Clinical Policy: Thyrotropin Alfa (Thyrogen)

Reference Number: ERX.SPA.176
Effective Date: 01.11.17
Last Review Date: 08.22
Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

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.
- Ablation: The effect of Thyrogen on thyroid cancer recurrence greater than 5 years post-remnant ablation has not been evaluated.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that 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;
4. 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
1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Thyroid Cancer (must meet all)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
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 a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration
IM: intramuscular
Tg: thyroglobulin
TSH: thyroid stimulating hormone

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

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Adjunctive diagnostic tool for serum Tg 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		

VI. Product Availability

Lyophilized powder for reconstitution: 0.9 mg

VII. References

1. Thyrogen Prescribing Information. Cambridge, MA: Genzyme Corporation; March 2020. Available at https://thyrogen.com/. Accessed April 18, 2022.
2. National Comprehensive Cancer Network. Thyroid Carcinoma Version 1.2022. Available at http://www.nccn.org. Accessed April 18, 2022.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
3Q 2018 annual review: no significant changes; references reviewed and updated.	04.30.18	08.18
3Q 2019 annual review: no significant changes; references reviewed and updated.	05.14.19	08.19
3Q 2020 annual review: no significant changes; references reviewed and updated.	05.04.20	08.20
3Q 2021 annual review: no significant changes; references reviewed and updated.	05.04.21	08.21
3Q 2022 annual review: no significant changes; reference reviewed and updated.	04.18.22	08.22

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.