

**THYROGEN® (THYROTROPIN ALFA FOR INJECTION) PROTOCOL FOR DIAGNOSTIC AND  
THERAPEUTIC USES IN PATIENTS WITH THYROID CARCINOMA  
VENTURA COUNTY MEDICAL CENTER**

The contents of this clinical practice guideline (CPG) are to be used as a guide. Healthcare professionals should use sound judgment and individualize patient care. This CPG is not meant to be a replacement for training, experience, CME or studying the latest literature and drug information.

**Introduction:**

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® (thyrotropin alfa for injection) is indicated 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 metastatic thyroid cancer.

**DOSAGE AND ADMINISTRATION**

- A two-injection regimen is recommended for Thyrogen® administration.
- The two-injection regimen is Thyrogen® 0.9 mg intramuscularly (IM), followed by a second 0.9 mg IM injection 24 hours later.
- After reconstitution with 1.2 mL Sterile Water for Injection, a 1.0 mL solution (0.9 mg thyrotropin alfa) is administered by intramuscular injection to the buttock.
- For radioiodine imaging or remnant ablation, radioiodine administration should be given 24 hours following the final Thyrogen® injection. Diagnostic scanning should be performed 48 hours after the radioiodine administration, whereas post-therapy scanning may be delayed additional days to allow background activity to decline.
- The following parameters are recommended for diagnostic radioiodine scanning with Thyrogen®:
  1. A diagnostic activity of 4mCi (148 MBq) <sup>131</sup>I should be used.
  2. Whole images should be acquired for a minimum of 30 minutes and/or should contain a minimum of 140,000 counts.
  3. Scanning times for single (spot) images of body regions should be 10-15 minutes or less of the minimum number of counts is reached sooner (i.e. 60,000 for a large field of view camera, 35,000 counts for a small field of view).
- For radioiodine ablation of thyroid tissue remnants, the activity of <sup>131</sup>I (Dose) is carefully selected at the discretion of the nuclear medicine physician.
- For serum Tg testing, the serum sample should be obtained 72 hours after the final injection of Thyrogen®.

SAFETY:

1. When Thyrogen®-stimulated serum, thyroglobulin (Tg) testing is performed in combination with radioiodine imaging, there remains a meaningful risk of missing a diagnosis of thyroid cancer or of underestimating the extent of disease.
2. Although Thyrogen® appeared non-inferior to thyroid hormone withdrawal in a study of postsurgical thyroid remnant ablation, long-term clinical outcome data are limited. Due to 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 hormone withdrawal for TSH elevation prior to remnant ablation.
3. Caution should be exercised in patients with a known history of heart disease and with significant residual thyroid tissue. Careful evaluation of benefit risk should be assessed for high risk elderly patients with functioning thyroid tumors undergoing Thyrogen® administration, to avoid palpitations or cardiac rhythm disorder.

SIDE EFFECTS AND RECAUTIONS:

- It is recommended that pretreatment with glucocorticoids be considered for patients in whom local tumor expansion may comprise vital anatomic structures (such as trachea, central nervous system, or extensive macroscopic lung metastases).
- In clinical studies, the most common side effects reported were nausea, headache, fatigue, vomiting, dizziness, paraesthesia, asthenia, insomnia, and diarrhea.

**Diagnostic Testing Schedule**

<i>Day 1</i>	<i>Day 2</i>	<i>Day 3</i>	<i>Day 4</i>	<i>Day 5</i>
<b>First Thyrogen® injection</b>	<b>Second Thyrogen® injection</b>	<b>Radioactive iodine dose</b>		<b>Serum Thyroglobulin with or without Whole Body Scan</b>

**Ablation Schedule**

<i>Day 1</i>	<i>Day 2</i>	<i>Day 3</i>	A post-ablation scan should be performed 3-5 days after the administration of <sup>131</sup> I
<b>First Thyrogen® Injection</b>	<b>Second Thyrogen® injection</b>	<b>Radioactive iodine dose</b>	