

## **Record of Recommendation**

### **Re: Funding lenalidomide (Revlimid<sup>®</sup>) in Multiple Myeloma**

**January 14, 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 January 22, 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 (MM) is a hematological malignancy of the plasma cells.
- ✓ For eligible patients, therapy includes an analogous stem cell transplant (ASCT) which can provide an overall survival of 48-60 months. ASCT is not a cure for MM and eventually all patients relapse and require additional therapy.
- ✓ Conventionally, patients not eligible for ACTS are treated with a regimen of melphalan and prednisone which can provide an overall survival of 30-36 mos.
- ✓ Other therapies available include dexamethasone, cyclophosphamide plus prednisone, thalidomide +/- steroids
- ✓ Bortezomib (Velcade<sup>®</sup>) is a relatively new therapy for MM and was approved for funding in Nova Scotia in 2007.
- ✓ There is no cure for MM however new approaches to therapy have changed the course of the disease with many patients living years after diagnosis.

- ✓ Lenalidomide (Revlimid®) is a new therapy for MM that is related to the drug thalidomide.

Projected Benefits:

- ✓ Two phase III studies (MM 009 and 010) show that lenalidomide plus dexamethasone is superior to dexamethasone therapy alone in terms of overall response rate, median duration of response, median time to progression and median overall survival (29.6 months versus 20.2 months and not reached versus 20.6 months)
- ✓ A subsequent intention to treat (ITT) pooled analysis of Studies 009 and 010 shows a median survival of 35 months versus 31 months. Approximately 47% of patients in the dexamethasone plus placebo group had ‘crossed-over’ to receive active treatment with lenalidomide, which can obscure the true difference in treatment effect.
- ✓ With the exception of dexamethasone, the benefits of lenalidomide versus other standard therapies in the treatment of MM has not been studied.

Projected Burdens:

- ✓ The most frequently reported adverse events include neutropenia, muscle cramps, constipation, diarrhea, nausea, tremor, dizziness, fatigue, insomnia and infection
- ✓ The manufacturer’s economic analysis suggests a cost per life year gained (LYG) of \$55,938 and a cost per quality adjusted life year (QALY) of \$81,559. Limitations to the analysis, including the use of a 30 year time horizon, suggest a higher cost per QALY.
- ✓ The estimated number of patients that would be treated per year is 10-11 with a predicted budget impact of approximately \$1,000,000.

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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 lenalidomide in combination with dexamethasone in adult patients with progressive MM after at least one previous treatment, not resistant to dexamethasone, documented measurable disease and an ECOG performance status of 0 – 2.”

- **The result of the vote was a majority in favor of not recommending funding.**