Clinical Policy: Thyrotropin alfa (Thyrogen)

Reference Number: PA.CP.PHAR.95
Effective Date: 01/18 Revision Log
Last Review Date: 10/16

Description
The intent of the criteria is to ensure that patients follow selection elements established by of Pennsylvania Health and Wellness ® clinical policy for the use of thyrotropin alfa (Thyrogen®).

Policy/Criteria
It is the policy of of Pennsylvania Health and Wellness that thyrotropin alfa (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. 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 thyroglobulin (Tg) testing in members who have previously undergone thyroidectomy;
3. Prescribed dose of Thyrogen 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: Refer to PA.CP.PHAR.57 – Global Biopharm Policy.

II. Continued Approval

A. Thyroid Cancer (must meet all)**:**

1. Currently receiving medication via of Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Thyrogen will be used as an adjunctive diagnostic tool for serum Tg testing;
3. Prescribed dose of Thyrogen 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 (must meet 1 or 2)**:**

1. Currently receiving medication via of Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies; or
2. Refer to PA.CP.PHAR.57 - Global Biopharm Policy.

Background

Description/Mechanism of Action:

Thyrotropin alfa is a recombinant human thyroid stimulating hormone (TSH). 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 TSH 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.

Formulations:

Thyrogen is supplied as a lyophilized powder containing 1.1 mg of thyrotropin alfa for single use after reconstitution with sterile water for injection.

FDA Approved Indications:

Thyrogen is a recombinant human thyroid stimulating hormone/intramuscular injection indicated for use 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.
  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.

Appendices

Appendix A: Abbreviation Key

IM: intramuscular

TSH: thyroid stimulating hormone

Tg: thyroglobulin
T4: thyroxine
T3: triiodothyronine

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

References
1. Thyrogen Prescribing Information. Cambridge, MA: Genzyme Corporation; March 2014. Available at https://thyrogen.com/. Accessed October 6, 2016.
2. Thyroid carcinoma (Version 1.2016). In: National Comprehensive Cancer Network Guidelines. Available at www.NCCN.org. Accessed October 6 2016.