Clinical Policy: Thyrotropin Alfa (Thyrogen)

Reference Number: LA.PHAR.95
Effective Date: 10.30.22
Last Review Date: 04.18.24~~06.13.23~~ Coding Implications
Line of Business: Medicaid Revision Log

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

****Please note: This policy is for medical benefit****

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

It is the policy of Louisiana Healthcare Connections 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 (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: LA.PMN.53 for Medicaid.

II. Continued Therapy

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

1. Currently receiving medication via Louisiana Healthcare Connections benefit 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 (1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: LA.PMN.53 for Medicaid.

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 policies – LA.PMN.53 for Medicaid, or evidence of coverage documents.

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IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration	Tg: thyroglobulin
IM: intramuscular	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 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		

VI. Product Availability

~~Lyophilized~~Single-dose vial lyophilized powder ~~for reconstitution~~: 0.9 mg

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VII. References

1. Thyrogen Prescribing Information. Cambridge, MA: Genzyme Corporation; March 2020. Available at: https://~~thyrogen.com/~~www.accessdata.fda.gov/drugsatfda_docs/label/2020/020898s063s065lbl.pdf. Accessed April ~~18, 2022~~25, 2023.
2. National Comprehensive Cancer Network. Thyroid Carcinoma Version 1.~~2022~~2023. Available at ~~http~~https://www.nccn.org~~-~~/professionals/physician_gls/pdf/thyroid.pdf. Accessed April ~~18, 2022.~~ 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	LDH Approval Date
Converted corporate to local policy.	09.22	10.30.22
Template changes applied to other diagnoses/indications and continued therapy section. Internal hyperlinks updated and references reviewed and updated. Added blurb this policy is for medical benefit only	06.13.23	10.05.23
Annual review: no significant changes; references reviewed and updated.	04.18.24	

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. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in ~~developingthis~~developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy,

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contract of insurance, etc.), as well as to state and federal requirements and applicable LHCC administrative policies and procedures.

This clinical policy is effective as of the date determined by LHCC. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. LHCC retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. 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. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom LHCC has no control or right of control. Providers are not agents or employees of LHCC.

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