

## **Record of Recommendation**

### **Re: Funding Pemetrexed (Alimta<sup>®</sup>) for the treatment of Non-Small Cell Lung Cancer (NSCLC)**

**March 9, 2011**

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 March 18, 2011. 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:**

- ✓ Lung cancer is the second most common type of cancer in both men and women (second to prostate and breast cancer) however it accounts for the highest number of deaths in both sexes. Most lung cancer (approximately 85%) is non-small cell (NSCLC) type.
- ✓ Pemetrexed (Alimta<sup>®</sup>) has been studied in NSCLC as a first line therapy, as a second line therapy and as maintenance therapy in patients who have not progressed after first line therapy. Subgroup analysis have been conducted on patients with non-squamous histology.

#### **Projected Benefits:**

- ✓ In the first line setting for patients with non-squamous cell NSCLC, overall survival with cisplatin/pemetrexed is improved versus cisplatin/gemcitabine (OS 11 months versus 10.1 months; PFS 5.26 months versus 4.96 months).
- ✓ As a second line therapy in patients with non-squamous histology, therapy with pemetrexed versus docetaxel improves OS (9.3 versus 8.0 months) and PFS (2.7 months versus 2.3 months).
- ✓ As maintenance therapy versus placebo for patients with non-squamous histology who had completed four cycles of initial therapy without progression, median overall survival was improved (15.5 versus 10.3 months).
- ✓ Pemetrexed is easier to infuse than other alternatives such as a taxane and is associated with fewer grade 3 or 4 hematological toxicities and all grade alopecia than gemcitabine. Versus docetaxel in the second line setting, pemetrexed is associated with less neutropenia and associated complications as well as less alopecia.

Projected Burdens:

- ✓ Grade 3 or 4 nausea was higher with cisplatin/pemetrexed than cisplatin/gemcitabine in the first line setting. In the maintenance setting versus placebo, grade 3 or 4 toxic events are more common with pemetrexed therapy.
- ✓ The estimated budget impact of pemetrexed therapy would be \$341,775 for 35 patients in 2011/12, \$427,770 for 44 patients in 2012/13 and \$485,100 for 50 patients in 2013/14.

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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 pemetrexed:

1. In combination with cisplatin as a **first line treatment option** in patients with advanced or metastatic NSCLC with non-squamous histology who have an ECOG performance status of 0-2.
2. As a single agent **second line treatment option** in patients with advanced or metastatic NSCLC with non-squamous histology who have an ECOG performance status of 0-2 after failure of only one prior line of therapy.
3. As a **single agent maintenance therapy option** in patients with advanced or metastatic NSCLC with non-squamous histology immediately following a non-pemetrexed containing first line platinum doublet who have an ECOG performance status of 0-2 and have achieved clinical benefit (tumor response or stable disease) from first line therapy.

In any one patient, only **one** of these options may be used during the course of therapy for the treatment of advanced or metastatic NSCLC.

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