Title:	**Recombinant human thyroid stimulating hormone (rhTSH) – diagnostic agent for use in well-differentiated thyroid cancer**
Agency:	Medical Services Advisory Committee (MSAC) Commonwealth Department of Health and Ageing GPO Box 9848 Canberra ACT 2601 Australia
Reference:	MSAC Application 1043 Assessment Report First printed: December 2002 **http://www.msac.gov.au** ISBN 0 642 82140 2

Aim

To assess the safety, effectiveness and cost-effectiveness of recombinant human thyroid stimulating hormone (rhTSH) for the detection of thyroid remnants and well-differentiated thyroid cancer in post-thyroidectomy patients maintained on hormone suppression and at risk of recurrence of thyroid cancer, relative to the comparator method of thyroid hormone therapy (THT) withdrawal.

Conclusions and results

Safety

To date, approximately 800 patients have received rhTSH in clinical trials. In general, the adverse events associated with the use of rhTSH appear to be mild in nature. The adverse events reported most frequently in association with rhTSH use are headache and nausea. However, there are also individual case studies that report serious adverse events associated with the swelling of metastases after rhTSH administration. To reduce the incidence of these serious adverse events, pre-treatment with corticosteroids may be considered prior to the administration of rhTSH in patients with metastatic disease in confined spaces. It is important to note that the adverse events associated with rhTSH should be considered in the context of the hypothyroidism experienced by patients undergoing THT withdrawal.

Effectiveness

- ***Diagnostic accuracy:*** The primary efficacy measure was the diagnostic accuracy using rhTSH relative to using the comparator, THT withdrawal. When used with concurrent serum Tg testing and whole body scanning (a positive patient being defined as a positive result in *either* detection method), the unadjusted sensitivity of rhTSH was 87 per cent, specificity was 95 per cent and accuracy 89 per cent. Thus the use of rhTSH instead of thyroid hormone therapy (THT) withdrawal would result in a reduction in overall diagnostic accuracy, such that 11 per cent of patients' disease status would be misclassified.
- ***Quality of life:*** Quality of life evidence in this assessment suggests that patients experience a poorer general quality of life during THT withdrawal compared with rhTSH. Although the magnitude of the differences is considerable, the effect is transient and infrequent.
- ***Cost-effectiveness:*** This assessment used a decision-analytic cost-utility model to determine the cost-effectiveness of rhTSH relative to THT withdrawal in the cohort of patients who have already had one negative follow-up using THT withdrawal. With significantly increased cost and only a marginal improvement in average utility, the incremental cost-effectiveness in this specific patient group is $AUD51,344 per quality-adjusted life-year.

Recommendation

MSAC recommended that on the strength of evidence pertaining to the diagnostic use of rhTSH in well-differentiated thyroid cancer, public funding should be supported for this procedure only in patients in whom THT withdrawal is medically contraindicated. In addition, on the basis of the current evidence, both rhTSH-stimulated whole body scanning and serum Tg testing should be undertaken concurrently. MSAC recommended that public funding for rhTSH should not be supported in patients who are able to tolerate THT withdrawal, on the basis of lower diagnostic accuracy and a high cost-effectiveness ratio. The Minister for Health and Ageing accepted this recommendation on 16 October 2002.

Methods

MSAC conducted a systematic review of the medical literature pertaining to rhTSH. A thorough search of the literature was carried out via electronic databases and health technology assessment websites. Those citations that met predefined inclusion criteria were included in the review of evidence. The value-for-money of rhTSH relative to the standard THT withdrawal method in the detection of well-differentiated thyroid cancer or thyroid remnants in post-thyroidectomy patients maintained on hormone suppression and at risk of recurrence of thyroid cancer, was evaluated using a decision-analytic cost-utility model.