Health PEI

SPECIAL AUTHORIZATION REQUEST FOR COVERAGE OF HIGH COST CANCER DRUGS

(Filgrastim, Capecitabine, Imatinib, Dasatinib, Erolotinib, Sunitinib, Pazopanib, Fludarabine, Sorafenib, Crizotinib, Tretinoin, Nilotinib, Temozolomide, Lenalidomide)

Part 1 - Patient Information

PEI Pharmacare

Patient's Name (last name, first name, middle initial)

Provincial Health Number **Date of Birth** (DD/MM/YYYY) **Sex:** Male Female

When patient available, please complete: refer to FOIPP

I authorize the prescriber to release information to PEI Pharmacare related to this Special Authorization Request.

Patients Signature (optional): **Date:**

Part 2 - Physician Information (Must be requested & prescribed by specialist in hematology or medical oncology, or a general practitioner acting under direction of those specialists)

Name **Telephone #**

Mailing Address **Fax #**

The PEI Pharmacare Program may request additional documentation to support this Special Authorization Request.

Personal information on this form is collected under section 31(c) of Prince Edward Island's Freedom of Information & Protection of Privacy (FOIPP) Act as it relates directly to and is necessary for providing services under the PEI High Cost Drug Program. If you have any questions about this collection of personal information, you may contact the program office at 902-368-4947, toll free # 1-877-577-3737 or at the address below.

Physician's Signature: Date:

To send completed Special Authorization Request or to obtain further information, please contact:

High Cost Drug Program
PEI Pharmacare, Sullivan Building
P.O. Box 2000, 20 Fitzroy St.
Charlottetown, PE C1A 7N8
Telephone: 1-902-368-4947 Toll Free # 1-877-577-3737
Fax: 1-902-368-4905

Drug Program Use Only

Accepted for Coverage (state dosage and anticipated dosing frequency): _____

Rejected for Coverage (state reason): _____

Effective Date (DD/MM/YYYY) **Termination Date** (DD/MM/YYYY):

Continued on Page 2 (over)...

Please note that the patient must also complete a copy of the High Cost Drug Program application form and return it and all required financial information to the PEI Pharmacare Office.

SPECIAL AUTHORIZATION REQUEST FOR COVERAGE OF HIGH COST CANCER DRUGS - PAGE 2

The above named applicant meets the following medical criteria for coverage of the medication selected below (please check the relevant box)at the dosing regime specified:

FILGRASTIM (NEUPOGEN) - Coverage will be approved for a maximum of 12 months at one time.	
Indicate Dosing Regime (required):	
☐	**Chemotherapy Support** - For use in patients treated with curative intent, where maintaining maximal dose intensity is likely to improve the cure rate, and where the risk of neutropenic fever is greater than 20%.
☐	**Chemotherapy Support** - For use in patients treated with curative intent, after an episode of neutropenic fever or where treatment is delayed beyond one week due to neutropenia.
☐	**High Dose Chemotherapy With Stem Cell Support** - For use in mobilizing stem cells in preparation for stem cell collection.

CAPECITABINE (XELODA) - Coverage will be approved for a maximum of 12 months at one time.	
Indicate Dosing Regime (required):	
☐	**Breast Cancer Metastases** - For use in patients who have failed or are intolerant to intravenous drugs or for use in combination with intravenous drugs for aggressive, high risk disease. Patients must have an ECOG status of 0-2.
☐	**Colon Cancer Adjuvant** - For curative treatment after surgery, alone or in combination with intravenous drugs. Patients must have an ECOG status of 0-2.
☐	**Colon Cancer Metastases** - For use as a single agent or in combination with intravenous drugs.
☐	**Rectal Cancer Adjuvant** - For curative treatment before or after surgery, alone or in combination with intravenous drugs, or during radiotherapy treatment**.**

IMATINIB (GLEEVEC) - Coverage will be approved for a maximum of 12 months at one time.	
Indicate Dosing Regime (required):	
☐	**Chronic Myelogenous Leukemia (CML)** - For use in patients with Philadelphia chromosome positive (Ph+) chronic myeloid leukemia (CML) or who demonstrate hematologic relapse or cytogenetic progression after interferon-alfa (INF-a) therapy. Patients must have an ECOG status of 0-2.
☐	**Gastrointestinal Stromal Tumours (GIST)** - For use in patients with Kit positive (CD117), metastatic or locally advanced, inoperable gastrointestinal stromal tumours or adjuvant treatment due to intermediate to high risk of relapse following complete resection of Kit (CD117) positive GIST. Patients must have an ECOG status of 0-2.
☐	**Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ALL)** - 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.

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SPECIAL AUTHORIZATION REQUEST FOR COVERAGE OF HIGH COST CANCER DRUGS - PAGE 3

The above named applicant meets the following medical criteria for coverage of the medication selected below (please check the relevant box)at the dosing regime specified:

DASATINIB (SPRYCEL) - **Coverage will be approved for a maximum of 12 months at one time.**	
Indicate Dosing Regime (required):	
☐	**Chronic Myelogenous Leukemia (CML)** - For use as a single agent for the treatment of adults with chronic, accelerated or blast phase chronic myelogenous leukemia (CML)
☐	**Philadelphia Chromosome Acute Lymphoblastic Leukemia (Ph+ALL)** - For the treatment of adults with Philadelphia chromosome acute lymphoblastic leukemia (Ph+ALL) with resistance or intolerance to prior therapy.

EROLOTINIB (TARCEVA) - **Coverage will be approved for a maximum of 12 months at one time.**	
Indicate Dosing Regime (required):	
☐	**Non-Small Cell Lung Cancer** - 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 or unknown.

SUNITINIB (SUTENT) - **Coverage will be approved for a maximum of 12 months at one time.**	
Indicate Dosing Regime (required):	
☐	**Renal Cell Carcinoma** - 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: • Sunitinib may be a first line option. • Sunitinib may not be used after another tyrosine kinase inhibitor (i.e., sorafenib) as sequential therapy. 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.
☐	**Gastrointestinal Stromal Tumor (GIST)** - 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.

PAZOPANIB (VOTRIENT) – Coverage will be approved for a maximum of 12 months at one time.	
Indicate Dosing Regime (required):	
	Renal Cell Carcinoma
☐	As a first line treatment for patients with advanced or metastatic clear cell renal carcinoma and good performance status
☐	For use as a single agent treatment for advanced or metastatic clear cell renal carcinoma in patients who are unable to tolerate sunitinib and who have an ECOG performance status of 0 or 1

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The above named applicant meets the following medical criteria for coverage of the medication selected below (please check the relevant box)at the dosing regime specified:

FLUDARABINE (FLUDARA) - **Coverage will be approved for a maximum of 12 months at one time.**	
Indicate Dosing Regime (required):	
☐	**Chronic Lymphocytic Leukemia (CLL)** - For the treatment of chronic lymphocytic leukemia (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.

SORAFENIB (NEXAVAR) - **Coverage will be approved for a maximum of 12 months at one time.**	
Indicate Dosing Regime (required):	
☐	**Renal Cell Carcinoma** - 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: • Sorafenib may be a second line option only after cytokine therapy. • Sorafenib may not be used after another tyrosine kinase inhibitor (i.e., sunitinib) as sequential therapy. • 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**.**
☐	**Hepatocellular Carcinoma** - 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. Copies of the results must accompany the Special Authorization request.

CRIZOTINIB (XALKORI) – Coverage will be approved for a maximum of 12 months at one time.	
Indicate Dosing Regime (required):	
☐	**Non–small Cell Lung Cancer** - For use as second-line therapy for the treatment of patients with ALK-positive advanced non-small cell lung cancer (NSCLC) with ECOG performance status ≤2.

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The above named applicant meets the following medical criteria for coverage of the medication selected below (please check the relevant box)at the dosing regime specified:

TRETINOIN (VESANOID) - Coverage will be approved for a maximum of 12 months at one time.	
Indicate Dosing Regime (required):	
☐	**Acute Promyelocytic Leukemia** - In combination with arsenic trioxide (Trisenox) in the first-line setting as a treatment for the induction of remission and/or consolidation of low to intermediate risk acute promyelocytic leukemia (APL) and 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.

NILOTINIB (TASIGNA) - Coverage will be approved for a maximum of 12 months at one time.	
Indicate Dosing Regime (required):	
	Leukemia (CML, progressed or intolerant of imatinib) - 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:
☐	Patients with CML in chronic phase who are intolerant to oral tyrosine kinase inhibitors (TKIs) (i.e. imatinib or dasatinib or both)
☐	Patients with CML in chronic phase who are resistant to imatinib
☐	Patients with CML that have progressed to accelerated phase while on imatinib therapy

TEMOZOLOMIDE (TEMODAL) - Coverage will be approved for a maximum of 12 months at one time.	
Indicate Dosing Regime (required):	
☐	**Malignant glioma**

LENALIDOMIDE (REVLIMID) – Coverage will be approved for a maximum of 12 months at one time.	
Indicate Dosing Regime (required):	
☐	**Multiple Myeloma –** after a treatment failure or intolerant of current chemotherapy
☐	**Myelodysplastic Syndrome -** transfusion dependent anemia due to low or intermediate-1 risk MDS associated with a deletion 5q cytogenetic abnormality . I**nitial approval period is six months.**

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