

Record of Recommendation

Re: Funding Rituximab (Rituxan[®])

September 12, 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 September 26th. 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: The Van Oers Trial included low grade non-hodgkins lymphoma patients with an ECOG status of 0 -2 who relapsed after or were resistant to a maximum of 2 non-rituximab containing systemic chemotherapy regimens. These were not newly diagnosed patients who just received initial chemotherapy. Patients were inducted with either CHOP or rituximab plus CHOP for 6 cycles. Complete and partial responders were then randomized to observation only or rituximab maintenance therapy (given every 3 months for 2 years). Results showed:

- ✓ an increase in median 3 year overall survival time of 8%.
- ✓ an increase in median progression free survival of 36.6 months (51.5 versus 14.9).

- ✓ therapy is well tolerated.

The data was further analyzed in this trial looking at patients who had CHOP vs. rituximab plus CHOP as induction therapy. The results were the following:

- ✓ an increase in median progression free survival of 30.6 months (42.2 versus 11.6) in patients receiving CHOP as induction therapy versus observation.
- ✓ an increase in median progression free survival of 28.8 months (51.8 versus 23) in patients receiving CHOP-R as induction therapy versus observation.
- ✓ the median progression free survival was 42.2 months for patients who received maintenance therapy after induction with CHOP versus 51.8 months for patients receiving maintenance therapy after induction with CHOP + rituximab.

Projected Burdens:

- ✓ The estimated cost per quality adjusted life year is reported at approx. \$18,000 based on the model provided by the drug company.
- ✓ Drug cost only per person for a two year course is approx. \$23,000.
- ✓ The annual budget impact is approx \$400,000 in 2007/08, \$1,329,400 in 2008/09 and \$1,734,000 in 2009/10 and then would be expected to level out.

Result of Vote:

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

“should the committee recommend funding of rituximab (Rituxan[®]) as Maintenance Therapy for Low-Grade Non-Hodgkin’s Lymphoma (NHL) as a single agent in patients with documented evidence of CD20+ low-grade NHL (excluding SLL), with an ECOG performance status of 0-2, who have received rituximab within the previous six months either as a single agent or as part of multi-agent chemotherapy, responded to that therapy, have a recommendation and choose to receive maintenance therapy. Patients would only be eligible for rituximab maintenance following their first exposure to a rituximab based induction treatment regimen.”

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

