



Re: Funding Cetuximab (Erbix[®]) in Treatment of Squamous Cell Carcinoma of the Head and Neck

February 25, 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 March 9, 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:

- ✓ Squamous cell carcinoma is the most common cause of head and neck cancers.
- ✓ In 2008, approximately 150 cases of squamous cell carcinoma of the head and neck (HNSCC) were diagnosed in Nova Scotia with >50% being locally advanced at the time of diagnosis.
- ✓ Standard therapy is surgery if the tumor is resectable or radiotherapy plus cisplatin.
- ✓ Cetuximab is a chemotherapeutic agent which competitively binds epidermal growth factor receptor (EGFR).

Projected Benefits:

- ✓ In locally advanced, non metastatic HNSCC patients, cetuximab plus radiotherapy was superior to radiotherapy alone in terms of overall survival, duration of locoregional control, progression free survival and overall all response rate in a group of patients who were treated with curative intent.
- ✓ At 54 month follow up, overall survival was 49 months versus 29.3 months with radiotherapy alone. Survival rates at three years increased from 45% to 55% and at five years, increased from 36% to 46%.

Projected Burdens:

- ✓ Side effects of cetuximab plus radiotherapy are similar to radiotherapy alone with the exception of infusion reactions (15% versus 2%) and rash (87% versus 10%). Other trials suggest some cardiac toxicity with cetuximab (2% arrest) and more severe infusion reactions (3%).
- ✓ Economic analysis has indicated a cost per LYG of \$18,591 with a cost per QALY of \$19,740. The cost of cetuximab therapy is approximately \$12,250 per patient (based on 8 weeks of therapy). With an estimated 15 patients per year, the budget impact is expected to be approximately \$185,000 per year.

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 (Erbix[®]) in combination with radiotherapy as first line therapy in patients with documented evidence of histologically confirmed locally advanced, non-metastatic HNSCC including oropharynx, hypopharynx or larynx who are unsuitable for concurrent cisplatin based chemotherapy.

In any one patient, the following conditions for unsuitability may include renal insufficiency, peripheral neuropathy, high risk of developing peripheral neuropathy (e.g. diabetes, underlying neurologic problems, hearing loss, co-morbid conditions, weight loss > 10% baseline body weight.

Cisplatin based chemoradiotherapy will remain the standard of care in the locally advanced HNSCC patient population. Cetuximab in combination with radiotherapy may be considered in patients unsuitable for cisplatin based chemoradiotherapy with ECOG of 0-2 and who wish to receive systemic therapy.”

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