

Record of Recommendation

Re: Funding Recombinant Humanized Thyroid Stimulating Hormone (rhTSH) in the Treatment of Thyroid Cancer

September 12, 2008

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 September 19, 2008. 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:

- ✓ Thyroid cancer is the most rapidly increasing cancer among Canadians and accounts for 2 % of all cancers. Most people (95%) survive thyroid cancer and it accounts for only 0.2% of cancer deaths.
- ✓ The treatment for most thyroid cancer is surgery followed by ablation of the thyroid with I-31 radioiodine (radioactive iodine).
- ✓ Before the radioactive iodine can be given, the thyroid must be suppressed by either 1) thyroid hormone withdrawal for 4 weeks and low iodine diet for 2 weeks or 2) use rhTSH (Thyrogen®) injections and low iodine diet for 2 weeks.

Projected Benefits: when used as a single agent for the preparation of radioiodine remnant ablation:

- ✓ rTsh (Thyrogen®) is associated with fewer side effects (and of shorter duration) than side effects associated with withdrawal of thyroid hormone therapy.
- ✓ This will result in a higher quality of life and likely less impact on patients' daily responsibilities and activities while they are undergoing cancer therapy.
- ✓ Rates of successful ablation are similar whether rhTSH (Thyrogen®) or withdrawal of thyroid therapy is used to prepare patients.

Projected Burdens:

- ✓ rhTSH (Thyrogen®) can cause nausea, headache and fatigue.
- ✓ The cost of rhTSH (Thyrogen®) is approximately \$1324.00 for two doses.
- ✓ The budget impact is expected to be approximately \$150,000 per year based on approximately 100 patients.

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 publicly fund Recombinant Humanized Thyroid Stimulating Hormone (rhTSH) as a single agent for preparation of radioiodine remnant ablation in patients with papillary or follicular thyroid cancer who have undergone thyroidectomy as treatment for thyroid cancer. RhTSH would be a reasonable alternate to thyroid hormone withdrawal in patients who are unable to tolerate the prolonged hypothyroidism state or who cannot achieve satisfactory elevation of endogenous TSH. In any one patient, this may include the following situations:

1. RhTSH may be used in any new patients (with papillary or follicular histology) in preparation for radioiodine remnant ablation.
2. A small proportion (10%) of these new patients may need the treatment multiple times.
3. RhTSH may be used in patients with previously incomplete remnant ablation or a recurrence (10%) of thyroid cancer and require therapeutic radioiodine ablation.”

Since Thyrogen® is an oral drug, funding would be through the Nova Scotia Pharmacare Programs.

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