

Record of Recommendation

Re: Funding sorafenib (Nexavar[®])

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 second 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 2% to 10% when compared to placebo.

- ✓ Progression free survival increased from 2.8 months to 5.5 months compared to placebo.
- ✓ Stable disease increased from 53% to 74% compared to placebo.
- ✓ Quality of life was found to be superior to interferon.

Projected Burdens:

- ✓ The drug cost only per patient is approx. \$5250.00 per month with a yearly cost of approximately \$31,500 per patient.
- ✓ The cost per life year gained is estimated at \$36,063. There was no estimate for cost per quality adjusted life year calculated. If a utility value of 0.7 (similar to Sunitinib (Sutent[®]) study) is used, the ICER per QALY rises to \$51,518.
- ✓ The budget impact is estimated to be an incremental increase of approx \$189,000 in 2007/08, \$220,500 in 2008/09 and \$252,000 in 2009/10 based on 12, 14 & 16 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 sorafenib (Nexavar[®]) As a single agent second line treatment in patients with documented evidence of histologically confirmed advanced or metastatic clear cell RCC, considered to be intermediate or low risk (according to Memorial Sloan-Kettering (MSKCC) prognostic score), have an ECOG performance status of 0 or 1 and progressed after prior cytokine therapy (or intolerance) within the previous 8 months. In any one patient, all of the following conditions must be met:

1. Sorafenib may be a second line option only after cytokine therapy.
 2. Sorafenib may not be used after another tyrosine kinase inhibitor (i.e. sunitinib) 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. sunitinib) may be allowed.
- **The result of the vote was a majority in favor of recommending funding. There were no dissenting opinions recorded.**

