Thyrogen Patient Kit

Please discuss the contents of this kit with your healthcare provider

Thyrogen
(thyrotropin alfa) for injection

Thyrogen is used to help prepare patients for a treatment to remove leftover thyroid tissue as well as for certain diagnostic tests to monitor for the recurrence of thyroid cancer.
During the preparation phase, Thyrogen allows you to stay on your thyroid hormone medication and may help avoid some of the signs and symptoms of acute hypothyroidism.

The contents of the kit include information on the thyroid cancer journey post thyroidectomy, Thyrogen, and financial assistance programs.

INDICATIONS:

Thyrogen 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 five years

Thyrogen (thyrotropin alfa) Prescribing Information. Genzyme Corporation. February, 2024

Thyrogen®
(thyrotropin alfa) for injection

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 have 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.

Please see click here for full Prescribing Information.

Thyrogen®
(thyrotropin alfa) for injection

Call 1-88-THYROGEN(1-888-497-6436) to speak with a dedicated Case Manager

The Thyrogen Patient Kit Contains the Following Information

Product Information

- What is Thyrogen?
- Administration Instructions and Schedule.
- Thyrogen Prescribing Information

Coverage, Support, and Financial Assistance Documents

- Coverage, Support, and Financial Assistance Programs
- Application for Thyrogen Co-Pay Program.
- Application for Thyrogen Patient Assistance Programs

Additional Information

- Elements of the thyroid cancer journey
- Post radioactive iodine ablation precautions
- Low Iodine Diet Card
- Patient Organizations.

Please see click here for full Prescribing Information.

What is Thyrogen (thyrotropin alfa)?

Thyrogen®
(thyrotropin alfa) for injection

Thyrogen helps you prepare your body for radioactive iodine (RAI) ablation and/ or diagnostic testing by raising the levels of thyroid stimulating hormone (TSH)

Thyrogen Helps you Maintain Function[1]

Thyrogen allows you to continue with your daily thyroid hormone replacement medication. Thyrogen administration was not associated with the signs and symptoms of hypothyroidism that accompanied THW as measured by the Billewicz scale.[6] See pg 5.

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. Re-searchers do not know if results would be similar over a longer period of time.

Thyrogen is covered by a majority of Commercial and Public Health Plans

Call ThyrogenONE at 188-THYROGEN (1-888-497-6436)

You can also visit our website at www.Thyrogen.com

Individuals will need to investigate whether their individual plan covers Thyrogen. Coverage is not guaranteed.

Please click here for full Prescribing Information

You've been prescribed Thyrogen. What should you do next?

Thyrogen®
(thyrotropin alfa) for injection

Each kit of Thyrogen contains two vials

- **CALL ThyrogenONE at 1-88-THYROGEN (1-888-497-6436) to see if you qualify for financial assistance**
- **Follow your doctor's directions on how to take your thyroid hormone medication**
- **ENSURE you can meet your appointment times for the administration of Thyrogen and subsequent treatment and/or testing procedures**
- **Thyrogen is administered by a licensed healthcare practitioner and is injected in the buttock for 2 consecutive days**

The Uses of Thyrogen[1]

To prepare for Radioactive Iodine Ablation (RAI)[1]

After removal of the entire thyroid, some patients may need another therapy to remove any leftover thyroid tissue. This procedure is called radioactive iodine (RAI) ablation.

Radioactive Iodine Capsule

To prepare for Diagnostic Testing[1]

After your initial treatment, your endocrinologist will monitor you to see if your initial treatment was effective or if your cancer has returned. Thyrogen may be used to prepare you for a stimulated thyroglobulin (Stim Tg) test or for a whole-body scan (WBS).

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.

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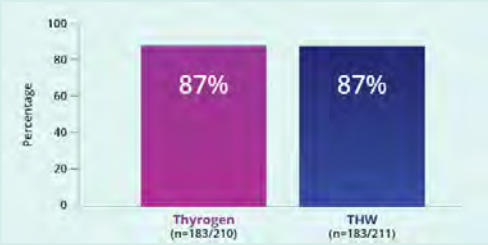
Thyrogen was shown to be effective in radioactive iodine (RAI) ablation

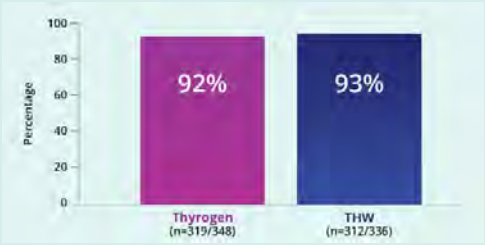
Thyrogen®
(thyrotropin alfa) for injection

Results from the 2 largest randomized clinical trials in differentiated thyroid cancer show Thyrogen is as effective as thyroid hormone medication for RAI ablation while allowing you to continue taking your thyroid hormone medication[2,3]

Study A
Successful remnant ablation rates in 421 evaluable patients[2]



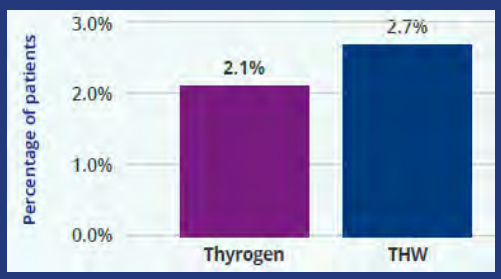
Study B
Successful remnant ablation rates in 684 evaluable patients[3]



- Thyrogen was compared with thyroid hormone withdrawal (THW) using 2 different doses of radioiodine (RAI) in patients with well-differentiated thyroid cancer who had undergone thyroidectomy
- In both studies, patients were randomized to 1 of 4 treatment groups: Thyrogen + low dose RAI, Thyrogen + high dose RAI, THW +low dose RAI, THW + high dose RAI.
- Ablation success rates were assessed at approximately 8 months post ablation

Five-year follow-up data of Thyrogen in Study A and Study B observed similar rates of thyroid cancer recurrence as thyroid hormone withdrawal.

Recurrence results in Study A: 421 evaluable patients[4]



This study had low and intermediate risk patients

Recurrence results in Study A: 684 evaluable patients[5]

There were low risk patients only in this **s**tudy

IMPORTANT SAFETY INFORMATION
Thyrogen Induced Hyperthyroidism:

- There have been reports of events that led to death in patients who have 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.

Thyrogen is covered by a majority of Commercial and Public Health Plans

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Please click here for full Prescribing Information

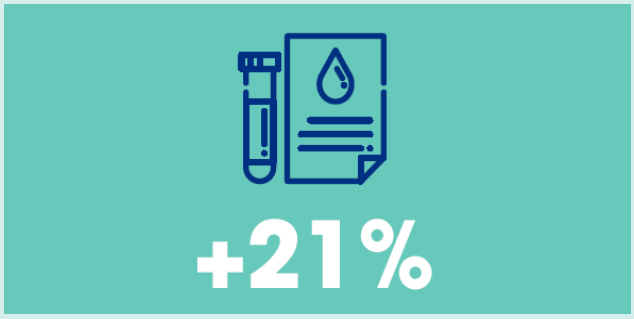
Thyrogen®
(thyrotropin alfa) for injection

Thyrogen was effective during diagnostic stimulated thyroglobulin (StimTg) testing with or without a whole body scan (WBS)

Results from 2 clinical trials in differentiated thyroid cancer show Thyrogen is as effective as thyroid hormone medication for diagnostic Stim Tg testing with or without WBS.

356 patients were studied in the 2 prospective, randomized trials

Disease detection rates were found to be similar between the scans after Thyrogen and scans after thyroid hormone withdrawal with or without thyroglobulin testing



A Thyrogen stimulated thyroglobulin detected 21% more patients with metastatic disease than thyroglobulin testing without stimulation

The two studies compared the following[6,7]:

- Radioactive iodine whole body scans (WBS) obtained after THYROGEN injections to radioactive iodine whole body scans after thyroid hormone withdrawal (THW).
- Combination of thyroglobulin (Tg) levels in the blood and WBS obtained after THYROGEN injections and after thyroid hormone withdrawal (THW).
- Symptoms of acute hypothyroidism before, during, and after Thyrogen injections and thyroid hormone withdrawal (THW).

IMPORTANT SAFETY INFORMATION :

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.

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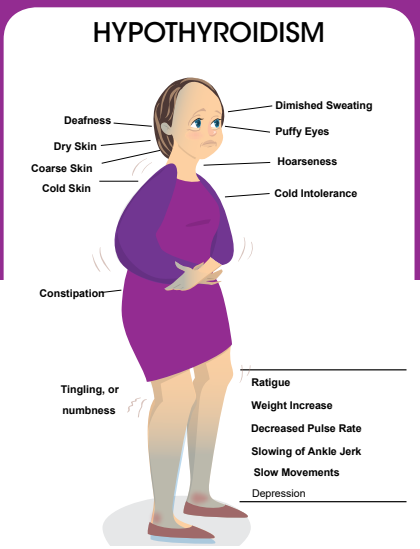
Help Avoid the Signs & Symptoms of Acute Hypothyroidism

Thyrogen® (thyrotropin alfa) administration was not associated with the signs and symptoms of hypothyroidism that accompanied thyroid hormone withdrawal as measured by the Billewicz scale.

Thyrogen® (thyrotropin alfa) for injection



In a study of 229 thyroidectomized patients with well-differentiated thyroid cancer, undergoing whole-body scans, thyroid hormone withdrawal (stopping thyroid hormone medication) was compared to Thyrogen. Thyrogen patients had less signs and symptoms of hypothyroidism than those who underwent thyroid hormone withdrawal.[6]

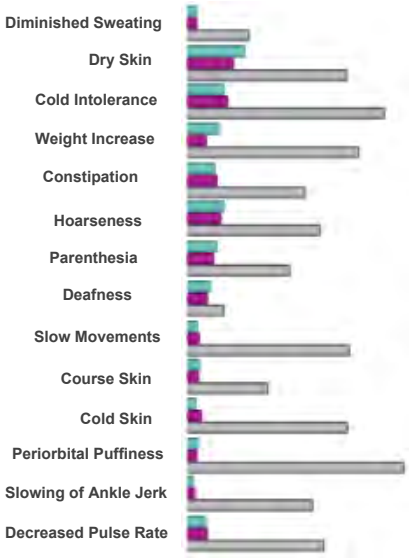
The signs and symptoms were measured by using a Billewicz scale. A Billewicz scale is an observer-rated set of clinical findings that has been widely used in assessing hypothyroidism. Higher scores are associated with a decrease in quality of life.

How did Thyrogen compare with thyroid hormone withdrawal in these studies?

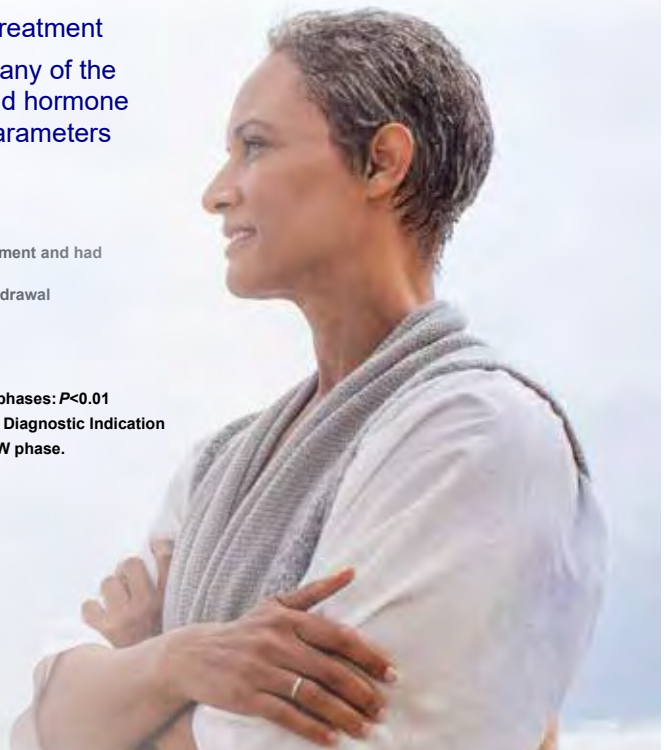
There were three sets of scores taken:

- For all patients during the pre-treatment phase when they were on thyroid hormone treatment.
- For the patients who took Thyrogen
- For the patients who were withdrawn from thyroid hormone replacement treatment

The chart below shows that patients who took Thyrogen did not experience any of the symptoms of hypothyroidism. However, the patients who went through thyroid hormone withdrawal experienced significantly worse signs and symptoms in all the parameters measured in the study



- All differences between euthyroid and hypothyroid phases: $P<0.01$
- Hypothyroid symptoms assessment, Billewicz Scale Diagnostic Indication
- 0.9 mg of Thyrogen every 24 hours × 2 doses vs THW phase.



The Billewicz scale is used by observers to assess hypothyroidism, based on a set of 14 signs and symptoms

ADVERSE REACTIONS

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

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Sudden Rapid Tumor Enlargement:

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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.

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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.

Please see click here for full Prescribing Information.

References

1. Thyrogen (thyrotropin alfa) Prescribing Information. Genzyme Corporation. Feb 2023
2. Mallick U, Harmer C, Yap B, et al. Ablation with low-dose radioiodine and thyrotropin alfa in thyroid cancer. N Engl J Med. 2012;366:1674-1685.
3. Schlumberger M, Catargi B, Borget I, et al. Strategies of radioiodine ablation in patients with low-risk thyroid cancer. N Engl J Med. 2012;366:1663-1673
4. Dehbi HM, Mallick U, Wadsley J, Newbold K, Harmer C, Hackshaw A. Recurrence after low-dose radioiodine ablation and recombinant human thyroid stimulating hormone for differentiated thyroid cancer (HiLo): long-term results of an open-label, non-inferiority randomised controlled trial. Lancet Diabetes Endocrinology. 2019;7(1):44-51.
5. Schlumberger M, Leboulleux S, Catargi B, et al. Outcome after ablation in patients with low-risk thyroid cancer (ESTIMABL1): 5-year follow-up results of a randomised, phase 3, equivalence trial. Lancet Diabetes Endocrinol. 2018;6(8):618-626.
6. Hänscheid H, Lassmann M, Luster M, et al. Iodine biokinetics and dosimetry in radioiodine therapy of thyroid cancer: procedures and results of a prospective international controlled study of ablation after rhTSH or hormone withdrawal. J Nucl Med. 2006;47(4):648-654.
7. Haugen BR, Pacini F, Reiners C, et al. A comparison of recombinant human thyrotropin and thyroid hormone withdrawal for the detection of thyroid remnant or cancer. J Clin Endocrinol Metab. 1999;84(11):3877-3885.

Thyrogen® (thyrotropin alfa) Administration Schedule

Thyrogen is given as an injection into the muscle of the buttock for two days in a row. These injections are given by a health care provider. If you are receiving Thyrogen for ablation or diagnostic testing the following schedule may be used:

Your Thyrogen ablation checklist and schedule (to be filled out by your doctor or nurse)

Follow a low-iodine diet before ablation therapy

☐ Start low-iodine diet on _____ ☐ End low-iodine diet on _____

☐ You will receive two Thyrogen injections. The dates, times and location for your appointments are listed on the schedule below.

☐ Ask your HCP about obtaining a pregnancy test before starting this protocol.

☐ Discuss radiation precautions with your health care providers to be started right after you receive radioactive iodine ablation on day

WHEN		WHAT	WHERE
Day	Date/Time	Schedule	Write in location
1		Thyrogen 0.9 mg IM injection #1	
2		Thyrogen 0.9 mg IM injection #2 This injection should follow 24 hours after the 1st Thyrogen injection	
3		Radioactive iodine ablation I-131 dose administered orally Radioiodine should follow 24 hours after the 2nd Thyrogen injection	
4			
5			
6,7 , or 8+		Post-therapy whole body scan (Your physician may decide that post-therapy scanning may be delayed additional days)	

Your Thyrogen Diagnostic Testing Schedule and Checklist for Whole Body Scan and Thyroglobulin Testing (to be filled out by your doctor or nurse)

☐ You are having both a stimulated thyroglobulin (Tg) blood test and a whole body scan (WBS) with Thyrogen

☐ Follow a low-iodine diet before the whole body scan
Start low-iodine diet on_____☐ End low-iodine diet on_____

☐ You will receive two Thyrogen injections. The dates, times and location for your appointments are listed on the schedule below.

☐ Ask your HCP about obtaining a pregnancy test

WHEN		WHAT	WHERE
Day	Date/Time	Schedule	Write in location
1		Thyrogen 0.9 mg IM injection #1	
2		Thyrogen 0.9 mg IM injection #2 This injection should follow 24 hours after the 1st Thyrogen injection	
3		☐Radioactive iodine I-131 Scanning dose administered orally. Radioiodine should follow 24 hours after the 2nd Thyrogen injection	
4			
5		☐I-131 whole body scan ☐Thyroglobulin (Tg) blood test	

Your Thyrogen Diagnostic Testing Schedule and Checklist for Stimulated Thyroglobulin Testing Only (to be filled out by your nurse or doctor)

☐ You are having only a stimulated thyroglobulin (Tg) blood test with Thyrogen

☐ You will receive two Thyrogen injections. The dates, times and location for your appointments are listed on the schedule below.

WHEN		WHAT	WHERE
Day	Date/Time	Schedule	Write in location
1		Thyrogen 0.9 mg IM injection #1	
2		Thyrogen 0.9 mg IM injection #2 This injection should follow 24 hours after the 1st Thyrogen injection	
3			
4			
5		☐Thyroglobulin (Tg) blood test	

Thyrogen®
(thyrotropin alfa) for injection

Thyrogen Coverage, Support, and Financial Assistance Programs

Coverage and Support

Thyrogen is covered by a majority of Commercial and Public Plans

The amount of insurance coverage you will receive is determined by two factors:

The Type of Insurance You are Enrolled In

Your Individual Coverage Plan

**While Thyrogen is covered by most commercial insurance plans and public payers, coverage is not guaranteed. Patients should call their insurance company with individual coverage questions.*

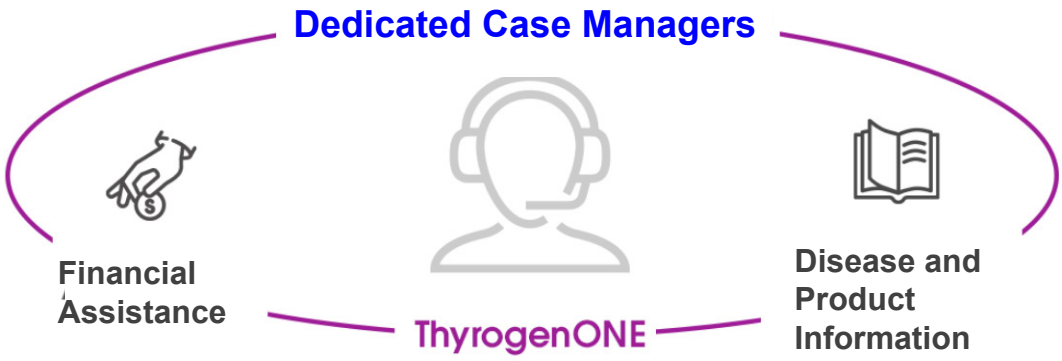
Your healthcare provider has prescribed Thyrogen.

What can you do next?

Call ThyrogenONE for Assistance

Call ThyrogenONE at 1-88-THYROGEN (1-888-497-6436). We have a dedicated team of case managers to help you with questions about eligibility, program benefits, and financial assistance for eligible patients.

ThyrogenONE- Just a phone call away!



Thyrogen®
(thyrotropin alfa) for injection

Thyrogen Coverage, Support, and Financial Assistance Programs

Financial Assistance Programs

Call ThyrogenONE at 1-88-THYROGEN (1-888-497-6436) to learn about potential options for financial support

We offer a few financial programs to help eligible* patients

How to Enroll into the Thyrogen Co-Pay Program

To help make treatment costs and co-pays more affordable, we created the Thyrogen Co-Pay Program. Through the program, financial assistance is available to help eligible*, commercially insured patients receive Thyrogen at:

$0 Co-Pay for up to $1,000 in a Calendar Year

With the Thyrogen Co-Pay Card

1. If you have commercial insurance, you may be eligible through the Thyrogen Co-Pay Program
2. To confirm you are eligible, you may call ThyrogenONE at 1-88-THYROGEN (1-888-497-6436) You may use the Thyrogen Co-Pay Self Application Form in your Patient Kit or download it from our website at www.Thyrogen.com.
3. Complete, sign, and fax the Co-Pay Self Application Form. You will be contacted by a ThyrogenONE case manager.
4. If you qualify, you will receive a Thyrogen Co-Pay Card in the mail. You may use the Thyrogen Co-Pay Card to pay up to $1,000 of your out of pocket expenses.
5. Already billed for Thyrogen? Call ThyrogenONE to apply for copay assistance.

* IMPORTANT NOTICE: Co-Pay program not valid for prescriptions covered by or submitted for reimbursement under Medicare, Medicaid, VA, DoD, TRICARE, or similar federal or state programs including any state pharmaceutical assistance programs. Not valid where prohibited by law. Sanofi Genzyme reserves the right to modify or discontinue the programs at any time. Savings may vary depending on patients' out-of-pocket costs. All program details provided upon registration.

The Thyrogen Patient Assistance Program (PAP)

With the Thyrogen Patient Assistance Program, eligible* patients may receive Thyrogen free of charge if they:

- Medically need Thyrogen, but no longer have insurance.
- If their insurance does not cover Thyrogen.
- Complete the Thyrogen Patient Assistance Program Application Form in your Patient Kit or download it from our website at www.Thyrogen.com

*Patients will need to meet the eligibility criteria, including household income to qualify. The ThyrogenONE team will research each patient's situation and determine eligibility. For more information call 1-88-THYROGEN (1-888-497-6436).

ThyrogenONE is also available to answer any questions. Case managers can be reached at 1-88-THYROGEN (1-888-497-6436)

Thyrogen®(thyrotropin alfa) Co-Pay Assistance Program Application

Please complete both pages of this application, sign and fax to 1-888-326-1002
You can also mail it to: ThyrogenONE Program, 6000 Park Lane, Pittsburgh, PA 15275

Contact Information

I am (please check one):

☐ Applying for myself

☐ Applying as the patient's custodial parent or legal guardian (explain): _____

_____

Patient's First Name: _____ Last Name: _____

Street Address: _____

City: _____ State: _____ Zip Code: _____

Date of Birth: _____

Email Address: _____

Phone Number: _____

Gender: M _____ F _____

Eligibility Information

1. Are you a resident of the United States or a U.S. territory? ☐YES ☐NO
2. Do you have commercial or private insurance? ☐YES ☐NO
3. Are your prescriptions paid for in part or in full under any state or federally funded programs, including but not limited to Medicare, Medicaid, VA, DoD, Tricare, or similar federal or state programs? ☐YES ☐NO
4. Are your prescriptions paid in part or in full by the military?
   If you answered yes to questions 3 or 4, you are not eligible for co pay assistance. Please contact ThyrogenONE at 1-888-497-9436 with questions. ☐YES ☐NO

Health Insurance Information

Primary Insurance Carrier: _____

Policy ID Number: _____ Plan Type (ie, HMO, PPO): _____

Telephone Number: _____

Secondary Insurance Carrier (if applicable): _____

Physician Information

Please fill in the following information about the doctor prescribing Thyrogen for you.

Physician First Name: _____ Physician Last Name: _____

Street Address: _____

City: _____ State: _____ Zip Code: _____

Phone Number: _____ Fax Number: _____

Physician's Specialty (if known): _____

Physician Office Contact (Name and Number): _____

For questions regarding the completion of this application form please call ThyrogenONE at 1-88-THYROGEN (1-888-497-6436)

sanofi

Authorization to Share Health Information

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.

By signing below, I certify that I have read and understand the Authorization to Share Health Information and agree to its terms.

Name: _____ (Print Name)

Signature: _____ Date: _____

PLEASE SIGN BOTH

Program Authorization

I am enrolling in the Thyrogen Co-Pay Assistance Program (the "Program"), provided by Genzyme Corporation (together with its affiliates, including Sanofi, "Sanofi Genzyme") and its third party business partners, vendors and other agents ("Agents") .Those with federal and state government insurance, such as Medicare, Medicaid, or TRICARE® are not eligible. Sanofi reserves the right to modify or discontinue the programs at any time. TRICARE is a registered trademark of the Department of Defense (DoD), Defense Health Agency (DHA).

By enrolling in the Program, I acknowledge and understand that (1) the Program will pay 100% of my eligible out-of-pocket drug costs for Thyrogen up to the Program maximum, (2) I will be responsible for paying any amounts over the maximum, and (3) the administration or injection related costs are not covered under the Program.

By signing this Program Authorization, I authorize Sanofi Genzyme and its Agents to use and share with my healthcare providers, specialty pharmacies and insurers information about me for the purpose of coordinating my enrollment and participation in the Program. I also authorize Sanofi Genzyme and its Agents to contact me by mail, telephone, and/ or email in connection with the Program and to inform me of available assistance programs, treatment and therapies, and insurance-related information. I further authorize Sanofi Genzyme and its Agents to de-identify my health information and use it in performing clinical research, patient and community education, business analytics, marketing studies or for other commercial purposes. I understand that this Program Authorization is valid for one year from date of my signature and that I must re-enroll annually for continued copay assistance.

I understand that I do not have to enroll in the Program and that if I choose not to enroll I can still receive my medication as prescribed by my physician. I may opt out of the Program at any time by writing to the ThyrogenONE,400 Holiday Drive,Foster-0, Floor 2, Pittsburgh, PA 15220 or by faxing to 1-888-326-1002.

By signing below, I certify that I have read and understand the Program Authorization and agree to its terms.

Name: _____ (Print Name)

Signature: _____ Date: _____

IMPORTANT NOTICE: The Co-Pay Program does not cover prescriptions eligible to be reimbursed, in whole or in part, by Medicaid, Medicare (including Medicare Part D), or other federal or state programs (including any state prescription drug assistance programs). No claim for reimbursement of any out-of- pocket covered by the Co-Pay Program may be submitted to any third-party payer, whether public or private. The Co-Pay Program is available only in the United States and cannot be combined with any other rebate/coupon, free trial, or similar offer. Co-Pay benefits are not transferable. Sanofi Genzyme reserves the right to rescind, revoke, modify, or amend this program without notice. Through your participation in the Co-Pay Program, you understand and agree to comply with the terms and conditions set forth above.

MAT-US-2013927-v4.0-11/2023

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APPLICATION

PATIENT Connection®

Sanofi Patient Connection® is a program (the "Program") to help you get access to the medications and resources you need at no cost. Patient Assistance Connection is part of the Program that provides select Sanofi prescription medications and vaccines, at no cost, if you meet certain eligibility requirements. Patient Assistance Connection is made possible through Sanofi Cares North America.

Regarding use of Authorized Representatives:

While patients are free to authorize family, care team members, or third-party representatives to complete and manage their Sanofi Patient Connection application please be aware that:

- The application can be fully completed by the patient and their licensed healthcare provider (HCP).
- Sanofi Patient Connection does not charge any fees for this service; application processing, medication, and shipping are all offered at no cost. Any fees charged to you by a third party completing this application on your behalf are not required by nor remitted to Sanofi.

Who may be eligible for Patient Assistance Connection?

In order to be eligible for this portion of the Program, you must meet the following requirements:

- You must be a resident of the US or the US territories and be under the care of a licensed HCP authorized to prescribe, dispense, and administer medicine in the US.
- You must have an annual household income of [≤400%] of the current Federal Poverty Level. If you may be eligible for Medicaid, you will be required to provide documentation of Medicaid denial before being assessed for patient assistance eligibility.
- If you are enrolled in Medicare Part D, you may also be eligible based on the income criteria noted above.
- You must have no insurance coverage or, for commercially insured patients, have no access to the prescribed product or treatment via your insurance.
- For vaccines, you must be 19 years of age or older (except for IMOVAX® Rabies).
- For Thyrogen®, you must be 18 years of age or older.

How do I apply?

To apply for Patient Assistance Connection, all information must be complete and include the following:

Patient Information:

- Complete all relevant information on page 2, and **sign and date** the REQUIRED patient authorizations for HIPAA consent and income verification on page 2.

Healthcare Provider:

- Ask your HCP to complete page 3 and **sign and date** it.
- Ask your HCP to mail or fax your completed application (only pages 2 and 3 are needed).

Missing information may delay processing of your application. **Do not include patient medical records with this application.** Your completed application may be submitted by your HCP as follows:

US Mail
Sanofi Patient Connection
PO Box 222138, Charlotte, NC 28222-2138

Fax
1.888.847.1797

What happens next?

When we receive your application, we will review it to see if you qualify for Patient Assistance Connection. If you are eligible:

1. You and your HCP will receive a letter notifying you of enrollment. If you are a Medicare Part D patient, your plan sponsor will also receive a letter notifying it of your enrollment.
2. You will be enrolled for 12 months. If you are a Medicare Part D patient, you will be enrolled through the end of the calendar year.
3. **Your medication will be sent directly to your HCP's office in approximately 5-7 business days from when you are approved.**

If you do not qualify for Patient Assistance Connection, we will send you and your HCP a letter with the reason for denial.

Note: Sanofi Patient Connection offers patients eligible for patient assistance programs a safe way to dispose of needles through the Sharps program. If you sign up for the Sharps program, you will receive a separate shipment for the Sharps container in order to dispose of your needles.

DO NOT INCLUDE PATIENT MEDICAL RECORDS WITH THIS APPLICATION.

P: 1.888.847.4877 · F: 1.888.847.1797
P.O. Box 222138 · Charlotte, NC · 28222-2138

PATIENT TO FILL OUT

Section 1. Patient Information

Patient first name	MI	Last name
SSN		DOB
Address		City
State	Zip	Preferred language (if not English)
Phone number ( )		
Email		
Household size ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ Other:		Annual household income

I permit Sanofi Patient Connection to speak with the following person and/or organization about the information on this application and the status of my application request.

Patient representative/organization name | Relationship to patient | Phone

Patient Authorizations

Sanofi Patient Connection does **not** charge any fees for this service; application processing, medication, and shipping are all offered at no cost. Any fees charged to you by a third party completing this application on your behalf are not required by nor remitted to Sanofi.

I have read and agree to the HIPAA Consent included in **Section 7** on page 4.

PATIENT SIGN (REQUIRED)

(1 of 3) **Patient signature/Legal representative if patient is <18 years** Date

I have read and agree to the Income Verification included in **Section 8** on page 5.

PATIENT SIGN (REQUIRED)

(2 of 3) **Patient signature/Legal representative if patient is <18 years** Date

I have read and agree to the Patient Certifications regarding receiving communications from Sanofi Patient Connection included in **Section 9** on page 5.

PATIENT SIGN (OPTIONAL)

(3 of 3) **Patient signature/Legal representative if patient is <18 years** Date

Section 2. Insurance Information

Insurance? ☐ Yes ☐ No ☐ If yes, is it Medicare Part D?

Primary insurance name	**Secondary** insurance name
Insurance phone ( )	Insurance phone ( )
Policy ID # Group #	Policy ID # Group #
Policyholder name (first/last)	Policyholder name (first/last)
Relationship to patient DOB	Relationship to patient DOB

Section 3. Resource Connection

[In order to fill out information below, patient signature required in Section 1.]

Do you want to participate in the Sharps needle disposal program?

☐ Yes ☐ No

Do you want the Program to help identify resources provided by other organizations?

☐ Yes ☐ No

Please note: You will receive a separate call from a Program associate with contact information for helpful resources checked on your application.

If yes, please mark which resources you may be interested in, if available:

☐ Clinical Support Services
☐ Nutritional Supplements (groceries, food banks, etc)
☐ Transportation Information
☐ Home Care Services (shelter, utilities, etc)
☐ Health Supplies
☐ Other (please elaborate):

DO NOT INCLUDE PATIENT MEDICAL RECORDS WITH THIS APPLICATION.

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P.O. Box 222138 · Charlotte, NC · 28222-2138

PRESCRIBER TO FILL OUT

Please check the appropriate box (prescriber and patient signature required for all applications)

☐ **Patient Assistance**	☐ **Benefits Verification (BV) and Patient Assistance**	☐ **BV only**
No cost medication program. Check this box for no cost medication.	Insurance coverage research and no cost medication program. Check this box if the patient has insurance coverage.	Insurance coverage research program. Check this box if only insurance coverage research is desired.

Section 4. Treatment and Prescribing Information *(See Section 6 for supported products)*

Patient name		DOB	
Product #1	☐ Vials ☐ Pens ☐ N/A	Product #2	☐ Vials ☐ Pens ☐ N/A
ICD-10 Code		ICD-10 Code	
Frequency		Frequency	
Dosage (# of units per day)	Qty	Dosage (# of units per day)	Qty

Section 5. Prescriber Information

Prescriber name		State where licensed	
Site/facility name		Office contact email	
Type ☐ Clinic ☐ Physician office ☐ Outpatient hospital ☐ Inpatient hospital			Phone ( )
Facility address*			Fax ( )
City		State	Zip Code
License #	NPI #	Tax ID #	DEA #

**Sanofi product must be shipped to the signing prescriber's office or hospital address authorized by the prescriber and not to a third party.*

I certify that the information provided is current, complete, and accurate to the best of my knowledge. I certify that the Sanofi product is medically necessary for this patient and that I am authorized under state law to prescribe and dispense the requested medication. I certify that I have obtained from my patient all required written authorization for the release of my patient's personal identification, medical, and insurance information to Sanofi US and/or Sanofi Cares North America and their agents and representatives. I understand that any information provided is for the sole use of the Program to verify my patient's insurance coverage, to assess, if applicable, patient's eligibility for participation in the Patient Assistance Program and to otherwise administer the Sanofi Patient Connection Program and related services. I understand that I am under no obligation to prescribe any Sanofi product and that I have not received, nor will I receive, any benefit from Sanofi or their agents or representatives for prescribing a Sanofi product. The facility address noted above in Section 5 is my office or hospital address. My signature certifies that any prescription products received from this Program will be used for the above-named patient only and will not be resold nor offered for sale, trade, or barter and will not be returned for credit, nor will payment be sought from any payer, patient, or other source for product received from the Program.

HCP SIGN (REQUIRED)

Prescriber signature (REQUIRED – no stamps)	**Printed name**	**Date**

Section 6. Products Available With Sanofi Patient Connection

- Adacel® (tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine adsorbed)
- Admelog® (insulin lispro injection) 100 Units/mL
- Apidra® (insulin glulisine injection) 100 Units/mL
- Imovax® Rabies Vaccine [Human Diploid Cell]
- Lantus® (insulin glargine injection) 100 Units/mL
- Lovenox® (enoxaparin sodium injection)*[1]
- MenQuadfi® (Meningococcal [Groups A, C, Y, W] Conjugate Vaccine)
- Mozobil® (plerixafor injection)[1]
- Multaq® (dronedarone) Tablets*
- Pentacel® Diptheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Inactivated Poliovirus and Haemophilus b Conjugate (Tetanus Toxoid Conjugate) Vaccine
- Priftin® (rifapentine) Tablets
- Soliqua® 100/33 (insulin glargine & lixisenatide) injection 100 Units/mL and 33 mcg/mL
- Tenivac® (tetanus and diphtheria toxoids adsorbed)
- Thymoglobulin® [Anti-Thymocyte Globulin (Rabbit)]*,[1]
- Thyrogen® (thyrotropin alfa)
- Toujeo® (insulin glargine injection) 300 Units/mL (1.5 mL or 3.0 mL pens)**

*Please see full US prescribing information, including Black Box warning.
**Regular SoloStar® is packaged as 3 pens per pack 450 units/pen; dials up to 80 units per single injection. Max SoloStar® is packaged as 2 pens per pack 900 units/pen; dials up to 160 units per single injection; Max pen dials in 2-unit increments.
[1]If applying for Drug Replacement (Lovenox®, Mozobil®, and Thymoglobulin®), a copy of the claim, denial, flow sheet(s), and drug dispensing log (with patient name, date of service, product NDC/Lot #, total dosage) must be submitted.
Full U.S. prescribing information for all Sanofi Patient Connection supported products can be accessed at www.sanofipatientconnection.com/medications-available. Sanofi Patient Connection will provide assistance for any medically appropriate use as described in the prescribing information.

Additional Information

- Sanofi Patient Connection ships most medications in a 90-day supply.
- A representative from Sanofi may contact you for follow-up on any adverse event you may report regarding a Sanofi product.

DO NOT INCLUDE PATIENT MEDICAL RECORDS WITH THIS APPLICATION.

P: 1.888.847.4877 · F: 1.888.847.1797
P.O. Box 222138 · Charlotte, NC · 28222-2138

Section 7. Authorization to Use and Disclose Health Information (REQUIRED)

***Patient:* Please read the following carefully, then date and sign where indicated in Section 1 on page 2.**

HIPAA Consent: I authorize my healthcare providers and staff; my health insurer, health plan, or programs that provide me health benefits (together, "Health Insurers") to disclose to, Sanofi US, its affiliated companies (ie, Sanofi Pasteur U.S. and Genzyme, a Sanofi Company), Sanofi Cares North America, and authorized third party agents involved in administration of this Program, (collectively "Program Sponsor"), health information about me, including information related to my medical condition, treatment, health insurance coverage, claims, prescriptions, and referral to and enrollment in this Program for purposes of determining my participation in, and administering, the Program, which may include contacting me as well as my doctor/healthcare provider, office/hospital staff, insurer (public/private) or others. I understand a representative from Sanofi may contact me for follow-up on any adverse event I may report regarding a Sanofi product. I authorize and consent to release of identifiable information about me including medical, financial and insurance records and information as required for participation in the Program. I understand that identifiable information about me will be kept confidential and will not be further used or disclosed except to administer the Program, or as required by law. I understand that information I authorize to be disclosed may be re-disclosed and is no longer protected by Federal privacy regulations. I agree that this authorization is voluntary and that I may refuse to sign this authorization. Refusal to sign will not affect my ability to obtain treatment but I will not be able to participate in this Program. Unless revoked, this authorization shall remain in effect throughout my participation in the Program, including subsequent reapplication as required. I may withdraw this authorization at any time by written notification to my doctor/healthcare provider; however, withdrawal of authorization will terminate my participation in this Program and will not affect information already disclosed under this Authorization.

I understand that it is my responsibility to follow up with my prescriber or the Program to make sure that my re-orders, as appropriate, are requested in a timely manner by my healthcare provider so I do not run out of medication. I understand that Sanofi US and Sanofi Cares North America reserve the right at any time and without notice to modify or change eligibility criteria or discontinue this Program. I understand that I may withdraw (take back) this Authorization at any time by calling 1.888.847.4877.

DO NOT INCLUDE PATIENT MEDICAL RECORDS WITH THIS APPLICATION.

P: 1.888.847.4877 · F: 1.888.847.1797
P.O. Box 222138 · Charlotte, NC · 28222-2138

Section 8. Income Verification

***Patient:* Please read the following carefully, then date and sign where indicated in Section 1 on page 2.**

Income Verification: I authorize Sanofi Patient Connection (SPC) under the Fair Credit Reporting Act to use my demographic information to access reports on my individual credit history from consumer reporting agencies. I understand that, upon request, SPC will tell me whether an individual consumer report was requested and the name and address of the agency that furnished it. I further understand and authorize SPC to use any consumer reports about me and information collected from me, along with other information they obtain from public and other sources, to estimate my income in conjunction with the Patient Assistance Program eligibility determination process, if applicable. I further understand that no free product may be submitted for reimbursement to any payer, including Medicare and Medicaid; and no free product may be sold, traded, or distributed for sale. If approved for the SPC Patient Assistance Program, I will not seek to have the value of any medication provided to me under this program counted toward my true-out-of-pocket (TrOOP) cost for prescription drugs for my Medicare Part D Plan. Continuation in the SPC Patient Assistance Program is conditioned upon timely verification of income. In addition, I agree to notify SPC if my insurance situation changes.

Section 9. Patient Certifications

***Patient:* Please read the following carefully, then date and sign where indicated in Section 1 on page 2.**

I authorize the Program to contact me by mail, telephone, or email, with information about the Program, disease state, and products, promotions, services, and research studies, and to ask my opinion about such information and topics, including market research and disease-related surveys. I further authorize the Program to de-identify my health information and use it in performing research, including linkage with other de-identified information the Program receives from other sources, education, business analytics, marketing studies, or for other commercial purposes. I understand that entities operating or administering parts of the Program may share identifiable health information with one another in order to de-identify it for these purposes and as needed to perform the Services or to send the communications listed above (the "Communications"). I understand and agree that the Program may use my health information for these purposes and may share my health information with my doctors, specialty pharmacies, and insurers. I understand that I may be contacted by the Program in the event that I report an adverse event associated with a Sanofi product.

I understand that I do not have to opt in to receive the Communications, and that I can still receive patient assistance through the Program, as prescribed by my physician. I may opt out of receiving the Communications offered by the Program, at any time by notifying a Program representative by telephone at 1-800-633-1610 or by mailing a letter to Sanofi US Customer Services, P.O. Box 5925 Mailstop 55A-220A5, Bridgewater, NJ 08807-5925. I also understand that the Services may be revised, changed, or terminated at any time.

DO NOT INCLUDE PATIENT MEDICAL RECORDS WITH THIS APPLICATION.

P: 1.888.847.4877 · F: 1.888.847.1797
P.O. Box 222138 · Charlotte, NC · 28222-2138

Elements of the Thyroid Cancer Journey

For Patients with Low- and Intermediate-Risk Differentiated Thyroid Cancer

Surgery

- Total or partial removal of thyroid gland depends on:
- Size of tumor(s)
- Type of tumor cells
- Extension beyond the thyroid and lymph node involvement

Thyroid Hormone Replacement Therapy

- Because all or part of your thyroid is removed during surgery, thyroid hormone replacement therapy may be necessary
- Thyroid hormone replacement therapy helps raise the levels of your thyroid hormones and controls/lowers your thyroid stimulating hormone (TSH) blood levels
- Thyroid hormone medication is taken for life and checked regularly

Evaluation Approximately 3-8 Weeks After Surgery [1,2]

- There are many ways to assess thyroid cancer after thyroidectomy.
- Typically these are referred to as personalized risk stratification and radioactive iodine selection protocols.
- Talk to your doctor to determine which tests are right for you.
- An example of evaluation after surgery, to help determine your treatment plan, may be the Orlov protocol.

Some tests that may be used to help guide your treatment plan include thyroglobulin, whole-body scan, neck ultrasound and TSH blood test.

Stimulated Thyroglobulin Blood Test and Neck Ultrasound

↓

Evaluate Stimulated Thyroglobulin Levels[2]

Low	Intermediate	Elevated
↓	↓	↓
No Routine Radioactive Iodine Ablation	**Possible Radioactive Iodine Ablation**	**Probable Radioactive Iodine Ablation**

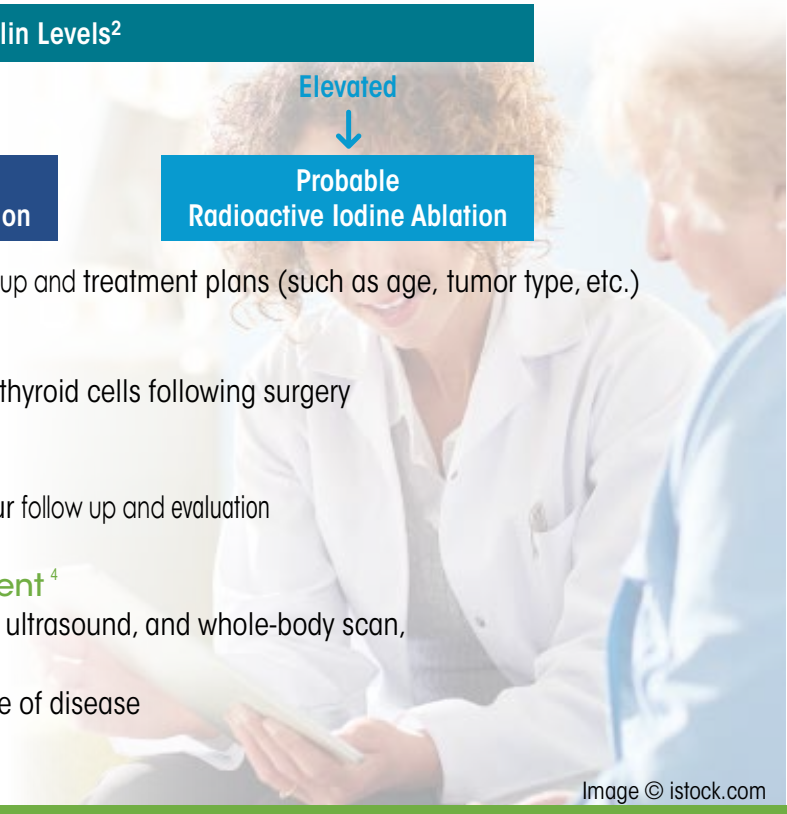
Your doctor may consider other factors when recommending follow up and treatment plans (such as age, tumor type, etc.)

Radioactive Iodine Ablation [3]

- Used to destroy any remaining normal or (if present) cancerous thyroid cells following surgery
- Taken by mouth usually in capsule form
- Take precautions following the use of radioactive iodine
- Given approximately 4-12 weeks after surgery, depending on your follow up and evaluation

Assessment of Status 6-18 Months After Initial Treatment [4]

- May include tests such as such as thyroglobulin blood test, neck ultrasound, and whole-body scan, (ask your doctor what tests are right for you)
- May also receive a stimulated thyroglobulin test to verify absence of disease
- Thyroglobulin blood testing may be repeated every 12 months
- Whole-body scan may provide additional information



How you respond to initial treatment guides the intensity of future treatment and monitoring

1. Adapted from Haugen BR, et al. *Thyroid.* 2016;26:1-133. 2. Orlov S, et al. *Endocrine.* 2015;50:130-137. 3.Carbello et al. Journal of Oncology. Volume 2012 | Article ID 707156 4. Tests for Thyroid Cancer; ACS.https://www.cancer.org/cancer/thyroid-cancer/detection-diagnosis-staging/how-diagnosed.html. Accessed August 2020

Each patient journey is unique. Please talk to your doctor to understand the treatment options available to you.

Continued on back

Elements of the Thyroid Cancer Journey

Glossary

RAI ablation
Administration of a radioactive form of iodine (^{131}I) to try to destroy any remnant (normal or cancerous) thyroid tissue left after surgery in the thyroid bed or neck.

Stimulated Thyroglobulin (Stim-Tg) Testing
The sensitivity of the Tg blood test can be enhanced by stimulating the body prior to the blood test with high levels of thyroid stimulating hormone (TSH). TSH stimulates thyroid cells to release thyroglobulin into the blood. TSH can be increased by stopping the thyroid replacement medication in preparation for the blood test.

Stopping the thyroid hormone medication may cause the patient to experience symptoms of hypothyroidism. As an alternative, your doctor may use Thyrogen, which increases TSH levels without stopping thyroid hormone replacement. Studies show that the highest degrees of sensitivity for Tg to detect thyroid cancer were noted following thyroid hormone withdrawal or stimulation.[1]

Thyroglobulin (Tg)
A large protein that acts as a storage site for thyroid hormones within the thyroid gland. Following surgical removal of a cancerous thyroid gland, the level of Tg in the bloodstream can be monitored to detect thyroid cancer recurrence.

Thyroid gland
A two-lobed gland lying at the base of the throat that produces hormones essential for a variety of metabolic processes in the body. When iodine is ingested, much of it goes to the thyroid gland.

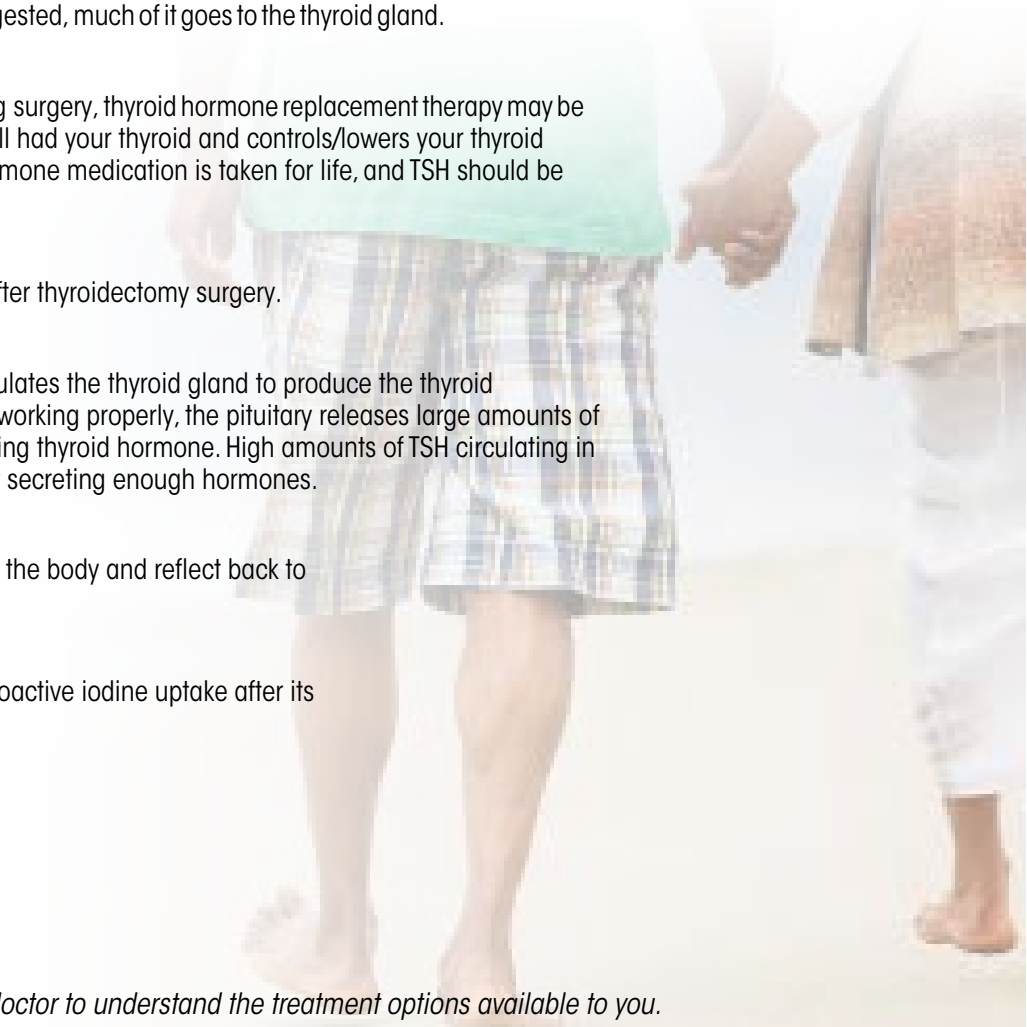
Thyroid hormone replacement therapy
Because all or part of your thyroid is removed during surgery, thyroid hormone replacement therapy may be necessary. This enables you to function as if you still had your thyroid and controls/lowers your thyroid stimulating hormone (TSH) blood levels. Thyroid hormone medication is taken for life, and TSH should be checked regularly.

Thyroid remnant
Some part of the original thyroid gland remaining after thyroidectomy surgery.

Thyroid-stimulating hormone (TSH)
A hormone secreted by the pituitary gland that stimulates the thyroid gland to produce the thyroid hormones T4 and T3. When the thyroid gland is not working properly, the pituitary releases large amounts of TSH to try to stimulate the thyroid gland into producing thyroid hormone. High amounts of TSH circulating in the bloodstream thus indicate that the thyroid is not secreting enough hormones.

Ultrasound
A type of scan that uses sound waves that pass into the body and reflect back to produce images.

Whole body scan (WBS)
A scan of the whole body used to view areas of radioactive iodine uptake after its oral administration.



Each patient journey is unique. Please talk to your doctor to understand the treatment options available to you.

Patient Organizations

Several organizations offer support and resources for thyroid cancer patients. Some of those are listed below for your reference.

American Cancer Society

The American Cancer Society provides information on thyroid cancer including an overview of US statistics, thyroid cancer testing, diagnosis, staging, and long-term management.

American Thyroid Association (ATA)

This group has resources for both thyroid physicians and patients. The ATA provides patient education, including a patient newsletter, and provides guidance for the management of thyroid cancer.

CancerCare

CancerCare provides free, professional support services for people affected by thyroid cancer, as well as educational information and support resources.

Light of Life Foundation

Founded by a thyroid cancer patient, Light of Life includes helpful perspectives on the disease as well as living with thyroid cancer, including a low iodine cookbook. This group organizes a national symposium and contributes to research in this area.

My Life Line

My Life Line provides free, private, patient websites for people affected by cancer, with the aim of building an online support community.

National Cancer Institute

This organization provides information on thyroid cancer to help patients and families further understand the disease and specific tips on coping with thyroid cancer. They have a number of resources on thyroid cancer management.

ThyCa

ThyCa is the Thyroid Cancer Survivors' Association. ThyCa provides many patient resources, including a low iodine diet guide and cookbook. The group conducts an annual international conference, and helps patients to find local support.

This listing is provided as a resource only and does not constitute an endorsement by Sanofi Genzyme of any particular organization or its programming. Additional resources on this topic may be available and should be investigated.

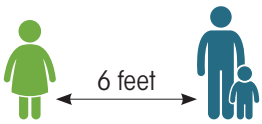
Post-treatment Information for Radioiodine Therapy

In order to ensure the safety of patients and families, the American Thyroid Association created recommendations for radiation safety. Talk to your doctor about specific restrictions or recommendations, and the length of time you should observe them based on your treatment.

Radioiodine is a radioactive substance that is commonly used in patients with well-differentiated thyroid cancer. The treatment dose of radioiodine swallowed will be absorbed through your gastrointestinal tract and will be taken up by any thyroid tissue that is present. Nearly all of the radioiodine will be eliminated from the body during the first week after treatment, primarily through urine. Small amounts will also be excreted in saliva, perspiration and feces.

Your doctor or member of the Radioiodine Treatment Team will discuss with you the following items and fill in the number of days related to each.

- ☐ Days that you need to stay >3 feet away from your adult family members and caregivers for at least 18 hours a day, and at least 6 feet away as much as possible.
- ☐ Days that you need to stay >6 feet away from babies, children younger than 16 years old and pregnant women.
- ☐ Days that you need to stay away from work and close contact with others in public places (movies, shopping, etc).
- ☐ Days that you need to stay away from school or day-care (includes both teachers and students).



General Recommendations (especially for patients sharing a bathroom)

- Flush the toilet after each time you use it; flush toilet paper and wipes;
- Always wash your hands well after using the toilet;
- Rinse the sink and wash your hands after brushing your teeth to wash away the saliva (spit);
- Do not share your toothbrush, razor, face cloth, towel, food or drinks, spoons, forks, glasses and dishes;
- Shower every day for at least the first 2 days after your treatment;
- Do not cook for other people. If cooking is necessary, use plastic gloves and dispose of in the specified plastic trash bag;
- Wash your dishes in a dishwasher or by hand; it is better not to use disposable (throw away) dishes which must be put into a specified plastic trash bag;
- Try to flush any tissues or any other items that contain anything from your body, such as blood, down the toilet; items that cannot be flushed, such as menstrual pads, bandages, paper/plastic dishes, spoons and forks and paper towels should be put in the specified plastic trash bag;
- Wash your underwear, pajamas, sheets, towels and any clothes that contain sweat, blood or urine by themselves; use a standard washing machine; you do not need to use bleach and do not need extra rinses;
- Have any one who helps you clean up vomit, blood, urine, or stool wear plastic gloves; the gloves should then be put in the specified trash plastic bag.

Recommendations After Therapy

AT HOME
Ask your doctor for the number of days to:

- ☐ Sleep alone in a bed that is >6 feet away from another person, and, if possible, use a separate bedroom or sleeping room all by yourself;
- ☐ Not kiss anyone or engage in sexual activity;
- ☐ Move your bowels every day and use a laxative if you need help;
- ☐ Empty your bladder (urinate) every hour or so during the day of, and day after your radioiodine treatment; follow your doctor's advice on how much fluid to drink;
- ☐ Use wipes (preferably flushable) to clean the toilet seat after use; men should sit down to urinate and use wipes to remove splatter of urine; wipe yourself dry after urinating so that you do not drip;
- ☐ For a phone you share with others, after use, wipe off the mouthpiece, or, while using, cover the phone with a plastic bag that, after use, is placed in specific plastic trash bag.

Post-treatment Information for Radioiodine Therapy

Trash Recommendations

- Keep the specified plastic trash bags separate from other trash; keep the bags away from children and animals;
- A member of your Radioiodine Treatment Team will tell you how and when to get rid of the specified plastic trash bag; you may be asked to bring the bag back to your treatment facility, or, after 80 days, the bag may be removed with other household trash.

Pets

- Usually pets will not receive enough radiation exposure to harm them. But do not sleep or come in close contact with pets (ask your doctor for how long) since your saliva, perspiration or other secretions may be carried away by the pet and transfered to other people.

OUTSIDE THE HOME
Ask Your Doctor or a member of the Radioiodine Treatment Team when:

- ☐ It will be safe to eat out, go shopping and attend events such as religious services, parties and movies;
- ☐ You will be able to return to work and to care for or teach others;
- ☐ It would be safe to donate blood;
- ☐ Special or longer distance travel is possible *(Note: For up to 3 months or more following radioiodine treatment you may set off radiation detectors at: national borders, airports, bus and train stations, tunnels, bridges, trash collection sites and even your place of employment); a member of your Radioiodine Treatment Team will issue you a letter or card describing the therapy and the phone number of a person knowledgeable about your treatment (usually at the treating facility) in case local law enforcement agents need to check on this information; you should keep the letter or card containing the information with you whenever you are traveling for at least 3 months.*

Emergency Care

- You will get an information card or letter at the time of your treatment that will show the date, type and amount of radioiodine that you were treated with; carry this card with you at all times for at least 3 months following your treatment;
- If you are in a traffic accident or any other medical emergency during the first week after your treatment, you should show this card to the medical people to let them know about the date and dose of your radioiodine treatment.

IMPORTANT INFORMATION FOR PATIENTS: RISKS OF RADIATION

Radiation exposure to others should always be **As Low As Reasonably Achievable**, a goal often abbreviated as **ALARA**. If you follow the above advice, the radiation from you to others is likely to be less than what they receive from radiation in nature over a year's time.

Contact your doctor if you have any questions, and particularly if any of the above instructions cannot be followed and/or if you see anything that may have accidentally or unavoidably increased exposure of others to radiation.

Adapted from Sisson J, et al. *Thyroid.* 2011;21:335-346.

Preparing for Scans with a Low-Iodine Diet

Before undergoing radioactive scanning, you may be asked by your physician to follow a low-iodine diet. The following diet tips and sample menus may help you manage your low-iodine diet. Of course, as with other aspects of your therapy, it's important to consult with your healthcare provider about diet changes and other test preparation.

Foods you can eat

- Kosher salt
- Egg whites
- Fresh non-cured meat from the butcher
- Fresh fruits and vegetables, washed well (limit bananas, spinach, and broccoli)
- Frozen vegetables with no added salt
- Canned peaches, pears and pineapples
- Matza/ Matzah/ MatzoHomemade bread made from non-iodized salt and oil (not soy) instead of butter or milk
- Natural unsalted peanut butter
- Clear sodas
- Coffee or tea made with distilled water (with non-dairy creamer only)
- Popcorn popped in vegetable oil or air popped, with non-iodized salt
- Sorbet (without FD&C red dye #3)

Foods to avoid that contain iodine

- Iodized salt and sea salt
- All dairy products (milk, sour cream, cheese, cream, yogurt, butter, ice cream)
- Margarine
- Egg yolks
- Seafood (fish, shellfish, seaweed, kelp)
- Foods that contain carrageen, agar-agar, align, or alginate (all of these are made from seaweed)
- Cured and corned foods (ham, bacon, sausage, corned beef, tuna, etc.)
- Marinated chicken or turkey
- Dried fruit
- Canned vegetables
- Bread products that contain iodate dough conditioners
- Chocolate
- Molasses
- Soy products (soy sauce, soy milk, tofu)
- Foods that contain FD&C Red Dye #3

Please note

A low-iodine diet does *not* restrict sodium or salt. It only restricts *iodized* salt or sea salt. Any salt that is labeled ***non-iodized*** may be used freely.

Menu Suggestions

The sample menus below are examples of meals that are suitable as part of a low-iodine diet

BREAKFAST Sample Menu

- ¼ cup quick-cooking oatmeal, ½ cup water or apple juice, 2 tsp. honey, and 2 tbsp. raisins (optional)
- 1 medium banana, apple, or pear
- 8 oz. (1 cup) orange, grape, or grapefruit juice (fresh or reconstituted with distilled water)
- 1 cup coffee or tea, with 2 tsp. sugar (optional) and 1 tsp. powdered non-dairy creamer (optional)
- 12 oz. (1 ½ cup) distilled water

LUNCH Sample Menu

- 1 roasted chicken breast (meat only) seasoned with black pepper, non-iodized salt, and fresh herbs
- 1 small garden salad seasoned with olive oil and lemon juice to taste
- 1 medium orange, apple, or plum
- 1 cup coffee or tea, with 2 tsp. sugar (optional) and 1 tsp. powdered non-dairy creamer (optional)
- 12 oz. (1 ½ cup) distilled water

DINNER Sample Menu

- 6 oz. fresh chicken, beef, or turkey breast, may use black pepper, fresh or dried herbs, vegetable oil to season
- 1 baked or mashed potato without skin
- 1 cup fresh vegetables (examples: green beans, carrots)
- 1 cup jello made with water (any color but red) or sorbet
- 12 oz. (1 ½ cup) distilled water

More Low-Iodine Diet Tips

- When you are maintaining your diet, it would be wise to avoid restaurant food, as it is difficult to determine the exact ingredients being used to prepare the food
- You may want to shop and freeze or store your ingredients before starting your diet to avoid being tempted by iodine-containing foods at the store

References
Thyroid Cancer Survivors' Association, Inc. (2015). *Low-Iodine Cookbook* (8th ed.). Accessed online at thyca.org February 2016.
The Light of Life Foundation, Inc. (2014). *The Light of Life Foundation Cookbook* (2nd ed.). Accessed online at lightoflifefoundation.org February 2016.

MAT-US-2024061-v3.0-02/2024