

Record of Recommendation

Re: Funding Oxaliplatin as Adjuvant Chemotherapy (FOLFOX Regimen) for Completely Resected Stage III Rectal Cancer

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:

- ✓ The FOLFOX chemotherapy regimen includes a combination of folinic acid (FOL), fluorouracil (F) and oxaliplatin (OX).
- ✓ Oxaliplatin (Eloxatin[®]) use in the FOLFOX chemotherapy regimen had previously been reviewed by CSTPC in June 2007.
- ✓ The review in 2007 was based on the results of the MOSAIC trial. The MOSAIC trial used the FOLFOX regimen as adjuvant therapy for patients with completely resected colon cancer. Rectal cancer patients were not included in the MOSAIC trial.
- ✓ Based on the results of the MOASAIC trial, funding was approved for completely resected stage III colon cancer patients. Now available six year survival data indicates an increase in overall survival for these patients (72.9% versus 68.7%).

- ✓ Rectal cancer patients were not included in the MOSAIC trial and it is unlikely that any large-scale similar trials will be completed for rectal cancer patients. Many Canadian centers are now funding oxaliplatin as adjuvant therapy for rectal cancer patients.
- ✓ Use and funding of the FOLFOX regimen in rectal cancer patients is based on an assumption that they will benefit to a similar degree as colon cancer patients, based on similarities in anatomy and histology. There is also evidence in patients with metastatic disease that the use of oxaliplatin benefits both colon and rectal patients.
- ✓ Rectal cancer patients are treated with radiation before surgery to reduce the likelihood of local recurrence whereas colon cancer patients are not. It is not known whether this difference in treatment pre-surgery will affect the benefit seen with the addition of oxaliplatin therapy post surgery.

Projected Benefits:

- ✓ The use of oxaliplatin (FOLFOX) therapy specifically in rectal cancer patients has not been studied in a clinical trial. If it is assumed that the benefit will be similar to stage III colon cancer patients in the MOSAIC trial, an increased rate of overall survival would be expected.

Projected Burdens:

- ✓ Oxaliplatin costs approximately \$11,560 for 16 weeks of therapy.
- ✓ The projected budget impact of using FOLFOX therapy as adjuvant therapy for stage III rectal cancer is \$346,800 (30 patients) in 2011/12, \$381,480 (33 patients) in 2012/13 and \$404,600 (35 patients) in 2013/14.

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 oxaliplatin in combination with 5-FU/LV infusional based chemotherapy (FOLFOX) as adjuvant therapy in patients who have documented evidence of completely resected stage III rectal cancer, with an ECOG performance status of 0-2, for whom adjuvant chemotherapy would be recommended”

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