Clinical Policy: Thyrotropin alfa (Thyrogen)

Reference Number: PA.CP.PHAR.95
Effective Date: 01/2018
Last Review Date: 07/2023

Revision Log

Description
Thyrotropin alfa (Thyrogen®) is a recombinant human thyroid stimulating hormone (TSH).

FDA Approved Indication(s)
Thyrogen is indicated for:

- Diagnostic: Use as an adjunctive diagnostic tool for serum thyroglobulin (Tg) testing with or without radioiodine imaging in the follow-up of patients with well-differentiated thyroid cancer who have previously undergone thyroidectomy.
- Ablation: Use as an adjunctive treatment for radioiodine ablation of thyroid tissue remnants in patients who have undergone a near-total or total thyroidectomy for well-differentiated thyroid cancer and who do not have evidence of distant metastatic thyroid cancer.

Limitation(s) of use:

- Diagnostic:
  - Thyrogen-stimulated Tg levels are generally lower than, and do not correlate with, Tg levels after thyroid hormone withdrawal.
  - Even when Thyrogen-stimulated Tg testing is performed in combination with radioiodine imaging, there remains a risk of missing a diagnosis of thyroid cancer or of underestimating the extent of disease.
  - Anti-Tg antibodies may confound the Tg assay and render Tg levels uninterpretable.
- Ablation: The effect of Thyrogen on thyroid cancer recurrence greater than 5 years post-remnant ablation has not been evaluated.

Policy/Criteria
It is the policy of PA Health & Wellness that thyrotropin alfa (Thyrogen) is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Thyroid Cancer (must meet all)**:**

1. Diagnosis of well-differentiated thyroid cancer;
2. Age ≥ 18 years;
3. Thyrogen will be used for one of the following (a or b):
   a. Adjunctive treatment for radioiodine ablation of thyroid tissue remnants and both of the following are met (i and ii):
      i. Member has undergone a near-total or total thyroidectomy;
      ii. There is no evidence of distant metastatic thyroid cancer;
   b. Adjunctive diagnostic tool for serum Tg testing in members who have previously undergone thyroidectomy;
3. Prescribed dose of Thyrogen does not exceed an initial 0.9 mg intramuscular (IM) injection followed by a second 0.9 mg IM injection 24 hours later.

Approval duration: 6 months (2 injections)

B. Other diagnoses/indications: Refer to PA.CP.PMN.53

II. Continued Approval

A. Thyroid Cancer (must meet all)**:**

1. Currently receiving medication via of PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. Thyrogen will be used as an adjunctive diagnostic tool for serum Tg testing;
4. If request is for a dose increase, new dose does not exceed an initial 0.9 mg IM injection followed by a second 0.9 mg IM injection 24 hours later.

Approval duration: 6 months (2 injections)

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via of PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies; or
2. Refer to PA.CP.PMN.53

III. Appendices

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration
IM: intramuscular
TSH: thyroid stimulating hormone
Tg: thyroglobulin
T3: triiodothyronine
T4: thyroxine

Appendix B: Therapeutic Alternatives

Not applicable

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): If Thyrogen is administered with radioiodine, the contraindications to radioiodine also apply to this combination regimen.
- Boxed warning(s): none reported.

IV. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Adjunctive diagnostic tool for serum thyroglobulin testing in well differentiated thyroid cancer	0.9 mg IM injection to the buttock followed by a second 0.9 mg IM injection to the buttock 24 hours later	See regimen
Adjunct to treatment for ablation in well differentiated thyroid cancer		

V. Product Availability

Single-dose vial lyophilized powder: 0.9 mg

VI. References

1. Thyrogen Prescribing Information. Cambridge, MA: Genzyme Corporation; March 2020. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/020898s063s065lbl.pdf. Accessed April 25, 2023.
2. National Comprehensive Cancer Network. Thyroid Carcinoma Version 1.2023. Available at https://www.nccn.org/professionals/physician_gls/pdf/thyroid.pdf. Accessed April 25, 2023.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J3240	Injection, thyrotropin alpha, 0.9 mg, provided in 1.1 mg vial

Reviews, Revisions, and Approvals	Date	Approval Date
References reviewed and updated.	04/2018	
3Q 2019 annual review: No changes per Statewide PDL implementation 01-01-2020	07/2019	
3Q 2020 annual review: added age limit; references reviewed and updated.	07/2020	
3Q 2021 annual review: no significant changes; references reviewed and updated.	07/2021	
3Q 2022 annual review: no significant changes; references reviewed and updated.	07/2022	
3Q 2023 annual review: no significant changes; references reviewed and updated.	07/2023	