Thyrogen®
(thyrotropin alfa) for injection

Please visit **www.Thyrogen.com** for information
For questions contact **1-88-THYROGEN**

Thyrogen (thyrotropin alfa)

Billing and Coding Guide

For Physician's Offices and Hospitals

The following is provided for informational purposes only and is not intended to substitute for the physician's independent diagnosis or treatment of each patient. Providers are responsible for the accuracy and validity of any claims, invoices, and related documentation submitted to payers. Physicians should contact the payer if they have any specific questions about coverage or payment. Any specific guidance or direction on the submission of claims offered by the payer supersedes the codes listed below. Use of the following codes does not guarantee reimbursement.

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PHYSICIANS' OFFICES — **Should always use the CMS 1500 Forms to make claims for Thyrogen**

(Please Refer to Sample CMS 1500 form on Page 4)

HOSPITALS — **Should always use the UB-04 to make claims for Thyrogen**

(Please Refer to Sample UB 04 Form on Page 5)

BILLING MEDICAID

Coverage for Thyrogen under a state Medicaid program may be provided as either a pharmacy benefit or a medical benefit. This will vary from state to state.

Pharmacy benefit claims may be submitted electronically by an approved specialty pharmacy.

Paper claims for either pharmacy or medical benefits may be submitted using the UB-04 form or a similar billing form approved by the state Medicaid office.

Medicaid claims for Thyrogen may be submitted using the CPT-4 code or the NDC code, whichever is appropriate for the specific state program.

BILLING MEDICARE

All services and supplies, including drugs, must represent an expense to the hospital in connection with the physician's treatment of patients in an outpatient setting.

Revenue code 636 may be required by the institution's fiscal intermediary.

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CATEGORY	CODE	DESCRIPTION
Revenue	250	Pharmacy, general
Revenue	636	Drugs requiring detailed coding
HCPCS	J3240	Thyrogen, 0.9 mg
CPT-4	96372	Therapeutic, prophylactic or diagnostic injection (specify substance or drug); subcutaneous or intramuscular
Service Units	1**	Thyrogen, 0.9 mg
ICD-10	C 73	Malignant neoplasm of the thyroid gland
NDC	58468-0030-2	Thyrogen®, 0.9 mg (2 vials Thyrogen)

**** EACH THYROGEN KIT CONTAINS 2 VIALS OF THYROGEN**
ON THE BILLING FORM, EACH VIAL SHOULD BE LISTED AS A SEPARATE LINE ITEM FOR THE DATE IT WAS ADMINISTERED

ThyrogenONE®
Ordering and Reimbursement

Streamlined resources from ThyrogenONE®

ThyrogenONE provides a single point of access

Same-day benefit verification and patient assistance

24/7 access through the online portal.

Monday through Friday 8 am - 8 pm ET

Phone: **1-88-THYROGEN (1-888-497-6436)**
Fax: **1-888-326-1002**
Web: **www.THYROGEN.com**

Adverse reactions should be reported promptly to Sanofi Genzyme Medical Information at: 1-800-745-4447, Option 2

Please visit **www.Thyrogen.com** for information
For questions contact **1-88-THYROGEN**

The CMS 1500 for Physician Office

HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

CARRIER

PICA

1. MEDICARE (Medicare#)	MEDICAID (Medicaid#)	TRICARE (ID#/DoD#)	CHAMPVA (Member ID#)	GROUP HEALTH PLAN (ID#)	FECA BLK LUNG (ID#)	OTHER (ID#)

1a. INSURED'S I.D. NUMBER (For Program in Item 1)	
2. PATIENT'S NAME (Last Name, First Name, Middle Initial)	Doe, John D
3. PATIENT'S BIRTH DATE MM DD YY / SEX	XX XX XX / M
4. INSURED'S NAME (Last Name, First Name, Middle Initial)	Doe, John D
5. PATIENT'S ADDRESS (No., Street)	5555 Any Street
6. PATIENT RELATIONSHIP TO INSURED	Self Spouse Child Other
7. INSURED'S ADDRESS (No., Street)	
CITY / STATE	Anytown / AS
8. RESERVED FOR NUCC USE	
CITY / STATE	
ZIP CODE / TELEPHONE (Include Area Code)	01010 / (xxx)xxx-xxxx
ZIP CODE / TELEPHONE (Include Area Code)	( )
9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)	
10. IS PATIENT'S CONDITION RELATED TO:	
11. INSURED'S POLICY GROUP OR FECA NUMBER	
a. OTHER INSURED'S POLICY OR GROUP NUMBER	
a. EMPLOYMENT? (Current or Previous)	YES NO
a. INSURED'S DATE OF BIRTH MM DD YY / SEX	M F
b. RESERVED FOR NUCC USE	
b. AUTO ACCIDENT? PLACE (State)	YES NO
b. OTHER CLAIM ID (Designated by NUCC)	
c. RESERVED FOR NUCC USE	
c. OTHER ACCIDENT?	YES NO
c. INSURANCE PLAN NAME OR PROGRAM NAME	
d. INSURANCE PLAN NAME OR PROGRAM NAME	
10d. CLAIM CODES (Designated by NUCC)	

PATIENT AND INSURED INFORMATION

12. ...MPLETING & SIGNING THIS FORM. ...thorize the release of any medical or other informati... ...efits either to myself or to the party who accepts ass... ...RE I authorize ...an or supplier for

SIGNED _____ DATE _____

14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY	QUAL.
	XX XX XX
15. OTHER DATE MM DD YY	QUAL.
16. DATES PATIEN UNABLE TO WORK IN CURRENT OCCUPATION MM DD YY	FROM TO
17. NAME OF REFERRING PROVIDER OR OTHER SOURCE	17a. / 17b. NPI
18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES MM DD YY	FROM TO
19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)	
20. OUTSIDE LAB?	YES NO / $ CHARGES
21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind.	A. C73 B. C. D. E. F. G. H. I. J. K. L.

24. A. DATE(S) OF SERVICE From MM DD YY To MM DD YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
1 01 01 16 01 01 16			J3240		A,B,C	xxx xx	1		NPI	
2 01 01 16 01 01 16			96372		A,B,C	xxx xx	1		NPI	
3 01 02 16 01 02 16			J3240						NPI	
4 01 02 16 01 02 16			96372						NPI	
5									NPI	
6									NPI	

PHYSICIAN OR SUPPLIER INFORMATION

*Dates are examples of administering Thyrogen on 2 consecutive days

25. FEDERAL TAX I.D. NUMBER	...NMENT? ...e back) O	28. TOTAL CHARGE $	29. AMOUNT PAID $	30. Rsvd for NUCC Use

31. SIGNATURE OF PHYSICIAN C... INCLUDING DEGREES OR CR... (I certify that the statements on ... apply to this bill and are made ...

SIGNED _____ DATE _____

33. BILLING PROVIDER INFO & PH # ( )

a. NPI b.

NUCC Instruction Manual available at: www.nucc.org *PLEASE PRINT OR TYPE* APPROVED OMB-0938-1197 FORM 1500 (02-12)

PRODUCT CODE (BOX 24D)
Document use of product with **J3240** (Thyrogen,0.9mg) mg.

DIAGNOSIS CODE (BOX 21)
Document appropriate ICD-10-CM diagnosis code(s) corresponding to patient's diagnosis.

Line A — primary diagnosis code.

DIAGNOSIS CODE (BOX 24E)
Specify diagnosis, from Box 21, relating to each CPT/HCPCS code listed in Box 24D.

SERVICE UNITS (BOX 24G)
Report unit of service. For example, 1 unit (Thyrogen® dose is 0.9 mg, per label).

PROCEDURE CODE (BOX 24D)
Document product administration with appropriate CPT code. Use CPT code representing procedure performed, such as 96372, Healthcare providers should consult the payer or Medicare contractor to determine which code is most appropriate for administration of Thyrogen.

This sample form is intended as a reference for coding and billing for product and associated services. It is not intended to be directive; the use of the recommended codes does not guarantee reimbursement. Healthcare providers may deem other codes or policies more appropriate and should select the coding options that most accurately reflect their internal system guidelines, payer requirements, practice patterns, and the services rendered. Healthcare providers are responsible for ensuring the accuracy and validity of all billing and claims for appropriate reimbursement.

UB-04 Claim Form for Outpatient Hospitals

DISCLAIMER: This is a reference sheet only. It is NOT inclusive of all applicable codes that may be reported on a UB-04 claim form. The inclusion of codes listed is not intended to suggest or imply that such codes reflect appropriate diagnoses for any particular patient. To ensure appropriate documentation and coding, Providers should contact their billing/finance department.

1	2	3a PAT. CNTL # / b. MED. REC. # / 5 FED. TAX NO	4 TYPE OF BILL
Anywhere Medical Center 111 ABC St Anywhere, CA 00001			13X

Bill type 13X for "Hospital outpatient"

8 PATIENT NAME	9 PATIENT ADDRESS
a DOE, JOHN W	a 123 MAIN ST
b	b ANYWHERE c CA d 00001 e

10 BIRTHDATE	11 SEX	12 ADMISSION DATE	13 HR	14 TYPE	15 SRC	16 DHR	17 STAT	CONDITION CODES 18	19	20	21	22	23	24	25	26	27	28	29 ACDT STATE	30

31 OCCURRENCE CODE / DATE	32 OCCURRENCE CODE / DATE	33 O CODE	CURRENCE SPAN ROM THROUGH	36 OCCURRENCE SPAN CODE FROM THROUGH	37

CPT code 96372 for "Therapeutic, prophylactic or diagnostic injection (specify substance or drug); subcutaneous or intramuscular"

VALUE CODES AMOUNT	40 VALUE CODES CODE AMOUNT	41 VALUE CODES CODE AMOUNT

Revenue code 0250 for "IV therapy"

42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES	49
0250	INJECTION, THYROGEN	96372	MMDDYY	X	XXX XX		
0636	THYROGEN, 0.9 MG	J3240	MMDDYY	1	XXX XX		

Use Revenue code 0250 or 0636 for "Drugs requiring specific information"

HCPCS code J3240 for "Thyrogen, 0.9 mg"

Input number of units administered (1 mg = 1 unit)

PAGE ____ OF ____ CREATION DATE TOTALS

50 PAYER NAME	51 HEALTH PLAN ID	52 REL INFO	53 ASG BEN	54 PRIOR PAYMENTS	55 EST. AMOUNT DUE	56 NPI / 57 OTHER PRV ID

58 INSURED'S NAME	59 P REL	60 INSURED'S UNIQUE ID	61 GROUP NAME	62 INSURANCE GROUP NO.

63 TREATMENT AUTHORIZATION CODES	64 DOCUMENT CONTROL NUMBER	65 EMPLOYER NAME

66 DX	67	A	B	C	D	E	F	G	H	68
	I	J	K	L	M	N	O	P	Q	

69 ADMIT DX	70 PATIENT REASON DX a b c	71 PPS CODE	72 ECI	73

74 PRINCIPAL PROCEDURE CODE / DATE	a. OTHER PROCEDURE CODE / DATE	b. OTHER PROCEDURE CODE / DATE	75

c. OTHER PROCEDURE CODE / DATE	d. OTHER PROCEDURE CODE / DATE	e. OTHER PROCEDURE CODE / DATE

76 ATTENDING	NPI	QUAL
LAST		FIRST
77 OPERATING	NPI	QUAL
LAST		FIRST
78 OTHER	NPI	QUAL
LAST		FIRST
79 OTHER	NPI	QUAL
LAST		FIRST

80 REMARKS	81CC a / b / c / d

81 CMS-1450 APPROVED OMB NO. THE CERTIFICATIONS ON THE REVERSE APPLY TO THIS BILL AND ARE MADE A PART HEREOF

Thyrogen®
(thyrotropin alfa) for injection

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..

Click here for full Prescribing Information

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MAT-US-2001121-v2.0-10/2023