



Re: Funding Cetuximab (Erbitux[®]) in Treatment of Metastatic Colorectal Cancer

June 24, 2009

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 July 6, 2009. 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:

- ✓ Colorectal cancer is responsible for approximately 9000 deaths per year in Canada, 370 in Nova Scotia.
- ✓ Colorectal cancer that has metastasized is not considered curable however newer treatments and strategies have increased average survival to over 20 months versus an expected 6-8 months without treatment.
- ✓ Standard first line and second line therapy for mCRC is the FOLFIRI followed by FOLFOX or vice versa with bevacizumab (Avastin[®]) added in combination with either first or second line therapy.
- ✓ Monoclonal antibody drugs such as cetuximab and panitumumab target epidermal growth factor receptors (EGFR) and represent potential third line therapies.

Projected Benefits:

- ✓ In an open label phase III randomized trial, cetuximab as a third line therapy plus best supportive care was compared to best supportive care alone.
- ✓ In a sub-analysis of patients who have wild- type KRAS (a small protein involved in EGFR signaling cascade), cetuximab treatment was associated with an increase in median overall survival (9.5 versus 4.8 months) and median progression free survival (3.7 versus 1.9 months).
- ✓ The effectiveness of cetuximab in patients who have a mutated KRAS is not significant, so patients are tested before treatment to determine whether they have mutant or wild-type KRAS
- ✓ Cetuximab treatment was associated with a positive effect on quality of life, with less physical deterioration and superior global and physical health at 8 and 16 weeks.

Projected Burdens:

- ✓ Side effects of cetuximab include rash, hypomagnesiumia (rare but serious) and allergies.
 - ✓ The manufacturer's budget impact analysis does not provide a comparison of cetuximab plus best supportive care versus best supportive care alone which was the design of the clinical trial evidence reviewed.
 - ✓ A committee estimation of the cost per life year gained (LYG) versus supportive care is approximately \$132,724 and the cost per quality adjusted life year (QALY) is approximately \$199,087.
 - ✓ The cost of cetuximab therapy is approximately \$24,000 per patient (based on 16 weeks of therapy). With an estimated 30-34 patients per year, the budget impact would be approximately \$800,000 per year.
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Result of Vote:

The vote was conducted electronically. The question the Committee was asked to vote on was:

“Should the Committee support a recommendation to the Deputy Minister of Health to fund cetuximab (Erbitux[®]) as a single third line agent in patients with documented evidence of progressive mCRC (following standard fluoropyrimidine, irinotecan and oxaliplatin based chemotherapy with or without bevacizumab), confirmed KRAS gene wild type only, and ECOG performance status 0 – 2.”

- **The result of the vote was a majority in favor of not recommending funding.**