

## **Record of Recommendation**

### **Re: Funding sunitinib (Sutent<sup>®</sup>) in Advanced Gastrointestinal Stromal Tumors (GIST)**

**January 9, 2008**

Discussion facilitated using the Decision Making Framework.

- All present will vote electronically when the vote is called by the chair. The voting process will be completed by 5 pm on January 24th. The decision will be made by a majority with dissenting voters given the opportunity to record their opinion. Dissenting opinions must be recorded within seven days of the result of the vote being announced.
- Core values and principles were reviewed and discussed along with competing obligations, constraints and relevant information.
- Options for a recommendation to the Deputy Minister were reviewed and each option was discussed. Two options were identified at this time:
  - 1) Approval of funding with restrictions
  - 2) Denial of funding
- An analysis of the projected benefits and burdens of each option was discussed.

Projected Benefits: as second line therapy in the treatment of Gastrointestinal Stromal Tumours (GIST)

- ✓ GIST is a disease in which rare mesenchymal stromal tumours arise in the GI tract.
- ✓ Surgery offers the only curative potential, however the recurrence of GIST is common and a majority of high-risk patients experience recurrence, with 2 years being the median time to recur.
- ✓ If surgery is not an option response rates with conventional chemotherapy are close to zero and highly resistant to radiotherapy. Prior to development of the tyrosine kinase inhibitors (TKI's), metastatic GIST was uniformly fatal within 1 –

- 2 years.
- ✓ Imatinib (Gleevec<sup>®</sup>), a TKI, is now the standard of care for GIST. Overall survival is 78% at a median follow-up of 2 years with more than 90% of pts achieving a partial response (PR) or stable disease (SD).
  - ✓ The dose of imatinib is 400 mg / day. When patients develop resistance to imatinib the dose is increased to 800 mg/ day with 33% of patients responding to the increased dose.
  - ✓ Sunitinib (Sutent<sup>®</sup>) is a multi-target/ broad-spectrum TK inhibitor, compared to imatinib (Gleevec<sup>®</sup>) which is highly selective and can be used in patients who have developed tolerance or are intolerant to imatinib.
  - ✓ Sunitinib has a different toxicity profile.
  - ✓ The median TTP and progression-free survival was increased more than four-fold in the sunitinib treatment arm vs. placebo (5.6 months versus 1.4 months) in patients who progressed or were intolerant to imatinib. Objective response rate (%PR) was 6.8 months in the sunitinib arm versus 0 in the placebo arm.
  - ✓ Sunitinib showed an acceptable safety profile with only 9% of patients discontinuing treatment due to non-fatal side effects vs. 8% of placebo patients.

#### Projected Burdens:

- ✓ The drug cost only per patient is approx. \$6947.92 per cycle (4 weeks on/ 2 weeks off).
- ✓ The estimated cost per quality adjusted life year is approx. \$ 79,884. However, the sensitivity analysis reveals a substantial variation in results with the best case scenario being \$42,801/QALY and worst case \$404,414/QALY.
- ✓ The budget impact is an estimated incremental increase of approx \$ 12,000 in the remainder of 2007/08, \$120,000 (4 patients) in 2008/09 and \$180,000 (6 patients) in 2009/10.

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#### Result of Vote:

The vote was conducted electronically. The question the Committee was asked to vote on is:

“Should the Committee support a recommendation to the Deputy Minister of Health to publicly fund Sunitinib (Sutent<sup>®</sup>) as a single agent for the treatment of Advanced GIST patients after failure of imatinib due to intolerance or resistance.

- **The result of the vote was a clear majority in favor of recommending funding. There were no dissenting opinions recorded.**

