

Record of Recommendation

Re: Funding Rituximab (Rituxan[®])

January 24, 2007

Discussion facilitated using the Decision Making Framework .

- Recognized constraints:
 - a. The list of comparators to use in the decision making process is still in active development.
- All present will vote electronically when the vote is called by the chair. The voting process will be completed by 5:00 pm on February 7, 2007. 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.
- There will be two recommendations going forward to the Deputy Minister:
 - 1) A recommendation on the use of Rituximab for first line treatment and the treatment of Rituximab-naïve patients who have been previously treated with chemotherapy.
 - 2) A recommendation on the use of Rituximab for the re-treatment of relapsed patients who have responded to therapy with Rituximab and maintained that response for one year or longer.
- Options for the recommendations 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 was discussed. This relates to the use of rituximab in first line treatment only. The data available to support the use of rituximab in re-treatment is Phase II retrospective data only and it is unlikely to become stronger because of the movement to using rituximab as maintenance therapy.

Projected Benefits (with Rituximab added to CVP versus CVP alone):

- ✓ An increase in median overall survival time of 6%
- ✓ An increase in median time to progression as a primary endpoint of 19 months (34 versus 15)
- ✓ An improvement in overall response rate over current treatment of 24% (81% versus 57%)
- ✓ Median duration of response 38 months versus 14 months
- ✓ No significant difference in toxicity reported although there have been some infusion related complications with rituximab

Projected Burdens:

- ✓ The estimated cost per quality adjusted life year is reported at \$35,753 based on the model provided by the drug company
- ✓ Drug cost only per person per median therapy duration is approx. \$23,120 for 8 cycles
- ✓ The annual budget impact is approx \$2,196,400 to treat the estimated 95 patients

Result of Vote:

- The vote was conducted electronically.

Question 1 - asked “should the committee recommend funding Rituximab for first line treatment and the treatment of Rituximab-naive patients who have been previously treated with chemotherapy.

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

Question 2 – asked “should the committee recommend funding Rituximab for the re-treatment of relapsed patients who have responded to therapy with Rituximab and maintained that response for one year or longer.

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

