Clinical Policy: Thyrogen

Reference Number: CP.PHAR.95
Effective Date: 03/12
Last Review Date: 12/15

Revision Log

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

Description

The intent of the criteria is to ensure that patients follow selection elements established by Centene® medical policy for the use of Thyrogen® (thyrotropin alfa for intramuscular injection).

Policy/Criteria

It is the policy of health plans affiliated with Centene Corporation® that Thyrogen is **medically necessary** for members meeting the following criteria:

I. Treatment

A. Thyrogen as part of the *treatment plan*, 2 injections (meets all):
   1. Age ≥18 years;
   2. Documented diagnosis of well-differentiated thyroid cancer;
   3. Has undergone a near-total or total thyroidectomy;
   4. No evidence of distant metastatic thyroid cancer;
   5. Thyrogen being used as adjunctive treatment for radioiodine ablation of thyroid tissue remnants.

II. Diagnosis

A. Thyrogen as a diagnostic tool following treatment, 2 injections (meets all):
   1. Age ≥18 years;
   2. Documented diagnosis of well-differentiated thyroid cancer;
   3. Has previously undergone thyroidectomy;
   4. Thyrogen being used as adjunctive diagnostic tool for serum thyroglobulin (Tg) testing with or without radioiodine imaging.

Background

Differentiated Thyroid Cancer

Thyroid cancer is stratified across three main histological types: 1) differentiated (papillary, follicular, Hürthle cell); 2) medullary; and 3) anaplastic (undifferentiated).[1] Differentiated thyroid cancers are associated with a relatively good prognosis and are typically treated with surgery followed by radioiodine and thyroid hormone replacement.[1] Thyrogen, a recombinant human thyroid stimulating hormone (rhTSH), facilitates radioiodine uptake through thyroid hormone production.[1,2] In this setting, Thyrogen is FDA approved for 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.[2] Thyrogen also stimulates the release of thyroglobulin (Tg) by thyroid cells and is FDA approved as an adjunctive diagnostic tool for serum Tg testing, with or without radioiodine imaging, in the follow-up of patients with well-

differentiated thyroid cancer who have previously undergone thyroidectomy.[2] In this latter setting, Tg serves as a tumor marker.[1,2]

Appendices

Appendix A: Abbreviation Key

TSH: thyroid stimulating hormone
Tg: thyroglobulin
T3: triiodothyronine
T4: thyroxine

References

1. Thyroid carcinoma: NCCN clinical practice guidelines in oncology. Version 2.2015. National Comprehensive Cancer Network, Inc. Available from www.nccn.org.
2. Thyrogen [package insert]. Cambridge, MA: Genzyme Corporation; March 2014. Available from https://thyrogen.com/healthcare.aspx.

Reviews, Revisions, and Approvals	Date	Approval Date
No clinical changes	11/12	12/12
Converted embedded SGM document into Centene policy	08/13	
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	

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.

Note: For Medicare members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs and LCDs should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.