MEDICATION COVERAGE POLICY

PHARMACY AND THERAPEUTICS ADVISORY COMMITTEE

POLICY	Thyroid Disorders	**P&T DATE:**	3/11/2025
THERAPEUTIC CLASS	Endocrine Disorders	**REVIEW HISTORY** (MONTH/YEAR)	3/24, 3/23, 7/22, 12/21, 12/20, 12/19, 12/18, 9/17, 12/16, 11/15
LOB AFFECTED	Medi-Cal		

This policy has been developed through review of medical literature, consideration of medical necessity, generally accepted medical practice standards, and approved by the Health Plan of San Joaquin/Mountain Valley Health Plan (Health Plan) Pharmacy and Therapeutic Advisory Committee.

Effective 1/1/2022, the Pharmacy Benefit is regulated by Medi-Cal Rx. Please visit https://medi-calrx.dhcs.ca.gov/home/ for portal access, formulary details, pharmacy network information, and updates to the pharmacy benefit.

All medical claims require that an NDC is also submitted with the claim. If a physician administered medication has a specific assigned CPT code, that code must be billed with the correlating NDC. If there is not a specific CPT code available for a physician administered medication, the use of unclassified CPT codes is appropriate when billed with the correlating NDC.

OVERVIEW

Treatment of hyperthyroidism and hypothyroidism is well-defined: methimazole and levothyroxine monotherapy are the mainstays of treatment for hyperthyroidism and hypothyroidism, respectively.[1,2]
The purpose of this coverage policy is to review the available agents (Table 1) and distinguish where the medications may be billed to. For agents listed for coverage under the medical benefit, this coverage is specific to outpatient coverage only (excludes emergency room and inpatient coverage).

Table 1: Available Anti-Thyroid & Thyroid Medications *(Current as of 12/2024)*

CPT Codes	Generic Name (Brand Name)	Available Strengths	Pharmacy Benefit	Outpatient Medical Benefit (Restrictions)
ANTI-THYROID MEDICATIONS				
--	Methimazole	5, 10 mg tablets	Yes	No
--	Propylthiouracil	50 mg tablet	Yes	No
THYROID MEDICATIONS				
--	Adthyza	15 mg, 16.25 mg, 30 mg, 32.5 mg, 60 mg, 65 mg, 90 mg, 97.5 mg, 120 mg, 130 mg tablets	Yes	No
--	Armour Thyroid	15, 30, 60, 90, 120, 180, 240, 300 mg tablets	Yes	No
--	Liothyronine sodium (Cytomel)	5, 25, 50 mcg tablets	Yes	No
--	Levothyroxine sodium (Euthyrox, Levoxyl)	25, 50, 75, 88, 100, 112, 125, 137, 150, 175, 200 mcg tablets	Yes	No
--	Nature-Throid	48.75, 65, 81.25, 97.5, 113.75, 130, 146.25, 162.5, 195, 260, 325 mg tablets	Yes	No
--	NP Thyroid	15, 30, 60, 90,120 mg tablets	Yes	No
--	Synthroid	25, 50, 75, 88, 100, 112, 125, 137, 150, 175, 200, 300 mcg tablets	Yes	No
--	Tirosint	13, 25, 50, 75, 88, 100, 112, 125, 137, 150, 175, 200 mcg capsules	Yes	No
--	Unithroid	25, 50, 75, 88, 100, 112,125, 137, 150, 175, 200, 300 mcg tablets	Yes	No
--	Westhroid	32.5, 65, 97.5, 130, 195 mg tablets	Yes	No
--	WP Thyroid	16.25, 32.5, 48.75, 65, 81.25, 97.5, 113.75, 130 mg tablets	Yes	No
THYROID EYE MEDICATIONS				
J3241	Teprotumumab-trbw (Tepezza)	500 mg vials	Yes	Yes (PA, QL)

MISCELLANEOUS				
J3240	Thyrotropin alfa (Thyrogen)	1.1 mg vial	Yes	Yes

PA = Prior Authorization Required *QL = Quantity Limit*

CLINICAL JUSTIFICATION

Methimazole is recommended for the treatment of all patients with Graves' Disease (except during the first trimester of pregnancy), in the treatment of thyroid storm, and in patients who refuse radioactive iodine therapy or surgery.[1] During the first trimester of pregnancy, propylthiouracil is preferred because it does not cross the placenta as readily, whereas methimazole has been associated with rare birth defects.[3] Levothyroxine monotherapy is the current standard of care for treating hypothyroidism. Levothyroxine (synthetic T4) is preferred over T3 agents (desiccated thyroid extracts and liothyronine) due to its long half-life and better gastrointestinal absorption.[2] As Thyrogen is diagnostic tool for thyroid cancer, there are no limits placed on its use.[12]

Tepezza (teprotumumab-trbw) is the only FDA approved medication for thyroid eye disease. Recent FDA labeling includes use regardless of disease activity of duration.[8] Therefore, criteria were created for Tepezza for both moderate-to-severe active and inactive thyroid eye disease. Requirements and limitations were established using guideline recommendations, clinical trial data, and package insert information.

EVALUATION CRITERIA FOR APPROVAL/EXCEPTION CONSIDERATION

Below are the coverage criteria and required information for agents with medical benefit restrictions. This coverage criteria has been reviewed and approved by the Health Plan Pharmacy & Therapeutics (P&T) Advisory Committee. For agents that do not have established prior authorization criteria, Health Plan will make the determination based on Medical Necessity criteria as described in Health Plan Medical Review Guidelines (UM06).

Thyroid Agents
Teprotumumab-trbw (Tepezza)

- **Coverage Criteria:** Tepezza is reserved for all of the following:
  - Either A or B
    - A) Moderate-to-severe active thyroid eye disease with a Clinical Activity Score ≥3 with either
      - Failure of a 4-week trial of a systemic corticosteroid (at up to maximally indicated doses), unless clinically significant adverse effects are experienced, or all are contraindicated OR
      - Significant proptosis and/or diplopia.
    - B) Inactive thyroid eye disease with Clinical Activity Score <3 or no additional inflammation or progression in proptosis/diplopia for ≥1 year with
      - Proptosis ≥3 mm from before thyroid eye disease and/or from normal.
  - Euthyroid or mild state (free thyroxine and triiodothyronine levels <50% +/− normal limits) hypothyroidism or hyperthyroidism AND
  - Patient must not have had optic nerve involvement within the last six months.
- **Limits:** Up to 10 mg/kg for the first IV infusion, followed by 20 mg/kg IV every 3 weeks for 7 additional infusions. Must be prescribed by an endocrinologist/ophthalmologist.
- **Required Information for Approval:** N/A
- **Other Notes:** Patient must not have planned surgical ophthalmological intervention or radiation during Tepezza use. Patients with pre-diabetes/diabetes must be currently managed by an endocrinologist. A history of progression of thyroid eye disease based on worsening of vision, soft tissue inflammation, motility, or proptosis is suggestive of active thyroid eye disease independently of the Clinical Activity Score. Significant proptosis is defined as not just a degree of proptosis ≥ 3 mm above the upper limit for race and sex but also as proptosis that impacts sufficiently on daily life and would justify the risks of treatment.

REFERENCES

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2. Garber JR, Cobin RH, Gharib H et al. Clinical Practice Guidelines for Hypothyroidism in Adults: Cosponsored by the American Association of Clinical Endocrinologists and the American Thyroid Association. *Endocr Pract*. 2012;18(6):988–1028.
3. Thyroid disease in pregnancy. Practice Bulletin No. 148. American College of Obstetricians and Gynecologists. *Obstet Gynecol*. 2015;125:996–1005.
4. Douglas RS, Kahaly GJ, Patel A, et al. Teprotumumab for the Treatment of Active Thyroid Eye Disease. N Engl J Med. 2020; 382: 341-352.
5. Douglas RS, Kahaly GJ, Ugradar S, et al. Teprotumumab Efficacy, Safety, and Durability in Longer-Duration Thyroid Eye Disease and Re-treatment: OPTIC-X Study. Ophthalmology. 2022;129(4):438-449. doi:10.1016/j.ophtha.2021.10.017
6. Bartalena L, Kahaly G, Baldeschi L, et al. The 2021 European Group on Graves' orbitopathy (EUGOGO) clinical practice guidelines for the medical management of Graves' orbitopathy. European Journal of Endocrinology. 2021; 185(4), G43-G67
7. Burch, H. B., Perros, P., Bednarczuk, T., Cooper, D. S., Dolman, P. J., Leung, A. M., ... & Stan, M. N. (2022). Management of thyroid eye disease: a Consensus Statement by the American Thyroid Association and the European Thyroid Association. Thyroid, 32(12), 1439-1470.
8. TEPEZZA (teprotumumab-trbw) [prescribing information] Horizon.
9. Douglas RS, Couch S, Wester ST, Fowler BT, Liu CY, Subramanian PS, Tang R, Nguyen QT, Maamari RN, Ugradar S, Hsu K, Karon M, Stan MN. Efficacy and Safety of Teprotumumab in Patients With Thyroid Eye Disease of Long Duration and Low Disease Activity. J Clin Endocrinol Metab. 2023 Dec 21;109(1):25-35. doi: 10.1210/clinem/dgad637. PMID: 37925673; PMCID: PMC10735297.
10. Smith TJ, Kahaly GJ, Ezra DG, et al. Teprotumumab for Thyroid-Associated Ophthalmopathy. N Engl J Med. 2017;376(18):1748-1761. doi:10.1056/NEJMoa1614949
11. Douglas RS, Kahaly GJ, Patel A, et al. Teprotumumab for the Treatment of Active Thyroid Eye Disease. N Engl J Med. 2020;382(4):341-352. doi:10.1056/NEJMoa1910434
12. THYROGEN (thyrogen alfa) [prescribing information] Genzyme Corporation.

REVIEW & EDIT HISTORY

Document Changes	Reference	Date	P&T Chairman
Creation of Policy	HPSJ Coverage Policy – Endocrine Disorders – Thyroid Disorders 2015-11.docx	11/2015	Johnathan Yeh, PharmD
Update to Policy	HPSJ Coverage Policy - Endocrine Disorders - Thyroid Disorders 2016-12.docx	12/2016	Johnathan Yeh, PharmD
Update to Policy	HPSJ Coverage Policy - Endocrine Disorders - Thyroid Disorders 2017-09.docx	09/2017	Johnathan Yeh, PharmD
Update to Policy	HPSJ Coverage Policy – Endocrine – Thyroid Disorders 2018-12.docx	12/2018	Matthew Garrett, PharmD
Review Policy	Thyroid Disorders	12/2019	Matthew Garrett, PharmD
Review Policy	Thyroid Disorders	12/2020	Matthew Garrett, PharmD
Review Policy	Thyroid Disorders	05/2021	Matthew Garrett, PharmD
Reactivation of Policy	Thyroid Disorders	07/2022	Matthew Garrett, PharmD
Review of Policy	Thyroid Disorders	03/2023	Matthew Garrett, PharmD
Review of Policy	Thyroid Disorders	03/2024	Matthew Garrett, PharmD
Review of Policy	Thyroid Disorders	03/2025	Matthew Garrett, PharmD

Note: All changes are approved by the Health Plan P&T Committee before incorporation into the utilization policy.