

Recommendations and Reasons

Committee to Evaluate Drugs (CED)

Dasatinib for acute lymphoblastic leukemia (ALL)

Product:

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

Class of drugs:

Anti-cancer agent; Tyrosine kinase inhibitor

Indication:

Treatment of acute lymphoblastic leukemia (ALL)

Manufacturer:

Bristol-Myers Squibb Canada

CED Recommendation

The CED recommended that dasatinib (Sprycel®) be funded through the Exceptional Access Program for the treatment of Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) according to specific criteria. The CED's recommendation was made on the basis that dasatinib offers a treatment option in Ph+ ALL patients who do not respond to, or are intolerant of, standard treatment.

Executive Officer Decision

Based on the CED's recommendation, the Executive Officer decided to fund dasatinib (Sprycel®) for the treatment of Ph+ ALL via the Exceptional Access Program according to specific criteria.

Status

Funded through the Exceptional Access Program.

Highlights of Recommendation:

- ◆ Dasatinib is an oral anti-cancer drug that can be used to treat the Philadelphia chromosome-positive subtype of acute lymphoblastic leukemia (Ph+ ALL).
- ◆ There are two key studies that assessed the use of dasatinib in the treatment of Ph+ ALL. Patients enrolled in these studies either had not responded to, or cannot tolerate the side effects of imatinib, a drug commonly used to treat this disease.
- ◆ In both trials, dasatinib treatment was given to all patients. Because dasatinib was not directly compared with a placebo or another active drug, no definitive conclusions can be drawn about its relative efficacy. However, the studies reported that a significant portion of patients showed a response to treatment. Patients in the studies also had a longer survival time than otherwise would be expected had they not received dasatinib.
- ◆ Prior to the availability of dasatinib, patients who do not respond to, or are intolerant of imatinib have no other treatment option aside from palliative care.
- ◆ The average daily cost for dasatinib is approximately \$150. It is difficult to assess the value for money for dasatinib. It is expected that the number of eligible patients for this treatment would be limited.
- ◆ **Overall, available evidence suggests that dasatinib provides clinical benefits in Ph+ ALL patients who cannot use imatinib, and it provides a treatment option to these patients who would otherwise have no other alternatives.**

Background:

Acute lymphoblastic leukemia (ALL) is an aggressive (fast-growing) type of blood cancer in which the body produces too many lymphoblasts (an immature type of white blood cell). Approximately 20 to 30 percent of adult patients with ALL have the Philadelphia chromosome-positive (Ph+) subtype of this disease. Patients with Ph+ ALL have a poor prognosis, low treatment response rates, a short remission duration, and poor survival.

Conventional treatment options for Ph+ ALL include chemotherapy and, in patients who are eligible, stem cell transplant.

Dasatinib belongs to a class of drugs called tyrosine kinase inhibitors, which prevents tumor growth by blocking important cellular enzymes.

continued...

Detailed Discussion:

- ◆ Data supporting the use of dasatinib in Ph+ ALL come from two studies in patients who have experienced intolerance or resistance to imatinib.
- ◆ There were no controlled patient groups in either of the two studies; all patients enrolled received dasatinib. Therefore, the actual incremental benefit provided by dasatinib could not be ascertained.
- ◆ More than a third of the patients in the trials had a major hematologic response (reduction in abnormal blood cells), and more than half of the patients had a major cytogenetic response (reduction in the number of cells with the abnormal Philadelphia chromosome). The median overall survival for patients in the studies was approximately eight months, which is longer than the usual survival time reported for patients in this setting.
- ◆ The average daily cost for dasatinib is approximately \$150. Based on the manufacturer's economic analysis, it is difficult to assess the cost-effectiveness of this drug.
- ◆ It is estimated that there are less than 25 patients annually in Ontario with Ph+ ALL who would require this drug.
- ◆ **Overall, the CED noted that dasatinib offers a therapeutic option for treating Ph+ ALL patients who are resistant or intolerant to imatinib.**
- ◆ The CED worked jointly with a subcommittee involving cancer experts to review this cancer drug, as it does for all cancer drug treatments.

EAP Funding Criteria:

Funding of dasatinib is considered via the Exceptional Access Program (EAP) according to the following criteria:

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

Cancer Care Ontario Information:

Information on Disease Site Evidence-based Series (EBS) and Practice Guidelines (PG):

<http://www.cancercare.on.ca/toolbox/qualityguidelines/diseasesite/>

Information on chemotherapy regimens:

<http://www.cancercare.on.ca/toolbox/drugs/drugformulary/>



Ministry of
Health and Long-Term Care
Ontario Public Drug Programs

For more information, please contact:

Ministry of Health and Long-Term Care

Ontario Public Drug Programs

Hepburn Block, 9th Floor

80 Grosvenor Street, Queen's Park

Toronto, Ontario M7A 1R3

or click: [http://www.health.gov.on.ca/](http://www.health.gov.on.ca/english/providers/program/drugs/ced_rec_table.html)

[english/providers/program/drugs/](http://www.health.gov.on.ca/english/providers/program/drugs/ced_rec_table.html)

[ced_rec_table.html](http://www.health.gov.on.ca/english/providers/program/drugs/ced_rec_table.html)