Medical Policy:

Thyrogen (thyrotropin alfa for injection)

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.172	January 2, 2024	July 15, 2019

The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

Thyrotropin (TSH) is a pituitary hormone that 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 organification, and synthesis and secretion of thyroglobulin (Tg), triiodothyronine (T3) and thyroxine (T4). The effect of thyroid stimulating hormone activation of thyroid cells is to increase uptake of radioiodine to allow scan detection or radioiodine killing of thyroid cells. TSH activation also leads to the release of thyroglobulin by thyroid cells. Thyroglobulin functions as a tumor marker which is detected in blood specimens.

Thyrogen® (thyrotropin alfa for injection) 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.

Thyrogen is also indicated for use as 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 metastatic thyroid cancer.

Length of Authorization

Coverage will be provided for 2 doses and may not be renewed.

Dosing Limits [Medical Benefit]

Max Units (per dose and over time):

- 1 billable unit daily for 2 doses

Guideline

I. Initial Approval Criteria

Thyrogen *may be considered medically necessary for the following groups:*

1. **Thyroid Carcinoma**
    A. For thyroglobulin (Tg) testing and radioiodine imaging in place of thyroid hormone withdrawal for **ANY** of the following groups with differentiated thyroid carcinoma:
        i. Patients in whom withdrawal from hormone supplement is contraindicated for medical reasons; **OR**
        ii. Members requiring serum Tg testing and radioiodine imaging who are unwilling to undergo thyroid hormone withdrawal testing and whose treating physician believes that use of a less sensitive test is justified; **OR**
        iii. Members who are either unable to mount an adequate endogenous thyroid stimulating hormone (TSH) response to thyroid hormone withdrawal; **OR**
        iv. Members who would otherwise be examined solely with a serum Tg test without undergoing hormone supplement withdrawal; **OR**
        v. Members with an undetectable Tg on thyroid hormone suppressive therapy to exclude the diagnosis of residual or recurrent thyroid cancer.
    B. To facilitate radioiodine ablation of remnant thyroid tissue after surgery for differentiated thyroid carcinoma, as an alternative to thyroid hormone withdrawal
        i. In patients who have undergone a near-total or total thyroidectomy for well-differentiated thyroid cancer; **AND**
        ii. Patient does not have evidence of metastatic thyroid cancer

Limitations/Exclusions

Thyrogen is not considered medically necessary for when any of the following selection criteria is met:

1. Treatment for diagnoses not FDA approved.
2. Authorization requests exceeding 0.9 mg every 24 hours for 2 doses.

II. Renewal Criteria

Authorization coverage may NOT by be renewed.

Dosage/Administration

Indication	Dose
All indications	Two-injection regimen: 0.9mg IM followed by second 0.9mg IM injection 24 hours later

Applicable Procedure Codes

Code	Description
J3240	Injection, thyrotropin alfa, 0.9mg, provided in 1.1mg vial, 1 billable unit = 0.9 mg

Applicable NDCs

Code	Description
58468-0030-xx	Thyrogen, 0.9mg powder for injection

ICD-10 Diagnoses

Code	Description
C73	Malignant neoplasm of thyroid gland
Z85.850	Personal history of malignant neoplasm of thyroid

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	1/2/2024	Annual Review: No Criteria Changes
EmblemHealth & ConnectiCare	5/02/2023	Annual Review :Removed code E04.2
EmblemHealth & ConnectiCare	1/17/2023	Transfer to New Template
EmblemHealth & ConnectiCare	7/15/2019	New Policy

References

1. Thyrogen [prescribing information]. Cambridge, MA: Genzyme Corporation; 2017.
2. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Thyroid Carcinoma. 2018.