligible patients should have good performance status and a life expectancy <math>\geq 24</math> weeks</li> <li>Treatment with pola-BR should continue for a maximum of 6 cycles (21 days per cycle), or unacceptable toxicity or disease progression, whichever occurs first</li> </ul>

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<b>Pomalidomide</b> Pomalyst®	Oral (capsule) 1 mg, 2 mg 3 mg, 4 mg	Pharmacare <b>MQWN</b>	<p><b><u>Multiple Myeloma – Relapsed and/or refractory</u></b></p> <ul style="list-style-type: none"> <li>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.</li> </ul> <p><b>Note:</b> Pomalidomide may be an option in rare instances where bortezomib is not tolerated or contraindicated but in all cases, patients should have failed lenalidomide.</p> <p><b>Clinical Note:</b> Due to its structural similarities to thalidomide, pomalidomide (Pomalyst) is only available through a controlled distribution program called RevAid® to minimize the risk of fetal exposure. Only prescribers and pharmacists registered with this program are able to prescribe and dispense pomalidomide (Pomalyst). In addition, patients must be registered and meet all the conditions of the program in order to receive the product. For information, call 1-888-RevAid1 or <a href="http://www.RevAid.ca">www.RevAid.ca</a>.</p> <p><b>Patients must apply for coverage under the High-Cost Drug Program.</b>  <b>If written by an oncologist, this medication does <u>not</u> require the submission of a Pharmacare Special Authorization form.</b></p>
<b>Ponatinib</b> Iclusig®	Oral (tablet) 15 mg	Pharmacare <b>MQWN</b>	<p><b><u>Chronic Myelogenous Leukemia (CML) and Acute Lymphoblastic Leukemia (ALL) - Philadelphia Chromosome (Ph+) positive</u></b></p> <ul style="list-style-type: none"> <li>For the treatment of patients with chronic, accelerated or blast phase chronic myelogenous leukemia (CML) or Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ALL) who have: <ul style="list-style-type: none"> <li>resistance or intolerance to two or more tyrosine kinase inhibitors (TKIs), OR</li> <li>confirmed T315i mutation positive disease.</li> </ul> </li> </ul> <p><b>Clinical Notes:</b></p> <ol style="list-style-type: none"> <li>Patients must have an ECOG performance status of ≤2.</li> <li>Treatment should be discontinued upon disease progression or unacceptable toxicity</li> </ol> <p><b>Patients must apply for coverage under the High-Cost Drug Program.</b>  <b>If written by an oncologist, this medication does <u>not</u> require the submission of a Pharmacare Special Authorization form.</b></p>
<b>Pralatrexate</b> Foloty®	Injectable (vial) 20mg/mL	CTC Formulary	For the treatment of patients with relapsed or refractory peripheral T-cell lymphoma (PTCL) who have received previous systemic therapy, none of which include romidepsin. Patients should have a good performance status. Treatment with pralatrexate should continue until disease progression or unacceptable toxicity.

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<b>Raltitrexed</b> Tomudex®	Injection (vial) 2 mg	CTC Formulary	<p><b><u>Colorectal Cancer – Metastatic</u></b></p> <ul style="list-style-type: none"> <li>Single agent treatment in patients with an intolerance or contraindication to fluoropyrimidine therapy (fluorouracil or capecitabine)</li> </ul> <p><b><u>Mesothelioma</u></b></p> <ul style="list-style-type: none"> <li>First line treatment of malignant mesothelioma in combination with cisplatin</li> </ul>
<b>Ramucirumab</b> Cyramza®	Injection (vial) 100 mg/10 mL 500 mg/50 mL	CTC Formulary	<p><b><u>Gastric Cancer or Gastro-esophageal junction adenocarcinoma</u></b></p> <ul style="list-style-type: none"> <li>In combination with paclitaxel for the treatment of patients with advanced or metastatic gastric cancer or gastro-esophageal junction (GEJ) adenocarcinoma with an ECOG performance status of 0 or 1, and with disease progression following first-line chemotherapy.</li> </ul>
<b>Regorafenib</b> Stivarga®	Oral (tablet) 40mg	Pharmacare MQWN	<p><b><u>Gastrointestinal Stromal Tumors (GIST)</u></b></p> <ul style="list-style-type: none"> <li>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.</li> </ul> <p><b><u>Unresectable Hepatocellular Carcinoma (HCC)</u></b></p> <ul style="list-style-type: none"> <li>For the treatment of patients with unresectable hepatocellular carcinoma (HCC) who have experienced disease progression on sorafenib or lenvatinib and meet all of the following criteria: <ul style="list-style-type: none"> <li>Child-Pugh class status of A.</li> <li>ECOG performance status of 0 or 1.</li> </ul> </li> </ul> <p><b><u>Clinical Notes:</u></b></p> <ul style="list-style-type: none"> <li>Treatment should continue until disease progression or unacceptable toxicity.</li> <li>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.</li> </ul> <p><b>Patients must apply for coverage under the High-Cost Drug Program. If written by an oncologist, this medication does <u>not</u> require the submission of a Pharmacare Special Authorization form.</b></p>

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<b>Ribociclib</b> Kisqali®	Oral (tablet) 200 mg	Pharmacare <b>MQWN</b>	<p><b><u>Breast Cancer – Metastatic</u></b></p> <ol style="list-style-type: none"> <li>In combination with an aromatase inhibitor for the treatment of patients with hormone receptor positive, HER2 negative or advanced or metastatic breast cancer who: <ul style="list-style-type: none"> <li>have not received prior endocrine therapy for advanced or metastatic disease, and</li> <li>are not resistant to prior (neo) adjuvant non-steroidal aromatase inhibitor (NSAI) therapy and</li> <li>do not have active or uncontrolled metastases to the central nervous system</li> </ul> <p><b><u>Renewal criteria:</u></b></p> <ul style="list-style-type: none"> <li>Confirmation that the patient has responded to treatment and there is no evidence of disease progression</li> </ul> <p><b><u>Clinical Notes:</u></b></p> <ul style="list-style-type: none"> <li>Patients must have a good performance status</li> <li>Resistance is defined as disease progression occurring during or within 12 months following NSAI therapy</li> <li>Treatment should be discontinued upon disease progression or unacceptable toxicity</li> </ul> </li> <li>In combination with fulvestrant for the treatment of patients with hormone receptor (HR) positive, HER2 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).</li> </ol> <p><b><u>Clinical Notes:</u></b></p> <ul style="list-style-type: none"> <li>Treatment should continue until unacceptable toxicity or disease progression</li> <li>Patients who progress ≤ 12 months from (neo) adjuvant therapy are eligible for treatment with ribociclib plus fulvestrant.</li> <li>Patients who experience disease progression on prior CDK 4/6 inhibitor therapy, fulvestrant or everolimus are not eligible for treatment with ribociclib with fulvestrant.</li> <li>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.</li> <li>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.</li> </ul> <p><b>Prescriptions written by PEI oncologists do not require Special Authorization. Patients must apply for coverage by the High-Cost Drug Program.</b></p>

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<b>Ripretinib</b> Qinlock®	Oral (tablet) 50mg	Pharmacare <b>MQWN</b>	<p><b><u>Gastrointestinal Stromal Tumours (GIST)</u></b> For the treatment of adult patients with advanced gastrointestinal stromal tumours (GIST) who have progression on or intolerance to imatinib, sunitinib, and regorafenib.</p> <p><b><u>Clinical Notes:</u></b></p> <ul style="list-style-type: none"> <li>• Patients must have a good performance status and no active central nervous system metastases.</li> <li>• Treatment should be discontinued upon disease progression or unacceptable toxicity.</li> </ul> <p><b>Prescriptions written by PEI oncologists do not require Special Authorization.</b> <b>Patients must apply for coverage by the High-Cost Drug Program.</b></p>

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<b>Rituximab</b> Rituxan® Riximyo® Ruxience® Truxima®	Injection (vial) Intravenous 100 mg/10 mL 500 mg/50 mL  Injection (vial) Subcutaneous 1,400 mg/11.7mL	CTC Formulary	<p>Approved for the following indications in <u>CD20 antigen positive</u> patients:</p> <p><b><u>Burkitt's Lymphoma</u></b></p> <ul style="list-style-type: none"> <li>Induction treatment in combination with standard chemotherapy</li> </ul> <p><b><u>Diffuse Large B-Cell Lymphoma (DLBCL)</u></b></p> <ul style="list-style-type: none"> <li>Induction treatment in combination with chemotherapy for DLBCL or transformed lymphoma. Consolidation or maintenance therapy is not approved.</li> <li>Re-treatment of patients with a Rituximab-containing regimen who have had a progression-free interval of greater than 6 months from last dose of Rituximab.</li> </ul> <p><b><u>Indolent (Low Grade) Lymphoma and Mantle Cell Lymphoma (MCL)</u></b></p> <ul style="list-style-type: none"> <li>Induction treatment in combination with chemotherapy for indolent low grade lymphomas (including follicular, marginal zone, and lymphoplasmacytic lymphoma) or mantle cell lymphoma</li> <li>Re-treatment of patients with a Rituximab-containing regimen who have had a progression-free interval of greater than 6 months from last dose of Rituximab</li> <li>Consolidation or maintenance therapy given every 3 months for 2 years (8 doses), initiated within 3 to 6 months of completing induction therapy, provided an adequate response to the induction Rituximab chemotherapy treatment was achieved (defined as a 50% or greater reduction in total disease burden).</li> <li><b><u>Note:</u></b> Maintenance therapy is NOT approved for transformed lymphoma, mantle cell lymphoma or chronic lymphocytic leukemia/small lymphocytic lymphoma</li> <li>A second consolidation or maintenance following a re-induction treatment is approved for patients who have a progression free interval &gt;3 years from last Rituximab maintenance dose</li> </ul> <p><b><u>Hodgkins Lymphoma</u></b></p> <ul style="list-style-type: none"> <li>In combination with chemotherapy for the treatment of patients with CD20+ve, lymphocyte predominant disease</li> </ul> <p><b><u>Blood and Marrow Transplant (BMT) Program</u></b></p> <ul style="list-style-type: none"> <li>Treatment with a maximum of 4 doses as part of the priming regimen prior to bone marrow harvest and autologous stem cell transplant in patients with lymphoma</li> </ul>
<b>Rituximab</b> Rituxan® Riximyo® Ruxience® Truxima®	Injection (vial) Intravenous 100 mg/10 mL 500 mg/50 mL	CTC Formulary	<p><b><u>Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL)</u></b></p> <ul style="list-style-type: none"> <li>First line treatment of fit chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) patients in combination with fludarabine and/or cyclophosphamide (FCR)</li> <li>In combination with Bendamustine (BR) for patients with CLL/SLL who are either previously untreated or who have received prior anti-CD20 therapy with a treatment free interval of greater than 3 years since the last dose of anti-CD20 therapy.</li> <li>In combination with venetoclax for up to 6 cycles in patients who have received at least 1 prior therapy</li> </ul>

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## Health PEI Formulary Drugs: Oncology

Drug	Dosage Form	Funding Program	Funded Eligibility Criteria
<b>Ruxolitinib</b> Jakavi®  (cont'd on next page)	Oral (tablet) 5mg, 10mg, 15mg, 20mg	Pharmacare <b>MQWN</b>	<p><b><u>Myelofibrosis</u></b></p> <ul style="list-style-type: none"> <li>For patients with intermediate to high-risk symptomatic Myelofibrosis (MF) as assessed using the Dynamic International Prognostic Scoring System (DIPSS) Plus or patients with symptomatic splenomegaly. Patients should have ECOG performance status less than or equal to 3 and be either previously untreated or refractory to other treatment.</li> </ul> <p><b><u>Polycythemia Vera</u></b></p> <ul style="list-style-type: none"> <li>For the treatment of patients with polycythemia vera who have demonstrated resistance or intolerance to hydroxyurea (HU).</li> </ul> <p><b><u>Renewal Criteria:</u></b>                      Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.</p> <p><b><u>Clinical Notes:</u></b></p> <ul style="list-style-type: none"> <li>Patients must have a good performance status.</li> <li>Treatment should be discontinued upon disease progression or unacceptable toxicity.</li> <li>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:                             <ul style="list-style-type: none"> <li>Need for phlebotomy to maintain hematocrit (HCT) &lt; 45%</li> <li>Uncontrolled myeloproliferation (i.e., platelet count &gt; 400 x 10<sup>9</sup>/L and white blood cell count &gt; 10 x 10<sup>9</sup>/L)</li> <li>Failure to reduce massive splenomegaly by greater than 50%, as measured by palpation</li> </ul> </li> <li>Intolerance to HU is considered if patients experience at least one of the following:                             <ul style="list-style-type: none"> <li>Absolute neutrophil count &lt; 1.0 x 10<sup>9</sup>/L, platelet count &lt; 100 x 10<sup>9</sup>/L or hemoglobin &lt; 100g/L at the lowest dose of HU required to achieve a response (a response to HU is defined as HCT &lt;45% without phlebotomy, and/or all of the following: platelet count &lt; 400 x 10<sup>9</sup>/L, white blood cell count &lt; 10 x 10<sup>9</sup>/L, and nonpalpable spleen).</li> <li>Presence of leg ulcers or other unacceptable HU-related nonhematological toxicities (defined as grade 3 or 4 or, more than one week of grade 2) such as mucocutaneous manifestations, gastrointestinal symptoms, pneumonitis, or fever.</li> <li>Toxicity requiring permanent discontinuation of HU, interruption of HU until toxicity resolved, or hospitalization due to HU toxicity.</li> </ul> </li> </ul>

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<b>Ruxolitinib</b> <b>Jakavi®</b>  (cont'd on next page)	Oral (tablet) 5mg, 10mg, 15mg, 20mg	Pharmacare <b>MQWN</b>	<p><b><u>Acute Graft-Versus-Host Disease</u></b>                      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:</p> <ul style="list-style-type: none"> <li>Clinically diagnosed grade II to IV aGvHD according to the NIH criteria (Harris et al. [2016]).</li> <li>Confirmed diagnosis of corticosteroid-refractory or corticosteroid-dependent aGvHD.</li> </ul> <p><b><u>Renewal criteria:</u></b></p> <ul style="list-style-type: none"> <li>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.</li> <li>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.</li> </ul> <p><b><u>Clinical Notes:</u></b></p> <ul style="list-style-type: none"> <li>Treatment should be discontinued upon the occurrence of any of the following:                             <ul style="list-style-type: none"> <li>progression of aGvHD, defined as worsening of aGvHD symptoms or occurrence of new aGvHD symptoms</li> <li>unacceptable toxicity</li> <li>addition of systemic therapies (other than calcineurin inhibitors) for aGvHD after day 28</li> <li>recurrence or relapse of underlying hematological malignancy.</li> </ul> </li> </ul> <p><b><u>Claim Notes:</u></b></p> <ul style="list-style-type: none"> <li>Must be prescribed by clinicians who have experience in the diagnosis and management of patients with aGvHD.</li> <li>Must not be added to patients' concurrent treatment of systemic therapies for the treatment of aGvHD other than steroids with or without calcineurin inhibitors.</li> <li>Approval: 6 months</li> </ul>

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<b>Ruxolitinib</b> Jakavi®	Oral (tablet) 5mg, 10mg, 15mg, 20mg	Pharmacare <b>MQWN</b>	<p><b><u>Chronic Graft-Versus-Host Disease</u></b> 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:</p> <ul style="list-style-type: none"> <li>Clinically diagnosed cGvHD staging of moderate to severe based on NIH consensus criteria</li> <li>Confirmed diagnosis cGvHD with inadequate response to corticosteroids or other systemic therapies</li> </ul> <p><b><u>Renewal criteria:</u></b></p> <ul style="list-style-type: none"> <li>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</li> </ul> <p><b><u>Clinical Notes:</u></b></p> <ul style="list-style-type: none"> <li>Treatment should be discontinued upon the occurrence of any of the following: <ul style="list-style-type: none"> <li>Progression of cGvHD, defined as worsening of cGvHD symptoms or occurrence of new cGvHD symptoms</li> <li>recurrence or relapse of underlying hematological malignancy</li> </ul> </li> </ul> <p><b><u>Claim Notes:</u></b></p> <ul style="list-style-type: none"> <li>Must be prescribed by clinicians who have experience in the diagnosis and management of patients with cGvHD.</li> <li>Must not be added to patients' concurrent treatment of systemic therapies other than steroids with or without calcineurin inhibitors.</li> <li>Initial Approval: 6 months</li> </ul> <p><b>Patients must apply for coverage under the High-Cost Drug Program. If written by an oncologist, this medication does <u>not</u> require the submission of a Pharmacare Special Authorization form.</b></p>
<b>Sacituzumab govitecan</b> Trodelvy®	Injection (vial) 180 mg	CTC Formulary	<p><b><u>Unresectable Locally Advanced or Metastatic Triple-Negative Breast Cancer (mTNBC)</u></b> For the treatment of adult patients with unresectable locally advanced or metastatic triple-negative breast cancer (mTNBC) who have received two or more prior therapies, at least one of them for metastatic disease.</p>

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Drug	Dosage Form	Funding Program	Funded Eligibility Criteria
<b>Selinexor</b> Xpovio®	Oral (tablet) 20mg	Pharmacare <b>MQWN</b>	<p><b><u>Multiple Myeloma</u></b> In combination with bortezomib and dexamethasone for the treatment of adult patients with multiple myeloma and who have received at least one prior therapy.</p> <p><b><u>Clinical Notes:</u></b></p> <ol style="list-style-type: none"> <li>1. Prior treatment with bortezomib/proteasome inhibitor is permitted if all the following criteria are met: <ul style="list-style-type: none"> <li>• Best response achieved with bortezomib/proteasome inhibitor was at least a partial response</li> <li>• Bortezomib/proteasome inhibitor not discontinued for grade 3 or higher toxicity</li> <li>• Bortezomib/proteasome inhibitor treatment-free interval has been at least six months.</li> </ul> </li> <li>2. Treatment should continue until disease progression or unacceptable toxicity.</li> </ol> <p><b>Prescriptions written by PEI oncologists do not require Special Authorization. Patients must apply for coverage by the High-Cost Drug Program.</b></p>

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<b>Selpercatinib</b> Retevmo®	Oral (capsule) 40 mg, 80 mg	Pharmacare <b>MQWN</b>	<p><b><u>Medullary Thyroid Cancer</u></b> 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.</p> <p><b><u>Clinical Notes:</u></b></p> <ul style="list-style-type: none"> <li>• Discontinuation for unacceptable toxicity or loss of clinical benefit.</li> <li>• Patients should have a good performance status.</li> <li>• Monotherapy only.</li> <li>• Confirm RET mutation prior to initiating therapy.</li> <li>• Patients with prior progression on a RET inhibitor are ineligible.</li> </ul> <p><b><u>Differentiated Thyroid Carcinoma (DTC)</u></b> 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 treatment with lenvatinib.</p> <p><b><u>Clinical Notes:</u></b></p> <ul style="list-style-type: none"> <li>• Discontinuation for unacceptable toxicity or loss of clinical benefit.</li> <li>• Patients should have a good performance status.</li> <li>• Monotherapy only.</li> <li>• Confirm RET mutation prior to initiating therapy.</li> <li>• Patients with prior progression on a RET inhibitor are ineligible.</li> </ul> <p><b><u>Non-Small Cell Lung Cancer</u></b> 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.</p> <p><b><u>Clinical Notes:</u></b></p> <ul style="list-style-type: none"> <li>• Discontinuation for unacceptable toxicity or loss of clinical benefit.</li> <li>• Patients should have a good performance status.</li> <li>• Monotherapy only.</li> <li>• Confirm RET mutation prior to initiating therapy.</li> <li>• Patients with prior progression on a RET inhibitor are ineligible.</li> </ul> <p><b>Prescriptions written by PEI oncologists do not require Special Authorization. Patients must apply for coverage by the High-Cost Drug Program.</b></p>

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Health PEI Formulary Drugs: Oncology

Drug	Dosage Form	Funding Program	Funded Eligibility Criteria
<b>Siltuximab</b> Sylvant®	Injection (vial) 100 mg, 400 mg	CTC Formulary	<p><b><u>Multicentric Castleman's Disease</u></b></p> <ul style="list-style-type: none"> <li>For previously treated or untreated multicentric Castleman's disease in patients who are human immunodeficiency virus (HIV) negative, human herpes virus-8 (HHV-8) negative and who have an ECOG performance status of less than or equal to 2. Treatment should continue until treatment failure.</li> </ul>
<b>Sorafenib</b> Nexavar®	Oral (tablet) 200 mg	Pharmacare <b>MQWN</b>	<p><b><u>Renal Cell Carcinoma – Advanced or Metastatic</u></b></p> <ul style="list-style-type: none"> <li>For use as a single agent second line treatment in patients with documented evidence of histologically confirmed advanced or metastatic clear cell renal cell carcinoma, considered to be intermediate or low risk (according to Memorial Sloan-Kettering (MSKCC) prognostic score, see below), have an ECOG performance status of 0 or 1 and progressed after prior cytokine therapy (or intolerance) within the previous 8 months. In any one patient all of the following conditions must be met: <ul style="list-style-type: none"> <li>Sorafenib may be a second line option only after cytokine therapy.</li> <li>Sorafenib may <b>NOT</b> be used after another tyrosine kinase inhibitor (i.e. sunitinib) as sequential therapy.</li> </ul> </li> </ul> <p>In the event of severe toxicity within the first 8 weeks of therapy, a switch to another tyrosine kinase inhibitor (i.e. sunitinib) may be allowed.</p> <p><b><u>Hepatocellular Carcinoma (HCC) – Advanced</u></b></p> <ul style="list-style-type: none"> <li>For use in patients with Child-Pugh Class A advanced hepatocellular carcinoma, who have progressed on trans-arterial chemoembolization (TACE) or are not suitable for the TACE procedure, and have an ECOG performance status of 0 to 2. Renewal of coverage requires no further progression of the patient's disease as evidenced by radiological or scan results.</li> </ul> <p><b>Patients must apply for coverage under the High-Cost Drug Program. If written by an oncologist, this medication does <u>not</u> require the submission of a Pharmacare Special Authorization form.</b></p>
<b>Streptozocin</b> Zanosar®	Injection (vial) 1 g	CTC Formulary	Treatment of metastatic islet cell carcinoma of the pancreas for symptomatic or progressive disease only

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<b>Sunitinib</b> Sutent®	Oral (tablet) 12.5 mg, 25 mg, 50 mg	Pharmacare <b>MQWN</b>	<p><b><u>Renal Cell Carcinoma – Advanced or Metastatic</u></b></p> <ul style="list-style-type: none"> <li>For use as a single agent first line treatment in patients with documented evidence of histologically confirmed advanced or metastatic clear cell renal cell carcinoma who have an ECOG performance status of 0 or 1. In any one patient all of the following conditions must be met: <ul style="list-style-type: none"> <li>Sunitinib may be a first line option.</li> <li>Sunitinib may <b>NOT</b> be used after another tyrosine kinase inhibitor (i.e. sorafenib) as sequential therapy.</li> </ul> </li> </ul> <p>In the event of severe toxicity within the first 8 weeks of therapy, a switch to another tyrosine kinase inhibitor (i.e. sorafenib) may be allowed.</p> <p><b><u>Gastrointestinal Stromal Tumor (GIST)</u></b></p> <ul style="list-style-type: none"> <li>For use as a single agent for the treatment of advanced gastrointestinal stromal tumor (GIST) patients after failure of imatinib due to intolerance or resistance.</li> </ul> <p><b><u>Pancreatic Neuroendocrine Tumors (pNET)</u></b></p> <ul style="list-style-type: none"> <li>For the treatment of patients with progressive, unresectable, locally advanced or metastatic, well or moderately differentiated pancreatic neuroendocrine tumors.</li> </ul> <p><b><u>Clinical Notes:</u></b></p> <ol style="list-style-type: none"> <li>Patients must have a good performance status.</li> <li>Treatment should be discontinued upon disease progression or unacceptable toxicity.</li> </ol> <p><b>Patients must apply for coverage under the High-Cost Drug Program.</b>  <b>If written by an oncologist, this medication does <u>not</u> require the submission of a Pharmacare Special Authorization form.</b></p>
<b>Tamoxifen</b> generics	Oral (tablet) 10 mg, 20 mg	Pharmacare <b>FGNQSW</b>	Open benefit
<b>Temozolomide</b> Temodal®, generics	Oral (capsule) 5 mg, 20 mg, 100 mg, 140 mg, 250 mg	Pharmacare <b>FGMNQSW</b>	<p>For the treatment of brain tumors (Malignant glioma)</p> <p><b>Patients requesting coverage under the High-Cost Drug Program must apply to this program.</b>  <b>If written by an oncologist, this medication does not require the submission of a Pharmacare Special Authorization form.</b></p>
<b>Testosterone</b> AndroGel® packets, generic	Transdermal gel 25 mg/2.5 g, 50 mg/5 g	Pharmacare <b>FNQSW</b>	<p>For the treatment of congenital and acquired primary or secondary hypogonadism in males with a specific diagnosis of:</p> <ul style="list-style-type: none"> <li><b>Primary</b> - Cryptorchidism, Klinefelter's, orchiectomy, and other established causes.</li> <li><b>Secondary</b> - Pituitary-hypothalamic injury due to tumors, trauma, radiation.</li> </ul> <p>Testosterone deficiency should be clearly demonstrated by clinical features and confirmed by two separate biochemical tests before initiating any testosterone therapy. Limited to 5 g/day gel.</p> <p><b>Older males with non-specific symptoms of fatigue, malaise or depression who have low testosterone (T) levels do not satisfy these criteria.</b>  <b>Requires submission of a Pharmacare Special Authorization form.</b></p>
<b>Testosterone</b> Testim®tube	50 mg/5 g	Pharmacare <b>FNQSW</b>	<p><i>*See Testosterone (AndroGel)</i></p> <p><b><i>Not interchangeable</i></b></p>

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<b>Thioguanine</b> 6-TG, Lanvis®	Oral (tablet) 40 mg	Pharmacare <b>FNQSW</b>	Open benefit
<b>rh-Thyrotropin alfa</b> Thyrogen®	Injection (vial) 0.9 mg/1 mL	Pharmacare <b>FNQSW</b>	<p><b><u>Thyroid cancer</u></b> For use as a single agent in patients who have documented evidence of thyroid cancer, who have undergone appropriate surgical and/or medical management, and require on-going evaluation to monitor for recurrence and metastatic disease. This includes:</p> <ul style="list-style-type: none"> <li>a) Primary use in patients with inability to raise an endogenous TSH level (<math>\geq 25</math> mu/L) with thyroid hormone withdrawal.</li> <li>b) Primary use in cases of documented morbidity in patients for whom severe hypothyroidism could be life threatening, such as unstable angina, recent myocardial infarction, class III to IV congestive heart failure, or uncontrolled psychiatric illness.</li> <li>c) Secondary use in patients with previous thyroid hormone withdrawal resulting in a documented life-threatening event.</li> </ul> <p><b>(This criteria is for clients of the Catastrophic Drug Program, only)</b></p> <ul style="list-style-type: none"> <li>d) 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 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</li> </ul> <p><b>Requires submission of a Pharmacare Special Authorization form.</b></p>
<b>Topotecan</b> Hycamtin®	Injection (vial) 4 mg	CTC Formulary	<p><b><u>Gynecology</u></b></p> <ul style="list-style-type: none"> <li>• Single agent treatment for recurrent or progressive epithelial ovarian, fallopian tube or primary peritoneal cancer after responding to at least 1 prior line of therapy</li> <li>• In combination with Cisplatin for treatment of recurrent or disseminated cervical cancer</li> </ul> <p><b><u>Small Cell Lung Cancer (SCLC) – Advanced</u></b></p> <ul style="list-style-type: none"> <li>• Second line single agent treatment after platinum failure</li> </ul>

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<b>Trametinib</b> Mekinist®	Oral (tablet) 0.5 mg, 2 mg	Pharmacare <b>MQWN</b>	<p><b><u>Melanoma – Adjuvant</u></b></p> <ul style="list-style-type: none"> <li>In combination with dabrafenib for the adjuvant treatment of patients with cutaneous melanoma who meet all of the following criteria <ul style="list-style-type: none"> <li>Stage IIIA (limited to lymph node metastases of greater than 1 mm) to stage IIID disease (AJCC 8th edition)</li> <li>BRAF V600-mutation positive</li> <li>Completely resected disease including in-transit metastases</li> </ul> </li> </ul> <p><b><u>Clinical Notes:</u></b></p> <ol style="list-style-type: none"> <li>Patients must have a good performance status.</li> <li>Treatment should continue until disease recurrence, unacceptable toxicity, or up to a maximum of 12 months.</li> </ol> <p><b><u>Claim Notes:</u></b></p> <ol style="list-style-type: none"> <li>Requests will be considered for patients with regional lymph nodes with micrometastases after sentinel lymph node biopsy.</li> <li>Requests will not be considered for patients who received adjuvant immunotherapy for greater than three months. Patients may switch to BRAF targeted therapy within the first three months of initiating immunotherapy to complete a total of 12 months of adjuvant treatment.</li> <li>Approval period: up to 12 months</li> </ol> <p><b><u>Melanoma – Advanced (Unresectable or Metastatic)</u></b></p> <ul style="list-style-type: none"> <li>For the treatment of patients with BRAF V600 mutation-positive unresectable or metastatic melanoma when used alone or in combination with dabrafenib.</li> </ul> <p><b><u>Clinical Notes:</u></b></p> <ol style="list-style-type: none"> <li>Patients must have an ECOG performance status of 0 or 1.</li> <li>If brain metastases are present, patients should be asymptomatic or have stable symptoms.</li> <li>Treatment should be discontinued upon disease progression or unacceptable toxicity</li> </ol> <p><b>Patients must apply for coverage under the High-Cost Drug Program.</b>  <b>If written by an oncologist, this medication does <u>not</u> require the submission of a Pharmacare Special Authorization form.</b></p>

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## Health PEI Formulary Drugs: Oncology

Drug	Dosage Form	Funding Program	Funded Eligibility Criteria
<b>Trastuzumab</b> Herceptin® Herzuma® Kanjinti® Ogivri® Trazimera®	Injection (vial) 150mg, 440mg	CTC Formulary	<p><b><u>Breast Cancer - Adjuvant and Neoadjuvant</u></b></p> <ul style="list-style-type: none"> <li>Treatment initiated in combination with or following adjuvant or neoadjuvant chemotherapy, for a total of 18 doses (every 3 week schedule) delivered within a time period not exceeding 14 months from initiation of therapy</li> </ul> <p><b><u>Breast Cancer – Metastatic</u></b></p> <ul style="list-style-type: none"> <li>First line treatment in combination with chemotherapy (taxane preferred) +/- pertuzumab in patients with de novo metastatic disease or for patients who relapse &gt; 6 months after receiving adjuvant trastuzumab therapy</li> <li>Maintenance treatment (+/- pertuzumab) after maximum response to initial combination chemotherapy and trastuzumab (+/- pertuzumab), continued until first disease progression</li> <li>Second line treatment option in combination with synergistic chemotherapy in patients that progress after a first line trastuzumab regimen</li> </ul> <p><b>Note:</b> Trastuzumab in combination with chemotherapy is considered a second line option in patients who experience disease relapse either during or within 6 months of completing adjuvant trastuzumab</p> <p><b><u>Gastroesophageal Cancer – Metastatic or Inoperable Locally Advanced</u></b></p> <ul style="list-style-type: none"> <li>In combination with capecitabine or intravenous 5-fluorouracil and cisplatin for the treatment of patients with HER2-positive metastatic or locally advanced (inoperable) adenocarcinoma of the stomach or gastro-esophageal junction who have not received prior anti-cancer treatment for their metastatic disease, followed by maintenance, single agent treatment until disease progression.</li> </ul>
<b>Trastuzumab deruxtecan</b> Enhertu®	Injection (vial) 100mg	CTC Formulary	<p><b><u>Breast Cancer – Unresectable Locally Advanced or Metastatic HER2-Positive</u></b></p> <p>As monotherapy, for the treatment of unresectable locally advanced or metastatic HER2- positive breast cancer in patients who have good performance status, and have either:</p> <ul style="list-style-type: none"> <li>Received at least 1 prior anti-HER2-based regimen (trastuzumab &amp; taxane) for unresectable locally advanced or metastatic disease, OR</li> <li>Experienced disease recurrence during or within 6 months of completing neoadjuvant or adjuvant treatment with an anti-HER2-based regimen (trastuzumab &amp; taxane).</li> <li>Patients must not have been treated with an anti-HER2 antibody-drug conjugate in the unresectable locally advanced or metastatic setting.</li> <li>Patients who were treated with an anti-HER2 antibody-drug conjugate for <i>early breast cancer (adjuvant)</i> may be eligible for trastuzumab deruxtecan (Enhertu) in the metastatic setting, provided there has been a minimum of 12 months from completion of adjuvant treatment, independent of disease progression.</li> </ul>
<b>Trastuzumab Emtansine (T-DM1)</b> Kadcyla®	Injection (vial) 100 mg, 160 mg	CTC Formulary	See Kadcyla®

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<b>Tretinoin</b> All trans retinoic acid, ATRA, Vesanoïd®, generic	Oral (capsule) 10 mg	Pharmacare <b>MQWN</b>	Open benefit if written by an oncologist upon notification to Pharmacare.  <b>Patients must apply for coverage under the High-Cost Drug Program.</b> <b>If written by an oncologist, this medication does <u>not</u> require the submission of a Pharmacare Special Authorization form.</b>
<b>Trifluridone &amp; Tipiracil</b> Lonsurf®	Oral (tablet) 15mg & 6.14mg, 20mg & 8.19mg	Pharmacare <b>MQWN</b>	<b><u>Gastrointestinal Cancer</u></b> For the treatment of adult patients with metastatic gastric cancer or adenocarcinoma of the gastroesophageal junction who meet the following criteria: <ul style="list-style-type: none"> <li>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.</li> <li>Patients should have a good performance status.</li> </ul> <b><u>Clinical notes:</u></b> <ul style="list-style-type: none"> <li>Trifluridine/tipiracil should be used in combination with best supportive care</li> <li>Treatment should be discontinued upon disease progression or unacceptable toxicity</li> <li>Requests will be considered for patients who have an intolerance or contraindication to platinum-based therapy</li> </ul> <b>Patients must apply for coverage under the High-Cost Drug Program.</b> <b>If written by an oncologist, this medication does <u>not</u> require the submission of a Pharmacare Special Authorization form.</b>
<b>Tucatinib</b> Tukysa®	Oral (tablet) 50mg, 150mg	Pharmacare <b>MQWN</b>	<b><u>Locally Advanced Unresectable or Metastatic HER2-Positive Breast Cancer</u></b> 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.  <b><u>Clinical Notes:</u></b> <ul style="list-style-type: none"> <li>Patients should have a good performance status.</li> <li>Treatment should be discontinued upon disease progression, unacceptable toxicity, or if both trastuzumab and capecitabine are discontinued.</li> </ul> <b>Prescriptions written by PEI oncologists do not require Special Authorization.</b> <b>Patients must apply for coverage by the High-Cost Drug Program.</b>

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<b>Vandetanib</b> Caprelsa®	Oral (tablet) 100mg, 300mg	Pharmacare <b>MQWN</b>	<p><b><u>Medullary Thyroid Cancer (MTC)</u></b> 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.</p> <p><b>Patients must apply for coverage under the High-Cost Drug Program. If written by an oncologist, this medication does <u>not</u> require the submission of a Pharmacare Special Authorization form.</b></p>
<b>Vemurafenib</b> Zelboraf®	Oral (tablet) 240 mg	Pharmacare <b>MQWN</b>	<p><b><u>Melanoma – Advanced (Unresectable or Metastatic)</u></b></p> <ul style="list-style-type: none"> <li>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 0 or 1. For BRAF V600 mutation positive patients who have progressed after first line treatment prior to vemurafenib availability, funding or vemurafenib as a second line agent may be considered.</li> </ul> <p><b>OR</b></p> <ul style="list-style-type: none"> <li>For use in combination with cobimetinib, for the treatment of patients with previously untreated BRAF V600 mutation-positive unresectable stage III or IV melanoma who have a good performance status. Treatment should continue until unacceptable toxicity or disease progression. If brain metastases are present, patients should be asymptomatic or have stable symptoms.</li> </ul> <p><b>Patients must apply for coverage under the High-Cost Drug Program. If written by an oncologist, this medication does <u>not</u> require the submission of a Pharmacare Special Authorization form.</b></p>

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Health PEI Formulary Drugs: Oncology

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<b>Venetoclax</b> Venclexta®  (cont'd on next page)	Oral (tablet) Starter pack, 10 mg, 50 mg, 100 mg	Pharmacare <b>MQWN</b>	<p><b><u>Chronic Lymphocytic Leukemia (CLL)</u></b></p> <p><b><u>Monotherapy:</u></b></p> <ul style="list-style-type: none"> <li>As monotherapy in patients with chronic lymphocytic leukemia (CLL) who have received at least one prior therapy and who have failed a B-cell receptor inhibitor (BCRi).</li> <li>Patients should have good performance status and treatment should be continued until disease progression or unacceptable toxicity.</li> </ul> <p><b><u>Combination therapy:</u></b></p> <ul style="list-style-type: none"> <li>As combination therapy with rituximab for the treatment of adult patients with chronic lymphocytic leukemia (CLL) who have received at least one prior therapy, irrespective of their 17p deletion status.</li> <li>Patients should be continued until disease progression or unacceptable toxicity up to a maximum of two years, whichever comes first.</li> </ul> <p><b><u>Clinical Notes:</u></b></p> <ul style="list-style-type: none"> <li>Patients currently receiving and responding to venetoclax monotherapy, but who have not achieved an adequate response are eligible to have rituximab added to venetoclax. The funded duration of venetoclax therapy from the point rituximab addition will be up to a maximum of 2 years.</li> <li>Patients may be re-treated with venetoclax plus rituximab if they responded to and completed two years of therapy with at least 12 months of progression-free interval.</li> <li>Patients with relapsed CLL will be eligible for sequencing venetoclax + rituximab and ibrutinib in second or third line settings, for either intolerance or disease progression, providing patients have not received prior treatment with either option and meet all other funding criteria.</li> </ul>

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<b>Venetoclax</b> Venclexta®  Venetoclax cont'd	Oral (tablet) Starter pack, 10 mg, 50 mg, 100 mg	Pharmacare <b>MQWN</b>	<p><b><u>VENETOCLAX WITH OBINUTUZUMAB FOR PREVIOUSLY UNTREATED CHRONIC LYMPHOCYTIC LEUKEMIA (CLL) OR SMALL LYMPHOCYTIC LYMPHOMA (SLL)</u></b></p> <ul style="list-style-type: none"> <li>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.</li> </ul> <p><b><u>Clinical Notes:</u></b></p> <ul style="list-style-type: none"> <li>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.</li> <li>Retreatment with a venetoclax based regimen is funded if relapse is greater than 12 months from completion of venetoclax in combination with obinutuzumab.</li> </ul> <p>Either ibrutinib or acalabrutinib is funded as a subsequent treatment option, provided all other funding criteria are met.</p> <p><b><u>VENETOCLAX WITH AZACITIDINE FOR NEWLY DIAGNOSED ACUTE MYELOID LEUKEMIA (AML)</u></b></p> <ul style="list-style-type: none"> <li>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.</li> </ul> <p><b><u>Clinical Notes:</u></b></p> <ul style="list-style-type: none"> <li>Treatment should continue until disease progression or unacceptable toxicity.</li> <li>All newly diagnosed AML patients who are ineligible for induction chemotherapy are eligible regardless of cytogenetic risk.,</li> <li>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.</li> </ul> <p><b><u>Claim Notes:</u></b></p> <ul style="list-style-type: none"> <li>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.</li> </ul> <p><b>Patients must apply for coverage under the High-Cost Drug Program.</b>  <b>If written by an oncologist, this medication does <u>not</u> require the submission of a Pharmacare Special Authorization form.</b></p>

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<b>Vinblastine</b>	Injection (vial)	CTC Formulary	Open benefit
<b>Vincristine</b>	Injection (vial) 2 mg/2 mL	CTC Formulary	Open benefit
<b>Vinorelbine</b>	Injection (vial) 50 mg/5 mL	CTC Formulary	<p><b><u>Breast Cancer – Metastatic</u></b></p> <ul style="list-style-type: none"> <li>One line of therapy as a single agent or within an approved combination regimen</li> </ul> <p><b><u>Non-Small Cell Lung Cancer (NSCLC) – Adjuvant</u></b></p> <ul style="list-style-type: none"> <li>Treatment of resected Stage IB, II or III disease In combination with Cisplatin</li> </ul> <p><b><u>Non-Small Cell Lung Cancer (NSCLC) – Advanced</u></b></p> <ul style="list-style-type: none"> <li>First line treatment in combination with platinum or Gemcitabine, or as a single agent as one line of therapy</li> </ul> <p><b><u>Gynecology</u></b></p> <ul style="list-style-type: none"> <li>Treatment of recurrent or progressive epithelial ovarian, fallopian tube or primary peritoneal cancer as a single agent after failure or contraindication to standard therapy</li> </ul>
<b>Vismodegib</b> Erivedge®	Oral (capsule) 150 mg	Pharmacare <b>MQWN</b>	<p><b><u>Basal Cell Carcinoma – locally advanced or metastatic</u></b></p> <ul style="list-style-type: none"> <li>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 OR</li> <li>As a single agent for the treatment of measurable metastatic basal cell carcinoma (BCC) Clinical</li> </ul> <p><b><u>Note:</u></b> 1. Patients must have an ECOG performance status of ≤2</p> <p><b><u>Clinical Note:</u></b> Vismodegib (Erivedge) is only available through a controlled distribution program called the Erivedge Pregnancy Prevention Program (EPPP). Under this program, only prescribers and pharmacies registered with the program are able to prescribe and dispense the product, respectively. In addition, Vismodegib can only be dispensed to patients who are registered and meet all the conditions of the EPPP.</p> <p><b>Patients must apply for coverage under the High-Cost Drug Program.</b>  <b>If written by an oncologist, this medication does <u>not</u> require the submission of a Pharmacare Special Authorization form.</b></p>

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<b>Zanubrutinib</b> Brukinsa®	Oral (capsule) 80mg	Pharmacare <b>MQWN</b>	<p><b><u>Chronic Lymphocytic Leukemia</u></b></p> <ol style="list-style-type: none"> <li>As monotherapy for adult patients with previously untreated chronic lymphocytic leukemia (CLL) / small lymphocytic lymphoma (SLL) for whom fludarabine-based treatment is inappropriate due to high-risk cytogenetic markers (i.e., del17p, TP53 mutation, or unmutated IGHV).</li> <li>As monotherapy for the treatment of adult patients with relapsed or refractory CLL / SLL who have received at least one prior systemic therapy.</li> </ol> <p><b><u>Clinical Notes:</u></b></p> <ol style="list-style-type: none"> <li>Patients must have a good performance status and no evidence of prolymphocytic leukemia or Richter's transformation.</li> <li>Treatment should be discontinued upon disease progression or unacceptable toxicity.</li> </ol> <p><b><u>Claim Notes:</u></b></p> <ul style="list-style-type: none"> <li>Requests will not be considered for patients who experience disease progression on a Bruton's tyrosine kinase (BTK) inhibitor or idelalisib.</li> </ul> <p><b><u>Waldenstrom Macroglobulinemia</u></b></p> <p>For the treatment of adult patients with relapsed or refractory Waldenstrom macroglobulinemia who have received at least one prior therapy and have not experienced disease progression on a Bruton's tyrosine kinase inhibitor.</p> <p><b><u>Clinical Notes:</u></b></p> <ol style="list-style-type: none"> <li>Patients must meet at least one criterion for treatment as per IWWM consensus panel.</li> <li>Patients must have a good performance status and no evidence of disease transformation.</li> <li>Treatment should be discontinued upon disease progression or unacceptable toxicity.</li> </ol> <p><b>Prescriptions written by PEI oncologists do not require Special Authorization. Patients must apply for coverage by the High-Cost Drug Program.</b></p>
<b>Zoledronic acid</b> Zometa®	Injection (vial) 4 mg/5 mL	CTC Formulary	<p>Approved for the following indications:</p> <ul style="list-style-type: none"> <li>Prevention of skeletal-related events in patients with metastatic castration-resistant prostate cancer with one or more documented bony metastases</li> <li>Treatment of patients with documented bone metastases from solid tumors (including breast cancer, lung cancer, renal cell carcinoma and other solid tumors)</li> <li>Tumor induced hypercalcemia</li> <li>Treatment of patients with multiple myeloma</li> </ul> <p><b><u>Note:</u> NOT approved for prevention or treatment of osteopenia or osteoporosis</b></p>

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