

## **Record of Recommendation**

### **Re: Funding sunitinib (Sutent<sup>®</sup>) in Renal Cell Carcinoma (RCC)**

**November 14, 2007**

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 November 28th. 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 first line therapy in the treatment of Renal Cell Carcinoma (RCC)

- ✓ Metastatic RCC is incurable with a median survival of 9-12 months. Prior to 2005 RCC was chemotherapy resistant.
- ✓ Currently treatment is interferon with response rates between 10-15%. There is considerable toxicity and patients need to be quite well to tolerate the treatment.
- ✓ Interleukin-2 is also used but is not readily available in most provinces (closest is Montreal). Although it works well in 5-7% of patients there is no way to predict who will respond. There is a lack of Phase III clinical studies and toxicities are very high.
- ✓ Response rates increased from 6% to 31% when compared to interferon.

- ✓ Progression free survival increased from 5 months to 11 months compared to interferon.
- ✓ Quality of life was found to be superior to interferon.

Projected Burdens:

- ✓ The drug cost only per patient is approx. \$6947.92 per cycle (4 weeks on/ 2 weeks off) with a yearly cost of approximately \$55,000 per patient.
- ✓ The estimated cost per quality adjusted life year is approx. \$144,232 with a cost of \$104,831 per life year gained.
- ✓ The budget impact is an estimated incremental increase of approx \$1,100,000 in 2007/08, \$1,237,500 in 2008/09 and \$132,000 in 2009/10 based on 40, 45 & 48 patients respectively.

---

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 first line treatment in patients with documented evidence of histologically confirmed advanced or metastatic clear cell RCC who have an ECOG performance status of 0 or 1.

In any one patient, all of the following conditions must be met:

1. Sunitinib may be a first line option.
  2. Sunitinib may not be used after another tyrosine kinase inhibitor (i.e. sorafenib) as sequential therapy.
  3. 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.
- **The result of the vote was a majority in favor of recommending funding. There were no dissenting opinions recorded.**