Thyrogen® (thyrotropin alfa for injection)

**Definition**

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 radiiodine to allow scan detection or radiiodine 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 radiiodine imaging in the follow-up of patients with well-differentiated thyroid cancer.

Thyrogen is also indicated for use as adjunctive treatment for radiiodine 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**

Max Units (per dose and over time) [Medical Benefit]:

- 1 billable unit daily for 2 doses

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 be renewed.

Dosage/Administration

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>All indications</td>
<td>Two-injection regimen: 0.9mg IM followed by second 0.9mg IM injection 24 hours later</td>
</tr>
</tbody>
</table>

Applicable Procedure Codes

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>J3240</td>
<td>Injection, thyrotropin alfa, 0.9mg, provided in 1.1mg vial, 1 billable unit = 0.9 mg</td>
</tr>
</tbody>
</table>

Applicable NDCs

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>58468-0030-xx</td>
<td>Thyrogen, 0.9mg powder for injection</td>
</tr>
</tbody>
</table>
Applicable Diagnosis Codes

<table>
<thead>
<tr>
<th>ICD-10</th>
<th>ICD-10 Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>C73</td>
<td>Malignant neoplasm of thyroid gland</td>
</tr>
<tr>
<td>E04.2</td>
<td>Nontoxic multinodular goiter [adjunct to radioiodine ablation]</td>
</tr>
<tr>
<td>Z85.850</td>
<td>Personal history of malignant neoplasm of thyroid</td>
</tr>
</tbody>
</table>

References

2) National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Thyroid Carcinoma. 2018.