

Record of Recommendation

Re: Funding Aprepitant (Emend[®]) as Antiemetic Therapy with Highly Emetogenic Cancer Chemotherapy

September 12, 2008

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 19, 2008. 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:

- ✓ Chemotherapy induced nausea and vomiting (CINV) is related to the properties of the chemotherapeutic agent used as well as the dose used and therapies can be classified as having minimal, low, moderate or high risk emetic potential.
- ✓ Aprepitant is the first antiemetic that is a neurokinase-1 receptor antagonist.
- ✓ Aprepitant is used in combination with 5-HT₃ antagonists (e.g. ondansetron) and dexamethasone, which are standard treatments currently used in the prevention of CINV.
- ✓ Four trials were reviewed examining the primary outcome of complete response i.e. no vomiting and no rescue medications. Three of these studies involved high dose cisplatin (>70mg/m²) which is highly emetogenic.

Projected Benefits: in patients receiving highly emetogenic chemotherapy consisting of

high dose cisplatin therapy:

- ✓ The addition of aprepitant was more effective than standard therapy in achieving complete response (no vomiting or rescue medications).
- ✓ Improvements in quality of life were observed with the use of aprepitant.

Projected Burdens:

- ✓ Aprepitant is generally well tolerated but can cause dyspepsia and fatigue.
 - ✓ There are potential drug interactions with aprepitant.
 - ✓ The cost of aprepitant is approximately \$90.54 per cycle of chemotherapy based on patients receiving three doses of aprepitant only per cycle.
 - ✓ The budget impact based on a median of 4 cycles of chemotherapy per patient and 65 patients is expected to be approximately \$25,000 per year.
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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 aprepitant: In combination with a 5-HT₃ antagonist and dexamethasone in adult cancer patients treated with chemotherapy that includes cisplatin as a single day therapy greater than or equal to 70mg/m² to prevent acute and delayed nausea and vomiting. Aprepitant may be considered as an option at the onset of cisplatin-based therapy ($\geq 70\text{mg/m}^2$) and commence with the first cycle of this HEC. In any one patient, the following criteria include:

1. Aprepitant will only be used with single day cisplatin-based therapy $\geq 70\text{mg/m}^2$ (and not multiple day cisplatin chemotherapy).
2. Aprepitant will not be used in patients receiving moderately emetogenic cancer chemotherapy or radiotherapy.
3. The 5-HT₃ antagonist should only be used on the first day of cisplatin therapy with aprepitant continuing on Day 2 and Day 3.
4. The dose of dexamethasone may be adjusted due to the increased levels of dexamethasone when combined with aprepitant.”

Since aprepitant (Emend®) is an oral drug, funding would be through the Nova Scotia Pharmacare Programs.

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