

## **Record of Recommendation**

### **Re: Funding Alemtuzumab (Mab Campath<sup>®</sup>)**

**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 27<sup>th</sup>. 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: The pivotal study was a non-comparative multi-centre trial with 93 patients enrolled. The patients were heavily pre-treated failures to alkylating agents.

- ✓ 2% complete response rate
- ✓ 31% partial response rate
- ✓ median survival of 16 months (usual is 8 months)

Projected Burdens:

- ✓ The toxicities with alemtuzumab are mainly infusion related (shakes, fever, rash) and although high can be controlled by pre-medicating. Other toxicities include 46% infections (18% grade III/IV) which can be severe.
- ✓ The pharmacoeconomic analysis reported the ICER against CHOP as \$72,439. However, the analysis is unreliable for various reasons including lack of efficacy data.
- ✓ Drug cost only per person per median therapy duration is approx. \$24,331.67.
- ✓ The annual budget impact is approx \$171,000.00 (to treat approximately seven patients for one 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 recommend funding of alemtuzumab (Mab Campath®) as a single agent in patients (excluding those with bulky adenopathy) with progressive and symptomatic chronic lymphocytic leukemia (CLL) who are refractory to both alkylator-based and fludarabine-based regimens.

- **The result of the vote was a clear majority in support of recommending funding. There were 17 votes cast with one submission failure. There were no dissenting opinions recorded.**