

MEDICATION COVERAGE POLICY

PHARMACY AND THERAPEUTICS ADVISORY COMMITTEE

POLICY	Thyroid Disorders	P&T DATE:	3/19/2024
THERAPEUTIC CLASS	Endocrine Disorders	REVIEW HISTORY (MONTH/YEAR)	5/21, 12/20, 12/19, 12/18, 9/17, 12/16, 11/15, 7/22, 3/23
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 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 11/2023)

CPT Codes	Generic Name (Brand Name)	Available Strengths	Pharmacy Benefit	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				
J3240	Thyrotropin alfa (Thyrogen)	1.1 mg vial	Yes	Yes
J3241	Teprotumumab-trbw (Tepezza)	500 mg vials	Yes	Yes (PA, QL)

PA = Prior Authorization Required

QL = Quantity Limit

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 patients with the following:
 - Moderate-to-severe thyroid associated orbitopathy with Clinical Activity Score for Graves Orbitopathy ≥ 4 .
 - 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.
 - Patient has not had a history of surgical intervention for thyroid eye disease.
 - Patient must not have had optic nerve involvement within the last six months.
- Limits:** Fill limit of 8 for a total of 8 doses. Must be prescribed by an endocrinologist/ophthalmologist.
- Required Information for Approval:** Prescription history or medical authorization history showing at least a 4-week trial of glucocorticoids except if intolerable or contraindicated.
- Other Notes:** Patient must not have planned surgical ophthalmological intervention during Tepezza use. Please note Tepezza is distributed exclusively by Accredo specialty pharmacy as a limited distribution drug.

Thyroid Agents *Thyrotropin alfa (Thyrogen)*

- Coverage Criteria:** None.
- Limits:** None.
- Required Information for Approval:** N/A

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

☒ REFERENCES

1. Bahn RS, Burch HB, Cooper DS et al. Hyperthyroidism and Other Causes of Thyrotoxicosis: Management Guidelines of the American Thyroid Association and the American Association of Clinical Endocrinologists. *Endocr Pract.* 2011;17(3):456-520.
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 prescribing information. Retrieved from: https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/761143s000lbl.pdf

☒ 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	9/2017	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	5/2021	Matthew Garrett, PharmD
Reactivation of Policy	Thyroid Disorders	7/2022	Matthew Garrett, PharmD
Review of Policy	Thyroid Disorders	03/2023	Matthew Garrett, PharmD
Review of Policy	Thyroid Disorders	03/2024	Matthew Garrett, PharmD

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