

Bulletin #767

September 28, 2009

BENEFIT CHANGES TO NBPDP

This update to the New Brunswick Prescription Drug Program (NBPDP) Formulary is effective September 28, 2009.

Included in this bulletin:

- **Special Authorization Additions and Revised Criteria**

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If you have any questions, please contact our office at 1-800-332-3691.

Yours truly,



Debbie LeBlanc
New Brunswick Prescription Drug Program

SPECIAL AUTHORIZATION ADDITIONS

Dasatinib (Sprycel®)
20mg, 50mg, 70mg tablets

Acute Lymphoblastic Leukemia (ALL)

For adult patients with Philadelphia chromosome positive acute lymphoblastic leukemia (ALL) whose disease is resistant to imatinib-containing chemotherapy (patient must have tried 600mg/day) or have experienced grade 3 non-hematologic toxicity, or grade 4 hematologic toxicity persisting for more than 7 days as a result of therapy with imatinib.

Initial approval period: 1 year.

- Renewal criteria: Written confirmation that the patient has benefited from therapy and is expected to continue to do so.

Renewal period: 1 year.

Sorafenib (Nexavar®)
200 mg tablet

Advanced Hepatocellular Carcinoma (HCC)

For patients with Child-Pugh Class A* who have:

- A performance status of 0, 1, or 2[†] on the basis of the Eastern Cooperative Oncology Group (ECOG) criteria; and
- Either progressed on trans-arterial chemoembolization (TACE) or not suitable for the TACE procedure.
- Coverage may be renewed for patients with documentation of radiography and/or scan results indicating no progression

Initial approval period: 6 months

Approval period for renewal: 1 year

Sorafenib will not be reimbursed if used with induction or adjuvant intent along with other curative-intent treatments; for maintenance therapy after trans-arterial chemoembolization; or if patients have Child-Pugh B or Child-Pugh C cirrhosis.

*A Child-Pugh score of 5-6 is considered class A (well-compensated disease); 7-9 is class B (significant functional compromise); and 10-15 is class C (decompensated disease).

[†] Patients who are asymptomatic and those who are symptomatic and in bed less than 50% of the time.

Capecitabine (Xeloda®)
150 mg and 500 mg tablets

Metastatic Colorectal Cancer (mCRC)

As part of the CAPOX (capecitabine-oxaliplatin) regimen for the first-line and second-line treatment of mCRC for patients with an ECOG performance status of 0-2*.

* Patients who are asymptomatic and those who are symptomatic and in bed less than 50% of the time.

SPECIAL AUTHORIZATION – REVISED CRITERIA

Erlotinib (*Tarceva*[®])
100 mg and 150 mg tablets

Non-small Cell Lung Cancer (NSCLC)

For the treatment of patients with locally advanced or metastatic NSCLC after failure of at least one prior platinum-based chemotherapy regimen.

Initial approval period: 6 month trial.

Renewal criteria: Written confirmation that the patient has responded to treatment and in whom there is no evidence of disease progression.

Renewal period: 6 months

Sorafenib (*Nexavar*[®])
200 mg tablet

Metastatic Renal Cell Carcinoma (MRCC)

As second-line therapy for patients with histologically confirmed metastatic clear cell renal cell carcinoma, who:

- have disease progression after prior cytokine therapy (e.g. interferon; aldesleukin) within the previous 8 months; and
- have a performance status of 0 or 1 on the basis of the Eastern Cooperative Oncology Group (ECOG) criteria[†]; and
- have a favourable or intermediate risk status, according to the Memorial Sloan-Kettering Cancer Center (MSKCC) prognostic score.

Initial approval period: 1 year.

Renewal criteria: Written confirmation that the patient has benefited from therapy and is expected to continue to do so.

Renewal period: 1 year.

[†] Patients who are asymptomatic and those who are symptomatic but completely ambulant

Dasatinib (*Sprycel*[®])
20mg, 50mg, 70mg tablets

Chronic Myeloid Leukemia (CML)

For adult patients with chronic phase CML

- with primary or acquired resistance to imatinib 600mg per day. Dosing recommendation: 100mg per day or 70mg two times daily
- who progress to accelerated phase on imatinib 600mg per day. Dosing recommendation: 140mg per day
- who have blast crisis while on imatinib 600mg per day. Dosing recommendation: 140mg per day
- who have intolerance to imatinib or have experienced grade 3 or higher toxicities to imatinib

Initial approval period: 1 year

Renewal criteria: Request for renewal must specify how the patient has benefited from therapy and is expected to continue to do so.

Renewal period: 1 year