

Record of Recommendation

Re: Funding Oxaliplatin (Eloxatin[®])

June 13, 2007

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 June 27th. 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 burden of each option was discussed.

Adjuvant Therapy- intent of therapy is curative

Projected Benefits:

Stage II — no significant difference when comparing 5FU/LV to 5FU/LV/Oxaliplatin for:

- ✓ Disease Free Survival- 79.9% vs 83.7%
- ✓ Overall Survival – 86.8% vs 86.8%

Stage III - significant difference when comparing 5FU/LV to 5FU/LV/Oxaliplatin for:

- ✓ Disease Free Survival- 58.9% vs 66.4%
- ✓ Overall Survival – 68.3% vs 72.9%

In all patients (Stage II & Stage III combined) Disease Free Survival was significant 67.4% vs 73.3% and Overall Survival was not significant 75.8% vs 78.5%.

The major significant toxicity is cold induced neuropathy. It has less nausea and renal toxicity than cisplatin and does not require pre-hydration.

Projected Burdens:

- ✓ The estimated cost per quality adjusted life year is reported at \$24,104 in Stage III. There is no PE data for Stage II.
 - ✓ Drug cost only per person per median therapy duration is approx. \$18,000.
 - ✓ The annual budget impact is approx. \$1.5 million in Year 1, \$1.6 million in Year 2 and \$1.7 million in Year 3 for 85, 90 & 95 patients respectively.
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Result of Vote:

- The vote was conducted electronically. The questions asked were:
 - 1) “should the committee recommend funding oxaliplatin (Eloxatin[®]) in combination with 5-FU/LV infusional based chemotherapy (FOLFOX) as adjuvant therapy in patients who have documented evidence of completely resected stage III colon cancer, with an ECOG performance status of 0-2 for whom adjuvant chemotherapy would be recommended.”
 - The result of the vote was a clear majority in favor of recommending funding. There were no dissenting opinions recorded. There were 20 votes cast with one submission failure.
 - 2) “should the committee recommend funding oxaliplatin (Eloxatin[®]) in combination with 5-FU/LV infusional based chemotherapy (FOLFOX) as adjuvant therapy in a select group of high risk patients who have documented evidence of completely resected stage II colon cancer, with an ECOG performance status of 0-2 for whom adjuvant chemotherapy would be recommended. This would include stage II patients with T4 lesions, inadequately sampled nodes, perforation or poorly differentiated histology.”
 - The result of the vote was a clear majority in favor of recommending funding. There were no dissenting opinions recorded. There were 20 votes cast with one submission failure.

Metastatic Therapy -(intent of therapy is palliative)

Projected Benefits:

- ✓ Oxaliplatin/LV/5FU (FOLFOX) versus IFL versus IROX (not used due to ↑ toxicity)

ORR= 45% vs 31%
Median TTP= 8.7 mo vs 6.9 mo vs 6.5 mo
Median OS = 19.5 mo versus 15.0 mo versus 17.4 mo

- ✓ LV5/FU2 versus oxaliplatin versus FOLFOX
ORR= 0% vs 1.3% vs 9.9%
Median TTP= 2.7 mo vs 1.6 mo vs 4.6 mo
Median OS = not reported

The major significant toxicity is cold induced neuropathy. It has less nausea and renal toxicity than cisplatin and does not require prehydration.

Projected Burdens:

- ✓ The estimated cost per quality adjusted life year is reported at \$34,738 to \$45,480 depending on the sequence of FOLFIRI & FOLFOX.
- ✓ Drug cost only per person per median therapy duration is approx. \$18,500
- ✓ The annual budget impact is approx \$1.1 million year 1, \$1.2 million year 2, and \$1.3 million year 3 based on 60,65, 70 patients respectively.

Result of Vote:

- The vote was conducted electronically. The question asked was:

“should the committee recommend funding oxaliplatin (Eloxatin[®]) in combination with 5-FU/LV infusional based chemotherapy (FOLFOX) in patients who have documented evidence of non-resectable locally advanced or metastatic colorectal cancer, as a first line or second line option, have an ECOG performance status of 0-2, for whom the combination would be recommended and who choose to receive chemotherapy

- **The result of the vote was a clear majority in favor of recommending funding. There were no dissenting opinions recorded. There were 19 votes cast with one submission failure.**

