

Reimbursement Policy

Thyroid Disease Testing

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I. Policy Description

Thyroid hormones are necessary for both prenatal and postnatal development, as well as metabolic activity in adults.¹

Thyroid disease includes conditions which cause hypothyroidism, hyperthyroidism, goiter, thyroiditis (which can present as either hypo- or hyperthyroidism), and thyroid tumors.²

Thyroid function tests are used in a variety of clinical settings to assess thyroid function, monitor treatment, and screen asymptomatic populations for subclinical or otherwise undiagnosed thyroid dysfunction.³

Terms such as male and female are used when necessary to refer to sex assigned at birth.

II. Indications and/or Limitations of Coverage

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request. Specifications pertaining to Medicare and Medicaid can be found in the "Applicable State and Federal Regulations" section of this policy document.

- 1) Thyroid function testing **MEETS COVERAGE CRITERIA** in the following situations:
 - a) For individuals with signs and symptoms consistent with hypothyroidism (see Note 1):
 - i) Thyroid stimulating hormone (TSH) testing to confirm or rule out primary hypothyroidism.
 - ii) Free T4 (fT4) testing as a follow up to abnormal TSH finding.
 - iii) TSH and fT4 testing in cases of suspected secondary hypothyroidism.
 - iv) For individuals being treated for primary hypothyroidism, monitoring with TSH and fT4 testing every 6 weeks upon dosage change and annually in stable individuals.
 - v) For individuals being treated for secondary hypothyroidism, monitoring with fT4 testing every 6 weeks upon dosage change and annually in stable individuals.

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- b) For individuals with signs and symptoms consistent with hyperthyroidism (see Note 2):
 - i) TSH testing to confirm or rule out overt hyperthyroidism.
 - ii) fT4 testing as a follow up to abnormal TSH findings.
 - iii) Total T3 (TT3) or free T3 (fT3) testing to confirm a diagnosis of hyperthyroidism.
 - iv) fT4 testing to distinguish between overt and subclinical hyperthyroidism.
 - v) Monitoring individuals after treatment for hyperthyroidism:
 - (a) In patients being treated for hyperthyroidism, repeat testing of TSH and fT4 should occur every 8 weeks.
 - (b) Annual monitoring after first year even if asymptomatic for risk of relapse or late-onset hypothyroidism.
- c) For asymptomatic individuals who have been prescribed drugs that can interfere with thyroid function and thus who are at an increased risk for thyroid disease, TSH testing at the following intervals:
 - i) Annually.
 - ii) When dosage or medication changes.
 - iii) If symptoms consistent with thyroid dysfunction develop.
- d) TSH testing for individuals capable of becoming pregnant who have experienced two or more pregnancy losses.
- e) TSH testing for individuals with a thyroid nodule.
- f) One-time TSH screening:
 - i) For asymptomatic individuals at high risk for thyroid disease due to:
 - (a) Personal or family history of thyroid dysfunction.
 - (b) Personal or family history of type 1 diabetes or other autoimmune disease.
 - ii) For individuals with disease or neoplasm of the thyroid or other endocrine glands.
 - iii) For individuals with chronic or acute urticaria.

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- iv) For pediatric individuals diagnosed with short stature.
 - v) For pediatric individuals with a clinical finding of failure-to-thrive.
 - g) TSH testing once every 3 months, with reflex fT4 and fT3 when TSH is abnormal, for individuals undergoing immune reconstitution therapy (IRT):
 - i) Individuals with active relapsing remitting multiple sclerosis (MS) undergoing therapy with alemtuzumab (Lemtrada).
 - ii) Individuals with HIV undergoing highly active antiretroviral therapy (HAART).
 - iii) Individuals following allogeneic bone marrow transplantation (BMT) or hematopoietic stem cell transplantation (HSCT).
 - h) For individuals with hypothalamic-pituitary disease, monitoring of TSH and fT4:
 - i) Biannually for individuals less than 18 years of age.
 - ii) Annually for individuals 18 years of age or older.
 - i) Annual screening of TSH and fT4 for individuals diagnosed with primary mitochondrial disease.
- 2) For individuals who are pregnant or who are postpartum and who have symptoms of thyroid dysfunction (see Note 1 and Note 2), TSH and fT4 testing (once every 4 weeks) **MEETS COVERAGE CRITERIA** (see Note 3).
 - 3) For individuals who are pregnant or who are postpartum and who have been diagnosed with hyperthyroidism, total T4 (TT4), antithyroglobulin antibody (Tg-Ab), thyrotropin receptor antibodies (TRAb), and antithyroid peroxidase antibody (TPOAb) **MEETS COVERAGE CRITERIA** (see Note 3).
 - 4) For individuals with hypothyroidism or hyperthyroidism, testing once every three years for thyroid antibodies (i.e., Tg-Ab, TPOAb, TRAb, thyroid-stimulating immunoglobulins [TSI]) **MEETS COVERAGE CRITERIA**.
 - 5) For individuals with thyroid cancer, testing for serum thyroglobulin and/or Tg-Ab levels for the detection of tumor recurrence, post-surgical evaluation, surveillance, and maintenance for differentiated thyroid carcinomas **MEETS COVERAGE CRITERIA**.
 - 6) For the evaluation of the cause of hyperthyroidism or hypothyroidism, testing for thyrotropin-releasing hormone (TRH) or thyroxine-binding globulin (TBG) **DOES NOT MEET COVERAGE CRITERIA**.

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- 7) For all other situations not mentioned above, testing of reverse T3, T3 uptake, and TT4 **DOES NOT MEET COVERAGE CRITERIA.**
- 8) For the assessment of hypothyroidism, measurement of TT3 and/or fT3 **DOES NOT MEET COVERAGE CRITERIA.**
- 9) To assess levothyroxine dose in hypothyroid patients, measurement of total or fT3 level **DOES NOT MEET COVERAGE CRITERIA.**
- 10) For asymptomatic nonpregnant individuals, testing for thyroid dysfunction during a general exam without abnormal findings **DOES NOT MEET COVERAGE CRITERIA.**

NOTES:

Note 1: Signs and symptoms of hypothyroidism include:

- Fatigue
- Increased sensitivity to cold
- Constipation
- Dry skin
- Unexplained weight gain
- Puffy face
- Hoarseness
- Muscle weakness
- Elevated blood cholesterol level
- Muscle aches, tenderness, and stiffness
- Pain, stiffness or swelling in your joints
- Heavier than normal or irregular menstrual periods
- Thinning hair

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- Slowed heart rate
- Depression
- Impaired memory

Note 2: Hyperthyroidism can mimic other health problems, which may make it difficult for doctors to diagnose. It can also cause a wide variety of signs and symptoms, including:

- Sudden weight loss, even when your appetite and the amount and type of food you eat remain the same or even increase
- Rapid heartbeat (tachycardia) — commonly more than 100 beats a minute — irregular heartbeat (arrhythmia) or pounding of your heart (palpitations)
- Increased appetite
- Nervousness, anxiety, and irritability
- Tremor — usually a fine trembling in your hands and fingers
- Sweating
- Changes in menstrual patterns
- Increased sensitivity to heat
- Changes in bowel patterns, especially more frequent bowel movements
- An enlarged thyroid gland (goiter), which may appear as a swelling at the base of your neck
- Fatigue, muscle weakness
- Difficulty sleeping
- Skin thinning
- Fine, brittle hair

Note 3: Due to significant changes in thyroid physiology during pregnancy, measurement of hormone levels should only be performed at labs that have trimester-specific normal ranges for

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their assay(s). While fT4 is the preferred test, TT4 may be useful if the TSH and fT4 results are discordant or when trimester-specific normal ranges for fT4 are unavailable.

III. Applicable State and Federal Regulations

DISCLAIMER: If there is a conflict between this Policy and any relevant, applicable government policy for a particular member [e.g., Local Coverage Determinations (LCDs) or National Coverage Determinations (NCDs) for Medicare and/or state coverage for Medicaid], then the government policy will be used to make the determination. For the most up-to-date Medicare policies and coverage, please visit the Medicare search website: <https://www.cms.gov/medicare-coverage-database/search.aspx>. For the most up-to-date Medicaid policies and coverage, visit the applicable state Medicaid website.

Food and Drug Administration (FDA)

Many labs have developed specific tests that they must validate and perform in house. These laboratory-developed tests (LDTs) are regulated by the Centers for Medicare and Medicaid (CMS) as high-complexity tests under the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88). LDTs are not approved or cleared by the U. S. Food and Drug Administration; however, FDA clearance or approval is not currently required for clinical use.

IV. Applicable CPT/HCPCS Procedure Codes

CPT	Code Description
80438	Thyrotropin-releasing hormone (TRH) stimulation panel; 1 hour This panel must include the following: Thyroid stimulating hormone (TSH) (84443 x 3)
80439	Thyrotropin-releasing hormone (TRH) stimulation panel; 2 hour This panel must include the following: Thyroid stimulating hormone (TSH) (84443 x 4)
83519	Immunoassay for analyte other than infectious agent antibody or infectious agent antigen; quantitative, by radioimmunoassay (eg, RIA)
83520	Immunoassay for analyte other than infectious agent antibody or infectious agent antigen; quantitative, not otherwise specified
84432	Thyroglobulin
84436	Thyroxine; total
84439	Thyroxine; free

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CPT	Code Description
84442	Thyroxine-binding globulin (TBG)
84443	Thyroid stimulating hormone (TSH)
84445	Thyroid stimulating immune globulins (TSI)
84479	Thyroid hormone (T3 or T4) uptake or thyroid hormone binding ratio (THBR)
84480	Triiodothyronine T3; total (TT-3)
84481	Triiodothyronine T3; free
84482	Triiodothyronine T3; reverse
86376	Microsomal antibodies (eg, thyroid or liver-kidney), each
86800	Thyroglobulin antibody

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Procedure codes appearing in Medical Policy documents are included only as a general reference tool for each policy. They may not be all-inclusive.

V. Evidence-based Scientific References

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