Clinical Policy: Thyrotropin Alfa (Thyrogen)

Reference Number: CP.PHAR.95
Effective Date: 03.12
Last Review Date: 11.17
Line of Business: 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 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.

  Limitations of use:
  - 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.

- 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 of use: 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 (which may include office chart notes and lab results) 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 ≥ 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 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

1. Refer to CP.PHAR.57 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. Previously received medication via Centene benefit or member has previously met initial approval criteria;
2. Documentation of positive response to therapy;
3. Thyrogen will be used as an adjunctive diagnostic tool for serum Tg testing;
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 or 2)**:**

1. Currently receiving medication via health plan benefit and documentation supports positive response to therapy.

Approval duration: Duration of request or 6 months (whichever is less); or

2. Refer to CP.PHAR.57 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 – CP.PHAR.57 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

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; March 2014. Available at https://thyrogen.com/. Accessed April 4, 2017.
2. Thyroid carcinoma (Version 1.2017). In: National Comprehensive Cancer Network Guidelines. Available at www.NCCN.org. Accessed April 4, 2017.

Reviews, Revisions, and Approvals	Date	Approval Date
Updated safety data and current references	12.13	01.14
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	
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

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.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

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.