

## **Record of Recommendation**

### **Re: Funding pemetrexed (Alimta<sup>®</sup>)**

**October 17, 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 October 31st. 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: Surgery is not an option in Stage III or IV NSCLC.

- ✓ The median survival time in a patient with Stage IV NSCLC who is untreated is 4 months (10% 1 year survival). The median survival for a patient treated with older drug regimens increases to 6 months (20% 1 year survival) and further increases to 8 months with some of the newer regimens (35% 1 year survival).
- ✓ First line chemotherapy is a cisplatin/carboplatin-based combination with either paclitaxel gemcitabine, vinorelbine or docetaxel with a median survival of 8 months and median overall survival of 32% at 1 year and 12% at 2 years.
- ✓ Pemetrexed (Alimta<sup>®</sup>) is indicated as a second line chemotherapy in NSCLC. In studies it has shown to have similar efficacy to docetaxel in response rate, progression free survival and overall survival.

- ✓ Pemetrexed has a different toxicity profile than docetaxel (a taxane) with less neutropenia, alopecia, peripheral neuropathy, and diarrhea.
- ✓ Pemetrexed is less labour intensive to administer than taxanes. Studies have not shown a difference in quality of life (QoL).

Patients on pemetrexed must take folic acid and receive Vitamin B12 injections to minimize toxicities. Studies have not shown a difference in quality of life (QoL). It is more expensive than docetaxel so the site team is recommending it be reserved for use in patients with advanced or metastatic NSCLC who have experienced peripheral neuropathy after first line taxane or vinorelbine based chemotherapy, patients at high risk of developing peripheral neuropathy, i.e. diabetes, underlying neurological problems – including paraneoplastic syndromes and patients unable to receive docetaxel due to administrative issues.

#### Projected Burdens:

- ✓ Patients on pemetrexed must take folic acid and receive Vitamin B12 injections to minimize toxicities.
- ✓ The estimated cost per quality adjusted life year is approx. \$63,000 versus docetaxel (q21d regimen) based on a cost minimization strategy.
- ✓ Drug cost only per person is approx. \$3646.50 per treatment with an average of 4 treatments per patient
- ✓ The budget impact (based on the company proposal) is an incremental increase of approx \$89,700 in 2007/08, \$112,150 in 2008/09 and \$134,500 in 2009/10 based on 20, 25 & 30 patients respectively.

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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 publicly fund pemetrexed as a single agent second line treatment in patients with advanced or metastatic NSCLC who have an ECOG performance status of 0-2, where docetaxel is not recommended for one of the following reasons:

1. The patient exhibits peripheral neuropathy after first line platinum based therapy.
2. The patient is at high risk of developing peripheral neuropathy (e.g. diabetes, underlying neurologic problems, neurologic paraneoplastic syndromes).
3. Patients who developed severe hypersensitivity reactions to taxane therapy.
4. Significant administrative issues exist (e.g. patient unable to receive docetaxel in another district).

In any one patient, only one of these options (i.e. docetaxel or pemetrexed) may be used.”

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

