

Record of Recommendation

Re: Funding Bortezomib (Velcade[®])

November 8, 2006

Discussion facilitated using the Decision Making Framework.

- Recognized constraints:
 - a. Although there have been several new members appointed there are still vacancies on the committee.
 - b. 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 pm on November 15th. 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 burden of each option was discussed

Projected Benefits:

- ✓ an increase in median overall survival time of 6.1 months (14% greater one year survival)
- ✓ An increase in median time to progression as a primary endpoint of 2.7 months (6.2 versus 3.5)
- ✓ An improvement in overall response rate over current treatment of 25% (43% versus 18%)

- ✓ Median duration of response 7.8 months versus 5.6 months
- ✓ No significant difference in toxicity reported. Committee members did discuss the management of the adverse effects experienced with standard therapy (high dose dexamethasone) and felt that there may be an advantage with Velcade[®].

Projected Burdens:

- ✓ The estimated cost per quality adjusted life year is reported at \$48,850 however this is an underestimate based on the methodology. The cost per quality adjusted life year is most likely closer to \$100,000.
- ✓ Drug cost only per person per median therapy duration is approx. \$26,700 for 2nd line therapy and \$22,300 for 3rd line therapy.
- ✓ The annual budget impact is approx \$602,100 to treat the estimated 25 patients.

Result of Vote:

The vote was conducted electronically. The question asked was “should the committee recommend funding bortezomib (Velcade[®]) for the treatment second line and beyond of multiple myeloma?”.

- **The result of the vote was a clear majority in support of recommending funding. There were 15 votes cast. There were no dissenting opinions recorded.**

