Thyrogen® (thyrotropin alfa) Patient Assistance Program Application

(Both the patient and the physician must complete the attached application for patient to be considered for assistance through Patient Assistance Program)

Thyrogen®(thyrotropin alfa), for intramuscular use

INDICATIONS AND USAGE

Thyrogen® (thyrotropin alfa) is a thyroid stimulating hormone indicated for:

Adjunctive Diagnostic Tool for Well-Differentiated Thyroid Cancer: 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 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-Tg testing is performed in combination with radioiodine imaging, there remains a risk of missing a diagnosis of thyroid cancer or underestimating the extent of the disease.
- Anti-Tg Antibodies may confound the Tg assay and render Tg levels uninterpretable.

Adjunct for Thyroid Remnant Ablation in Well-Differentiated Thyroid Cancer: 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 distant metastatic thyroid cancer.

Limitations of Use:

- The effect of Thyrogen on thyroid cancer recurrence greater than 5 years post-remnant ablation has not been evaluated.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

If Thyrogen is administered with radioiodine, the contraindications to radioiodine also apply to this combination regimen. Refer to the radioiodine prescribing information for a list of contraindications for radioiodine.

WARNINGS AND PRECAUTIONS

Thyrogen-Induced Hyperthyroidism:

- There have been reports of death in non-thyroidectomized patients and in patients with distant metastatic thyroid cancer in which events leading to death occurred within 24 hours after administration of Thyrogen. Caution should be exercised in patients who have substantial thyroid tissue still in situ or functional thyroid cancer metastases, specifically in the elderly and those with a known history of heart disease.
- Hospitalization for administration of Thyrogen and post-administration observation in patients at risk should be considered.

Stroke:

- There are post marketing reports of stroke in young women with risk factors for stroke, and neurological findings suggestive of stroke (e.g., unilateral weakness) occurring within 72 hours of Thyrogen administration in patients without known central nervous system metastases. The relationship between THYROGEN administration and stroke is unknown. Patients should be well-hydrated prior to treatment with Thyrogen.

Sudden Rapid Tumor Enlargement:

- Sudden, rapid and painful enlargement of residual thyroid tissue or distant metastases can occur following treatment with Thyrogen. Pretreatment with glucocorticoids should be considered for patients in whom tumor expansion may compromise vital anatomic structures.

Risks Associated with Radioiodine Treatment:

- If THYROGEN is administered with radioiodine (RAI), the warnings and precautions for RAI apply to this combination regimen. Refer to the RAI prescribing information for a full list of the warnings and precautions for RAI.

ADVERSE REACTIONS

The most common adverse reactions reported in clinical trials were nausea and headache.

USE IN SPECIFIC POPULATIONS

Pregnancy:

- If THYROGEN is administered with radioiodine, the combination regimen is contraindicated in pregnant women.
- Available data with THYROGEN use in pregnant women are insufficient to evaluate for a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes.

Lactation:

- The concomitant use of THYROGEN and radioiodine (RAI) is contraindicated in lactating women. If THYROGEN is administered with RAI for diagnostic use, discontinue breastfeeding after RAI administration because of the potential for serious adverse reactions from RAI in the breastfed infant.
- If THYROGEN is not administered with RAI, the developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for THYROGEN and any potential adverse effects on the breastfed child. There are no available data on the presence of thyrotropin alfa in human milk, the effects on the breastfed infant, or the effects on milk production.

Pediatric Use: Safety and effectiveness in pediatric patients have not been established.

Geriatric Use: Results from controlled trials do not indicate a difference in the safety and efficacy of Thyrogen between adult patients less than 65 years and those over 65 years of age.

Renal Impairment: Elimination of Thyrogen is significantly slower in dialysis-dependent end stage renal disease patients, resulting in prolonged elevation of TSH levels.

Please see accompanying full Prescribing Information also available here: http://products.sanofi.us/Thyrogen/thyrogen.pdf

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Please return completed application by fax

Phone: 1.88.THYROGEN (1.888.497.6436) (M – F, 8:00am – 6:00pm EST) // Fax: 1.888.326.1002 // Website: www.thyrogen.com

Please complete all applicable sections on pages 1, 2 and 3. This application cannot be processed without applicable signatures.

Sanofi Genzyme will provide up to two (2) kits of Thyrogen® (thyrotropin alfa) per year for eligible uninsured and underinsured patients through the patient assistance program. If approved, shipment will be coordinated with the requesting physician. This is not a replacement program; applications must be submitted prior to Thyrogen use. Thyrogen received through this program shall not be resold and providers shall not bill any patient or third party payer, including Medicare and Medicaid. This program is not meant to induce a physician to use or prescribe Thyrogen. The program provides drug only; patients would need to find alternative means to support other medical costs associated with follow-up diagnostic tests and treatment, if necessary. Sanofi Genzyme reserves the right to review patient profiles, grant requests based on patient need and to change program guidelines or terminate the program at any time without notification.

PATIENT DEMOGRAPHICS		
First Name:	Last Name:	DOB:
Street Address:		City:
State:	Zip:	Phone:
Contact (if other than patient):	Relationship:	Phone:

PATIENT ELIGIBILITY	
Does patient reside in U.S. or Puerto Rico?	☐ Yes ☐ No
Does patient have health insurance?	☐ Yes ☐ No
If patient has insurance, please complete remaining questions in this section:	
Has coverage for Thyrogen been denied?	☐ Yes ☐ No
Have you received a letter from patient's insurance plan regarding denial or non-coverage of Thyrogen? (If yes, please attach documentation.)	☐ Yes ☐ No

INSURANCE DETAILS (Please complete OR attach copies of front and back of insurance cards.)

Primary Insurance:	Policy #	Group #	Phone#
Secondary Insurance:	Policy #	Group #	Phone#
Prescription Insurance:	Policy #	Group #	Phone#

PATIENT CONSENT AND SIGNATURE

I certify that the information provided is current, complete, and accurate to the best of my knowledge. By signing below, I consent to my participation in the ThyrogenONE program and request that ThyrogenONE, Sanofi Genzyme, their affiliated companies, agents, representatives and contractors use the information in this form to assess my eligibility for participation in the patient assistance program, including verifying my insurance coverage and facilitating prior authorization if needed, and to refer me to, or determine my eligibility for, other programs or alternate sources of funding assistance or coverage that may be available to assist me with the costs of my treatment. I understand that ThyrogenONE, Sanofi Genzyme, and their agents, contractors and representatives have the right to revise, change, or terminate this program (and the assistance provided) at any time, without notice.

I authorize my healthcare providers and staff to disclose to Sanofi Genzyme, and its affiliates and agents, health information about me, including patient-related information provided throughout this form and related to my medical condition, treatment with prescribed Sanofi Genzyme therapies, health insurance coverage, claims, and prescriptions (together, "My Information"). My healthcare providers, specialty pharmacies, and Sanofi Genzyme (including its agents and affiliates) may use and disclose My Information for the purposes of providing certain support services, including benefit verification and drug fulfillment. Once my Information has been disclosed to Sanofi Genzyme, I understand that federal privacy laws may no longer protect it from further disclosure. However, Sanofi Genzyme agrees to protect My Information by using and disclosing it only for the purposes authorized in this Authorization or as otherwise required by law. I understand that I may have certain rights under applicable data privacy laws regarding My information, including the right to access My information held by Sanofi Genzyme. For further information regarding these rights, please reference the Sanofi Genzyme's Global Privacy Policy at www.sanofi.com/en/our-responsibility/sanofi-global-privacy-policy. I understand that if I decline to sign this Authorization, it will not affect my eligibility to obtain medical treatment, my ability to seek financial assistance from other sources, or my insurance enrollment or eligibility for insurance coverage.

PATIENT OR LEGAL GUARDIAN SIGNATURE: **DATE:**

Please see the accompanying full Prescribing Information for more details.

SANOFI GENZYME

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Patient Name:_____ DOB: _____

CLINICAL INFORMATION

In accordance with the full Prescribing Information for Thyrogen, please certify whether patient meets the following four (4) medical criteria:

1.) Diagnosis: Malignant neoplasm of thyroid gland (ICD-10 C73)
2.) Disease type: Well-differentiated thyroid cancer [papillary, follicular, or Hürthle cell]
3.) Surgical history: Patient has undergone total or near-total thyroidectomy
4.) Metastatic disease: Patient has no current evidence of distant (outside of neck region) metastatic disease

☐ I certify that the patient meets all the above criteria.

☐ Patient does not meet all the above criteria. Please specify:

_____

_____

☐ Unknown or uncertain whether patient meets all the above criteria. Please specify:

_____

_____

PRESCRIPTION FOR THYROGEN

Prescriber: Please complete all fields. Illegible RXs will be returned.
Thyrogen (thyrotropin alfa) 1.1mg vial, packaged 2 vials per kit. SIG-Administer 0.9mg IM (intramuscular)

ICD-10/Diagnosis Code:	**Dosage & Administration:**	**Procedure Type:**	**First Thyrogen Injection Date:**
☐ C73 ☐ Other: _____	☐ Q24 HR x 2 Doses	☐ Ablation ☐ Follow Up Testing: ☐ First ☐ Subsequent	____/____/____

PRESCRIBER SIGNATURE: DATE:

PRESCRIBER CERTIFICATION AND STATEMENT OF MEDICAL NECESSITY

I certify that the information provided is current, complete, and accurate to the best of my knowledge. I certify that Thyrogen is medically necessary for this patient and that I will be supervising the patient's treatments. I certify that I have obtained from my patient all required written authorizations, in accordance with State and Federal law for the disclosure of the information provided above to ThyrogenONE®, Sanofi Genzyme, and their agents, contractors and representatives for the purposes of assessing patient's eligibility for participation in the patient assistance program, including verifying my patient's insurance coverage and facilitating prior authorization if needed, and for otherwise administering the ThyrogenONE program, including coordinating shipments of Thyrogen under the ThyrogenONE program, referring patient to other programs or alternate sources of funding assistance or coverage, and de-identifying patient information for use in monitoring, evaluating and prescribing ThyrogenONE. I understand that application to the patient assistance program does not guarantee that assistance will be obtained. By signing this document, I attest that the financial information I have provided is complete and accurate. If at any time it is deemed necessary to audit the patient's financial information, I will provide supportive documentation to ThyrogenONE. I agree that I will not submit claims or otherwise seek payment from any source for product provided through the patient assistance program. I understand that ThyrogenONE, Sanofi Genzyme, and their agents and representatives have the right to revise, change, or terminate this program (and the assistance provided) at any time, without notice.

PRESCRIBER SIGNATURE: DATE:

Please see the accompanying full Prescribing Information for more details.

MAT-US-2009111
Updated April 2020

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Patient Name:_____ DOB: _____

FACILITY INFORMATION				
Prescriber Name:				
State License #:	NPI:			
DEA #:	Tax ID:			
Prescriber Specialty:	☐ Endocrinology	☐ Nuclear Medicine	☐ Surgery	Other: _____
Facility Name:				
Phone:	Fax:			
Clinic Address:				
City:	State:	Zip:		
Contact Name:	Title/Role:			
Contact Phone:	Contact Email:			

SHIPPING INFORMATION		
Check if same as above: ☐		
Facility Name:		
Department:		
Shipping Address:		
Corresponding DEA #:		
City:	State:	Zip:
Phone:	Fax:	

Please see the accompanying full Prescribing Information for more details.

SANOFI GENZYME