

## **Record of Recommendation**

### **Re: Funding nab-paclitaxel (Abraxane<sup>®</sup>) in the Treatment of Metastatic Breast Cancer.**

**March 10, 2010**

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 19, 2010. 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:**

- Taxanes, which includes paclitaxel and docetaxel, are important drugs in the treatment of metastatic breast cancer.
- Both paclitaxel and docetaxel are associated with significant toxicities such as alopecia, fatigue, nail changes, myelosuppression, neuropathy and hypersensitivity reactions. Patients are pre-treated for hypersensitivity reactions, but they are still a concern and physicians are required on-site during administration.
- Taxanes are highly hydrophobic and the vehicles used to deliver the medications are responsible for some toxicities such as hypersensitivity reactions and fluid retention.
- In nab-paclitaxel, the paclitaxel is bound to nanoparticles of albumin and delivered in a cremophor-free formulation. This formulation requires less time for administration, is associated with only rare hypersensitivity reactions and has less frequent and less severe myelosuppression and peripheral neuropathy.

**PROJECTED BENEFITS:**

- In a phase III study, nab-paclitaxel was more effective than regular paclitaxel in a q 3 week regimen in terms of response rate and time to progression, and a non-significant trend to greater median overall survival.
- In phase II study, nab-paclitaxel was associated with an increase in progression free survival versus docetaxel (statistically significant with weekly paclitaxel dosing).
- Nab-paclitaxel is associated with fewer hypersensitivity reactions, less severe myelosuppression and peripheral neuropathy, and requires less time for administration.
- Nab-paclitaxel can be provided in community hospitals, allowing treatment closer to patients' homes.

**PROJECTED BURDENS:**

- Nab-paclitaxel shares side effects associated with other taxanes. However, there is a reduction in important side effects such as hypersensitivity reactions and myelosuppression.
- Nab-paclitaxel will replace therapies already funded, with minimal overall budget impact.

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 nab-paclitaxel as a single agent treatment option in a q3 week schedule (as first, second, or third line therapy) for patients with metastatic breast cancer who have an ECOG performance status of 0 to 2 and who choose to receive systemic chemotherapy. Nab-paclitaxel in the adjuvant setting is currently not recommended.

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- **The result of the vote was a majority in favor of recommending funding.**
  - **The Deputy Minister has accepted this recommendation and funding provided.**