

Record of Recommendation

Re: Funding bortezomib (Velcade[®]) for previously untreated multiple myeloma (in combination with melphalan and prednisone)

September 9, 2009

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 21, 2009. 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.

Background:

- ✓ Multiple myeloma is a malignancy of plasma cells which primarily affects older adults.
- ✓ For patients under 70 years of age, stem cell transplant is the preferred option, for those not eligible for stem cell transplant, initial therapy is usually with melphalan and prednisone.
- ✓ Bortezomib (Velcade[®]) is currently funded as a single agent for relapsed or refractory multiple myeloma, after other therapies have failed.
- ✓ Bortezomib has more recently been studied as a first line therapy for patients who are not eligible for stem cell transplant.

- ✓ The VISTA trial is a large phase III randomized controlled trial which compared bortezomib/melphalan/prednisone (VMP) to melphalan/prednisone (MP) in newly diagnosed multiple myeloma patients.

Projected Benefits:

- ✓ Patients receiving VMP therapy versus MP therapy had improvements in several measures of response, including time to progression (24 months versus 16.6 months), progression-free survival and overall survival (3year: 72% versus 59%) and improved time to next treatment (28 months versus 19 months).

Projected Burdens:

- ✓ Bortezomib costs approximately \$57,980 for 9 cycles of therapy.
- ✓ Funding in the first line setting (for an estimated 15 patients) will require incremental funding of up to \$800,000 per year.
- ✓ The manufacturer estimates a cost per life year gained of \$44,526 and a cost per QALY of approximately \$56,488.

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 fund bortezomib (Velcade[®]) in combination with melphalan and prednisone (VMP) for the treatment of patients with previously untreated multiple myeloma who are unsuitable for stem cell transplant.

This is in addition to the previously approved indication as a single agent in the second line and beyond setting of refractory or relapsed multiple myeloma.

- **The result of the vote was a majority in favor of recommending funding.**

This recommendation has been accepted by the Deputy Minister of Health.