Thyrogen®
thyrotropin alfa – rch

Note: In Australia, Thyrogen is funded under two systems: PBS, for therapeutic use, and MBS, for diagnostic use.

MBS

Diagnostic Follow up

Diagnostic detection of thyroid remnants and well differentiated thyroid cancer in post-thyroidectomy patients on hormone suppression therapy

Establish whether the patient meets the reimbursement criteria. See reverse for checklist.

Hospital Purchase

Refer patient to local Nuclear Medicine facility with private script for Thyrogen.

Hospital Pharmacy/Nuc Med facility purchase Thyrogen via wholesaler (~$1,825 depending on dispensary fee)

Thyrogen is administered as per schedule, pre WBS and Tg test.

Hospital Nuclear Medicine dept. bulk bill patient MBS item 12201: $2,318.40

Private Purchase

The prescribing specialist purchase Thyrogen from the local pharmacy for (~$1,825 depending on dispensary fee, private script)

Thyrogen is administered as per schedule, pre WBS and Tg test.

Bill patient for MBS item 12201: $2,392.90

Patient claims rebate at Medicare and receives a cheque payment for the prescribing specialist: $2,318.40

Thyrogen® Medical Benefits Scheme (MBS):[2] Patient Eligibility Checklist

Thyrogen (thyrotropin alfa-rch), for diagnostic follow-up of thyroid cancer, is reimbursed under the MBS (Item 12201). There is a strict criteria that needs to be met for the patient to qualify for reimbursement. Below is a check list that will assist you in determining whether your patient meets this criteria. Both Section A and Section B must be completed. Please see reverse for the full MBS listing.

Section A: ALL below boxes need to be ticked to complete section A:

For the detection of recurrent well-differentiated thyroid cancer (WDTC) in a patient who:

- ☐ Has had a total thyroidectomy; and
- ☐ Has had one ablative dose of radioactive iodine; and
- ☐ Is maintained on thyroid hormone therapy; and
- ☐ Is at risk of recurrence; and
- ☐ Did not have evidence of well differentiated thyroid cancer on at least one previous whole body scan or serum thyroglobulin test when withdrawn from thyroid hormone therapy
- ☐ Has not claimed Thyrogen on the **MBS** in the last 12 months

Section B: ONE of the below boxes needs to be ticked to complete section B:

- ☐ When withdrawn from thyroid hormone therapy, the patient experienced severe psychiatric disturbances (some symptoms include: major depression or depression, psychomotor slowing and anxiety[1,2]) when hypothyroid
- ☐ The patient has unstable coronary artery disease
- ☐ The patient has hypopituitarism
- ☐ The patient has a high risk of relapse or exacerbation of a previous severe psychiatric illness*

Item includes:

- The cost of supplying Thyrogen and the equivalent of a subsequent specialist attendance;
- An assessment that the patient meets the criteria prescribed by the item; the supply of Thyrogen;
- Ensuring that Thyrogen is injected (either by the administering practitioner** or by another practitioner***) in two doses at 24 hour intervals, with the second dose being administered 72 hours prior to whole body study with radioactive iodine and serum thyroglobulin test; and
- Arranging the whole body radioactive iodine study (item 61426) and the serum thyroglobulin test (item 66650).

MBS

MBS Item Number 12201 – Thyrogen (thyrotropin alfa – rch)

Administration, by a specialist or consultant physician in the practice of his or her specialty, of thyrotropin alfa-rch (recombinant human thyroid-stimulating hormone), and arranging services to which both items 61426 and 66650 apply, for the detection of recurrent well-differentiated thyroid cancer (WDTC) in a patient who:

(a) has had a total thyroidectomy and 1 ablative dose of radioactive iodine; and
(b) is maintained on thyroid hormone therapy; and
(c) is at risk of recurrence; and
(d) on at least one previous whole body scan or serum thyroglobulin test when withdrawn from thyroid hormone therapy did not have evidence of well differentiated thyroid cancer; and
(i) withdrawal from thyroid hormone therapy resulted in severe psychiatric disturbances when hypothyroid; or
(ii) withdrawal is medically contraindicated because the patient has:
– unstable coronary artery disease; or
– hypopituitarism ; or
– a high risk of relapse or exacerbation of a previous severe psychiatric illness payable once only in any twelve month period.

Fee: $2,392.90 **Benefit:** 75% = $1,794.70 85% = $2,318.40

(See Para D1.24 of explanatory category)

D1.24 Administration of thyrotropin alfa-rch for the detection of recurrent well-differentiated thyroid cancer (Item 12201)

D1.24.1 Thyrotropin alfa-rch is a diagnostic agent that allows patients to remain on thyroid hormone therapy while being assessed for recurrent cancer. This item was introduced following an assessment by the Medical Services Advisory Committee (MSAC) of the available evidence relating to the safety, effectiveness and cost-effectiveness of thyrotropin alfa-rch. MSAC found that the use of thyrotropin alfa-rch is associated with a lower diagnostic accuracy than when the patient has withdrawn from thyroid hormone therapy. Accordingly, benefits are payable under the item only for patients in whom thyroid hormone therapy withdrawal is medically contraindicated and where concurrent whole body study using radioactive iodine and serum thyroglobulin are undertaken. Services provided to patients who do not demonstrate the indications set out in item 12201 do not attract benefits under the item. D1.24.2 "Severe psychiatric illness" is defined as patients with a severe pre-existing psychiatric illness who are currently under specialist psychiatric care. D1.24.3 The item includes the cost of supplying thyrotropin alfa-rch and the equivalent of a subsequent specialist attendance. "Administration" means an attendance by the specialist or consultant physician (the administering practitioner) that includes: • an assessment that the patient meets the criteria prescribed by the item; the supply of thyrotropin alfa-rch; • ensuring that thyrotropin alfa-rch is injected (either by the administering practitioner or by another practitioner) in two doses at 24 hour intervals, with the second dose being administered 72 hours prior to whole body study with radioactive iodine and serum thyroglobulin test; and • arranging the whole body radioactive iodine study and the serum thyroglobulin test. D1.24.4 Where thyrotropin alfa-rch is injected by the administering practitioner, benefits are not payable for an attendance on the day the second dose is administered. Where thyrotropin alfa-rch is injected by: a general practitioner - benefits are payable under a Level A consultation (item 3); other practitioners – benefits are payable under item 52.

All the information in this table is drawn from the Medicare Benefits Schedule, effective 1 January, 2013.

PBS Information: Diagnostic indication: This product is not listed on the PBS for diagnostic use. This indication is reimbursed on the MBS, Item 12201. Conditions apply.

Please review Product Information before prescribing. Full Product Information is available from Genzyme by calling Medical Information on 1800 818 806.

MINIMUM PRODUCT INFORMATION THYROGEN® thyrotropin alfa powder for injection

INDICATION THYROGEN is indicated for: 1. use with serum thyroglobulin (Tg) testing, with or without radioactive iodine imaging, undertaken for the detection of thyroid remnants and well-differentiated thyroid cancer in post-thyroidectomy patients maintained on hormone suppression therapy, and; 2. therapeutic use in post-thyroidectomy patients maintained on hormone suppression therapy in the ablation of thyroid remnant tissue in combination with radioactive iodine **CONTRAINDICATIONS** There are no known contraindications to the use of THYROGEN. **PRECAUTIONS** THYROGEN may be used as an adjunctive diagnostic tool to detect recurrent or residual cancer in combination with radioiodine. Thyroid hormone withdrawal Tg testing with radioiodine imaging remains the standard diagnostic modality to assess the presence, location and extent of thyroid cancer. The use of THYROGEN in conjunction with Tg testing alone (without radioimaging) should be restricted to patients at low risk of disease recurrence. The use of THYROGEN should be directed by physicians knowledgeable in the management of patients with thyroid cancer. Even when THYROGEN-stimulated Tg testing is performed in combination with radioiodine imaging, there remains a meaningful risk of missing a diagnosis of thyroid cancer or of underestimating the extent of disease. **ADVERSE EFFECTS** The safety profile of patients who received THYROGEN as adjunctive treatment for radioiodine ablation of thyroid tissue remnants who have undergone a thyroidectomy for well-differentiated thyroid cancer did not differ from that of patients who received THYROGEN for diagnostic purposes. Most common adverse drug reactions were nausea and headache. Other common adverse drug reactions included fatigue, vomiting, dizziness, paraesthesia, asthenia and diarrhea. **INTERACTIONS WITH OTHER MEDICINES** Formal interaction studies between THYROGEN and other medicinal products have not been performed. **DOSAGE AND ADMINISTRATION** A two-injection regimen is recommended for THYROGEN administration. 0.9 mg intramuscularly (IM) followed by a second 0.9 mg IM injection 24 hours later. For radioiodine imaging or treatment, radioiodine administration should be given 24 hours following the final THYROGEN injection. Diagnostic scanning should be performed 48 hours after radioiodine administration (72 hours after the final administration of THYROGEN), whereas post-therapy scanning may be delayed additional days to allow background activity to decline. For serum Tg testing, the serum sample should be obtained 72 hours after the final intramuscular injection of THYROGEN. **SPECIAL GROUPS AND PREGNANCY CLASSIFICATION** Pregnancy Category B2. THYROGEN should not be used during pregnancy. It is not known whether the drug is excreted in human milk. Patients given THYROGEN should not breastfeed. The safety and effectiveness of THYROGEN use in children below the age of 18 years has not been assessed. Careful evaluation should be considered for high-risk elderly patients and patients with significant impaired renal function. **PRESENTATIONS, STORAGE** THYROGEN is supplied as a kit containing two 5 mL vials of thyrotropin alfa per kit. Each vial after reconstitution with Sterile Water for injection, (1.2 mL), contains thyrotropin alfa 0.9 mg/mL. THYROGEN should be stored at 2°-8°C. **NAME OF SPONSOR** Genzyme Australasia Pty Ltd, 12-24 Talavera Road, Macquarie Park, NSW 2113. Date of Preparation: 30 November 2012, Based on Full PI with TGA approval date of 13 June 2012. Thyrogen® is a registered trademark of Genzyme Corporation. sanofi-aventis Australia Pty Ltd trading as Genzyme ABN 31 008 558 807. **Reference: 1.** Medicare Benefit Schedule, 1 November 2012. **2.** Constant EJ et al. J Clinical Endocrinology and Metabolism 2001;86(8):3864-3870. AU.THYR.13.03.004

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