

Sunitinib (for GIST)

Product:

SUNITINIB (Sutent®)
12.5mg, 25mg, 50mg capsule

Class of drugs:

Multi-kinase inhibitor; anti-cancer agent

Indication:

Treatment of gastrointestinal stromal tumours (GIST)

Manufacturer:

Pfizer Canada Inc.

CED Recommendation

The CED recommended that sunitinib (Sutent) be funded through the Exceptional Access Program (EAP) for the treatment of metastatic gastrointestinal stromal tumour (GIST) according to specific criteria, on the basis that it appears to be an effective treatment for a rare disease.

Executive Officer Decision

Based on the CED's recommendation, the Executive Officer has decided to provide public funding for sunitinib (Sutent) for the treatment of unresectable and/or metastatic gastrointestinal stromal tumour (GIST) through the EAP.

Status

Funding available through the Ontario Public Drug Programs under the EAP, according to specific criteria.

Highlights of Recommendation:

- ◆ Sunitinib (Sutent) has been shown to be effective in treating GIST in patients who cannot have their tumour surgically removed or who have metastatic (advanced) disease.
- ◆ Results from a clinical trial show that sunitinib (Sutent) improves survival in patients with metastatic GIST in whom imatinib therapy is no longer effective.
- ◆ Patients with metastatic GIST who have tried and failed imatinib therapy may be prescribed sunitinib (Sutent) as second-line therapy.
- ◆ There are currently no recommended alternatives to sunitinib (Sutent) for second-line treatment of metastatic GIST.
- ◆ The cost of sunitinib (Sutent) therapy is close to \$7,000 per six-week cycle.
- ◆ **Overall, the CED noted that sunitinib (Sutent) appears to be an effective treatment for a rare disease. The CED also noted that patients with GIST who have failed or are intolerant to imatinib have no other treatment options.**
- ◆ The CED recommended funding sunitinib (Sutent) through the Exceptional Access Program for the treatment of unresectable and/or metastatic GIST according to specific clinical criteria. Please refer to the "Detailed Discussion" section for details of the criteria.
- ◆ The CED worked jointly with a subcommittee involving cancer experts to review this cancer drug, as is done for all other cancer drug treatments.

Background:

Gastrointestinal stromal tumour (GIST) is a rare, aggressive cancer.

The term "metastatic" describes a cancer that has spread to organs distant from the original tumor site. Metastatic GIST is the most advanced stage of the disease.

Studies show that GIST that cannot be removed by surgery or that has spread is usually not responsive to chemotherapy. Radiation therapy is also unsuitable for treating this type of disease.

Until recently, patients have usually been offered treatments that help with the symptoms of GIST. Currently, imatinib is the standard first-line treatment for this disease.

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Detailed Discussion:

- ◆ The manufacturer, Pfizer Canada Inc., asked the Ontario Ministry of Health and Long-Term Care to list sunitinib (Sutent) on the Ontario Drug Benefit (ODB) Formulary for the treatment of metastatic GIST.
- ◆ There is one randomized trial comparing sunitinib (Sutent) to placebo for treating metastatic inoperable or recurrent GIST that is intolerant or resistant to imatinib: Demetri GD et al. Efficacy and safety of sunitinib (Sutent) in patients with advanced gastrointestinal stromal tumour after failure of imatinib: a randomized controlled trial. *Lancet*. 2006;368:1329-3.
- ◆ The Committee noted that currently available data are from an interim analysis.
- ◆ The study showed a significant longer median time-to-progression (TTP) with sunitinib (Sutent) (27.3 vs. 6.4 weeks; hazard ratio (HR)=0.33; p<0.001).
- ◆ The median progression-free survival (PFS) was 24.1 weeks {95% CI 11.1-28.3} for sunitinib (Sutent), and 6.0 weeks [4.4-9.0] for placebo); HR=0.33; 95% C.I. (0.24-0.47); p<0.0001.
- ◆ The overall survival did not reach statistical significance, according to the level specified in the interim analysis.
- ◆ Fatigue, diarrhea, nausea, vomiting and anemia are the most common side effects of sunitinib (Sutent).
- ◆ Grades 3 and 4 hematological and non-hematological side effects were noted to be more common in the sunitinib (Sutent) group.
- ◆ Overall, although the data submitted consisted only of interim results, the Committee noted the impressive progression-free survival rates from the Demetri et al trial. The Committee recognized that patients with GIST who do not respond or cannot tolerate imatinib have no other treatment options. For these patients, sunitinib (Sutent) is a viable alternative.

- ◆ The CED recommended funding sunitinib (Sutent) for the treatment of GIST through the Exceptional Access Program, with the following criteria:
 - Sunitinib (Sutent) at a dose of 50 mg per day (4 weeks on, 2 weeks off), is a recommended treatment option in patients with c-KIT expressing (CD117+) unresectable or metastatic/recurrent GIST who demonstrate:
 - Early progression (within 6 months) while on imatinib
 - Progression following treatment with optimum (escalated) doses of imatinib (800 mg per day)
 - Intolerance to imatinib
 - Treatment should continue until progression or intolerance.
 - Such patients should also be encouraged to participate in appropriate clinical trials.

Cancer Care Ontario (CCO) Information:

Information on CCO chemotherapy regimens for GIST is available at: http://www.cancercare.on.ca/index_chemoRegimensbyDisease.htm

The Sarcoma Disease Site Group (DSG) Program in Evidence Based Care guideline for imatinib in GIST is available at:

http://www.cancercare.on.ca/index_sarcomaGuidelines.htm

CEDAC Recommendation:

(<http://www.cadth.ca/index.php/en/cdr/recommendations>)

The Canadian Expert Drug Advisory Committee (CEDAC) recommended that sunitinib (Sutent) be listed with criteria as treatment for GIST.



Ministry of
Health and Long-Term Care
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