

## **Record of Recommendation**

### **Re: Funding Docetaxel/Cyclophosphamide (TC) as Adjuvant Therapy in Operable Invasive Breast Cancer**

**April 9, 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 April 23rd. 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:** Projected benefits of docetaxel in combination with cyclophosphamide as an adjuvant therapy option in patients who have operable invasive breast cancer (Stage I-III).

- The results of a randomized open label two arm Phase III multicentre trial studying TC (docetaxol/cyclophosphamide) versus AC (doxorubicin/cyclophosphamide) in patients with Stage I to III operable invasive breast cancer patients with complete surgical excision of the primary tumour found at 5 year follow-up that TC was associated with superior disease free survival (DFS) 86% versus 80% and overall survival (OS) 90% versus 87% compared to the previous standard AC chemotherapy.

- The same study at 7 year follow-up found a DFS rate of 81% versus 75% and an OS rate of 87% versus 82%.
- More nausea and vomiting occurred on the AC arm (grade 1 to 4,  $p < 0.01$ ). In the AC group, one patient died from congestive heart failure (CHF) and four died from myocardial infarction (MI) versus two patients in the TC arm.
- With further follow-up at 7 years, 3 additional long term related fatalities were observed in the AC arm consisting of CHF, myelodysplastic syndrome and myelofibrosis.

**PROJECTED BURDENS:**

- More grade 1 and 2 myalgias, arthralgias, edema ( $p < 0.01$ ), and febrile neutropenic events (6% versus 12%) occurred on the TC arm.
- The cost of treatment with TC is approximately \$6,587 compared to AC at \$1,298.
- The estimated cost per quality adjusted life year is approx. \$ 16,611.
- The budget impact is expected to result in an increase of \$224,600 (to treat 40 patients 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 publicly fund docetaxel in combination with cyclophosphamide (TC) as an adjuvant therapy option in patients who have documented evidence of Stage I to Stage III operable invasive breast cancer with complete surgical excision of the primary tumour who are candidates for systemic chemotherapy for low – moderate risk disease.”

- **The result of the vote was a clear majority in favor of recommending funding. 15 votes were cast with one abstention. There were no dissenting opinions recorded.**

