

Clinical Policy: Thyrotropin Alfa (Thyrogen)

Reference Number: CP.PHAR.95

Effective Date: 03.12

Last Review Date: 08.18

Line of Business: Medicaid, HIM-Medical Benefit

[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.
 - Anti-Tg antibodies may confound the Tg assay and render Tg levels uninterpretable. Therefore, in such cases, even with a negative or low-stage Thyrogen radioiodine scan, consideration should be given to further evaluating patients.
- Ablation: The effect of Thyrogen on long-term thyroid cancer outcomes has not been determined. Due to the relatively small clinical experience with Thyrogen in remnant ablation, it is not possible to conclude whether long-term thyroid cancer outcomes would be equivalent after use of Thyrogen or use of thyroid hormone withholding for TSH elevation prior to remnant ablation.

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 health plans affiliated with Centene Corporation[®] 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 \geq 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 the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid and HIM.PHAR.21 for health insurance marketplace.

II. Continued Therapy

A. Thyroid Cancer (must meet all):

1. Currently receiving medication via Centene 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. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid and HIM.PHAR.21 for health insurance marketplace

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 – CP.PMN.53 for Medicaid, HIM.PHAR.21 for health insurance marketplace 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
Not applicable

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 powder for reconstitution: 1.1 mg

VII. References

1. Thyrogen Prescribing Information. Cambridge, MA: Genzyme Corporation; April 2017. Available at: <https://thyrogen.com/>. Accessed April 30, 2018.
2. National Comprehensive Cancer Network. Thyroid Carcinoma Version 2.2017. Available at: https://www.nccn.org/professionals/physician_gls/pdf/thyroid.pdf. Accessed April 30, 2018.

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
Updated with current references Revised Limitation of Use within Indication Included efficacy data	10.14	01.15
Converted policy to new template. Added adult age limitation to criteria. Shortened background. Added appendices for abbreviations and safety. Limited references to updated PI and NCCN guidelines.	12.15	12.15
Removed specialist requirement and updated disclaimer language	03.16	

Reviews, Revisions, and Approvals	Date	Approval Date
Updated policy template. Combined diagnostic and therapeutic uses under one criteria set (“Thyroid Cancer”). Removed age restriction. Added max dosing criteria. Added continued criteria set. Added continued approval for diagnostic use. Approval duration for initial and continued is set at 6 months per NCCN monitoring recommendations.	10.16	11.16
Converted to new template; references reviewed and updated	09.17	11.17
3Q 2018 annual review: no significant changes; HIM-Medical added; references reviewed and updated.	04.30.18	08.18

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. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

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, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. 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. The Health Plan 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 the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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