



## Medical Policy Manual **Approved Revision: Do Not Implement Until 6/2/21**

### Thyrotropin Alfa (Thyrogen®)

NDC CODE(S) 58468-0030-XX THYROGEN 1.1MG Solution Reconstituted (GENZYME)

#### DESCRIPTION

Thyrotropin alfa is a recombinant human thyroid stimulating hormone (rhTSH) preparation which a heterodimeric glycoprotein comprised of two non-covalently linked subunits of amino acid residues. The amino acid sequences of these two subunits together are identical to that of human pituitary TSH. The activity of thyrotropin alfa is determined relative to a reference standard calibrated against the World Health Organization (WHO) TSH reference standard.

Thyrotropin (rhTSH) stimulates the thyroid gland to produce thyroid hormone. Binding of thyrotropin alfa to TSH receptors on normal thyroid epithelial cells or on well-differentiated thyroid cancer tissue stimulates iodine uptake and synthesis and secretion of thyroglobulin (Tg), triiodothyronine (T3) and thyroxine (T4).

The effect of rhTSH activation of thyroid cells is to increase uptake of radioiodine to allow detection or radioiodine killing of thyroid cells. TSH activation also leads to the release of Tg by thyroid cells. Tg functions as a tumor marker which is detected in blood specimens.

#### POLICY

- Thyrotropin alfa for the treatment/diagnosis of well-differentiated thyroid carcinoma is considered **medically necessary** if the medical appropriateness criteria are met. **(See Medical Appropriateness below.)**
- Thyrotropin alfa for the treatment of other conditions/diseases is considered **investigational**.

#### MEDICAL APPROPRIATENESS

##### INITIAL APPROVAL CRITERIA

- Patient is **at least 18 years of age; AND**

##### Thyroid carcinoma

- Patient has a diagnosis of well-differentiated thyroid cancer; **AND**
  - Used as an adjunctive diagnostic test; **AND**
    - Patient has had previous thyroidectomy; **OR**
  - Used as an adjunctive treatment for radioiodine ablation; **AND**
    - Patient has undergone total/near-total thyroidectomy; **AND**
    - Patient does not have distant metastases

##### RENEWAL CRITERIA

- Authorizations cannot be renewed.

##### DOSAGE/ADMINISTRATION

| INDICATION | DOSE |
|------------|------|
|------------|------|

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|----------------|--|
| Thyroid Cancer | Two-injection regimen: 0.9 mg administered intramuscularly followed by a second 0.9 mg intramuscular injection 24 hours later. |
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### **LENGTH OF AUTHORIZATION**

Coverage will be for two doses and may not be renewed.

### **DOSAGE LIMITS**

#### **Max Units (per dose and over time) [HCPCS Unit]:**

- 1 billable unit daily for 2 doses

### **APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS**

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

### **IMPORTANT REMINDER**

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the Medical Policy and a health plan, the express terms of the health plan will govern.

### **ADDITIONAL INFORMATION**

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

### **SOURCES**

1. Thyrogen [package insert]. Cambridge, MA; Genzyme; March 2020. Accessed January 2021.
2. Mallick U, Harmer C, Yap B, et al, "Ablation With Low-Dose Radioiodine and Thyrotropin Alfa in Thyroid Cancer," N Engl J Med, 2012, 366(18):1674-85.
3. Pacini F, Ladenson PW, Schlumberger M, et al, "Radioiodine Ablation of Thyroid Remnants After Preparation With Recombinant Human Thyrotropin in Differentiated Thyroid Carcinoma: Results of an International, Randomized, Controlled Study," J Clin Endocrinol Metab, 2006, 91(3):926-32.
4. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Thyroid Carcinoma. 2.2020. National Comprehensive Cancer Network, 2020. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed January 2021.



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5. Haugen BR, Alexander EK, Bible KC, et al. 2015 American Thyroid Association management guidelines for adult patients with thyroid nodules and differentiated thyroid cancer: the American Thyroid Association Guidelines Task Force on Thyroid Nodules and Differentiated Thyroid Cancer. *Thyroid*. 2016;26(1):1-133. doi: 10.1089/thy.2015.0020.
6. Lexi-Comp Online. (2020, March). AHFS DI. Thyrotropin Alfa. Retrieved February 1, 2021 from Lexi-Comp Online with AHFS.
7. MICROMEDEX Healthcare Series. Drugdex Evaluations. (2020, April). *Thyrotropin Alfa*. Retrieved February 1, 2021 from MICROMEDEX Healthcare Series.

**EFFECTIVE DATE** 6/2/2021

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