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 used to help identify thyroid disease by testing the blood for a hormone called thyroglobulin in the follow up of patients with a certain type of thyroid cancer known as well differentiated thyroid cancer. It is used with or without a radiology test using a form of iodine.

Limitations of Use:

- The effect of Thyrogen on long term thyroid cancer outcomes has not been determined.
- When Thyrogen is used to help detect thyroid cancer, there is still a chance all or parts of the cancer could be missed.

Thyrogen is also used to help patients prepare for treatment with a form of iodine, called radioiodine, to remove leftover thyroid tissue in patients who have had surgery to take out the entire thyroid gland for patients with well differentiated thyroid cancer who do not have signs of thyroid cancer which has spread to other parts of the body.

Limitations of Use:

- In a study of people being prepared for treatment with a form of iodine after thyroid surgery, results were similar between those who received Thyrogen and those who stopped taking their thyroid hormone for up to 5 years after treatment. Researchers do not know if results would be similar over a longer period of time.

IMPORTANT SAFETY INFORMATION

Patients should not use Thyrogen with radioiodine if they have a contraindication to the use of radioiodine. Please consult with your doctor for a list of contraindications for radioiodine.

Thyrogen can cause serious side effects, including:

Thyrogen-Induced Hyperthyroidism:

- There have been reports of events that led to death in patients who not had surgery to have their thyroid gland removed, and in patients with thyroid cancer cells that have spread to other parts of the body.
- Patients over 65 years old with large amounts of leftover thyroid tissue after surgery, or with a history of heart disease, should discuss with their physicians the risks and benefits of Thyrogen.
- Thyrogen can be administered in the hospital for patients at risk for complications from Thyrogen administration.

Stroke:

- Since Thyrogen was first approved for use, there have been reports of central nervous system problems such as stroke in young women who have a higher chance of having a stroke, and weakness on one side of the body. The relationship between THYROGEN administration and stroke is unknown. Patients should remain hydrated prior to treatment with Thyrogen.

Sudden Rapid Tumor Enlargement:

- Leftover thyroid tissue after surgery and cancer cells that have spread to other parts of the body can quickly grow and become painful after Thyrogen administration. Patients with cancer cells near their windpipe, in their central nervous system, or in their lungs may need treatment with a glucocorticoid (a medication to help prevent an increase in the size of the cancer cells before using Thyrogen.)

Risks Associated with Radioiodine Treatment:

- If THYROGEN is administered with radioiodine (RAI), the serious side effects for RAI apply to this combination regimen. Please consult with your doctor for a list of contraindications for radioiodine.

ADVERSE REACTIONS

In clinical studies, the most common side effects reported were nausea and headache.

USE IN SPECIFIC PATIENT POPULATIONS

Pregnant patients: Notify your healthcare provider immediately in the event of a pregnancy. If THYROGEN is administered with radioiodine, the combination regimen should not be used in pregnant women. Thyrogen should be given to a pregnant woman only if the doctor thinks there is a clear need for it.

Breastfeeding patients: If THYROGEN is administered with radioiodine, the combination regimen should not be used in breastfeeding women. It is not known whether Thyrogen can appear in human milk. Breastfeeding women should discuss the benefits and risks of Thyrogen with their physician.

Children: Safety and effectiveness in young patients (under the age of 18) have not been established.

Elderly: Studies do not show a difference in the safety and effectiveness of Thyrogen between adult patients less than 65 years and those over 65 years of age.

Patients with kidney disease: Thyrogen exits the body much slower in dialysis patients and can lead to longer high TSH levels.

Click here for full Prescribing Information.

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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.

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Updated April 2026
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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.

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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:	

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