

MEDICATION COVERAGE POLICY

PHARMACY AND THERAPEUTICS ADVISORY COMMITTEE

POLICY	Thyroid Disorders	P&T DATE:	5/11/2021
THERAPEUTIC CLASS	Endocrine Disorders	REVIEW HISTORY (MONTH/YEAR)	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 HPSJ Pharmacy and Therapeutic Advisory Committee.

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 Thyroid Disorders Coverage Policy is to review the coverage criteria of HPSJ's formulary anti-thyroid and thyroid agents (*Table 1*).

Table 1: Available Anti-Thyroid & Thyroid Medications (Current as of 05/2021)

Generic Name or Brand Name	Available Strengths	Formulary Limits	Average Cost per Rx
ANTI-THYROID MEDICATIONS			
Methimazole	5, 10 mg tablets	-	\$4.31
Propylthiouracil	50 mg tablet	-	\$37.46
THYROID MEDICATIONS			
Armour Thyroid	15, 30, 60, 90, 120, 180, 240, 300 mg tablets	-	\$35.27
Cytomel	5, 25, 50 mcg tablets	NF	--
Euthyrox	25, 50, 75, 88, 100, 112, 125, 137, 150, 175, 200 mcg tablets	NF	\$4.65
Levothyroxine sodium	25, 50, 75, 88, 100, 112, 125, 137, 150, 175, 200, 300 mcg tablets	-	\$8.34
Levoxyl	25, 50, 75, 88, 100, 112, 125, 137, 150, 175, 200 mcg tablets	NF	\$32.39
Liothyronine sodium	5, 25, 50 mcg tablets	-	\$26.53
Nature-Throid	48.75, 65, 81.25, 97.5, 113.75, 130, 146.25, 162.5, 195, 260, 325 mg tablets	NF	\$11.73
NP Thyroid	15, 30, 60, 90, 120 mg tablets	-	\$18.58
Synthroid	25, 50, 75, 88, 100, 112, 125, 137, 150, 175, 200, 300 mcg tablets	NF	\$42.87
Tirosint	13, 25, 50, 75, 88, 100, 112, 125, 137, 150, 175, 200 mcg capsules	NF	\$147.14
Unithroid	25, 50, 75, 88, 100, 112, 125, 137, 150, 175, 200, 300 mcg tablets	NF	--
Westhroid	32.5, 65, 97.5, 130, 195 mg tablets	NF	--
WP Thyroid	16.25, 32.5, 48.75, 65, 81.25, 97.5, 113.75, 130 mg tablets	NF	--
THYROID EYE MEDICATIONS			
Tepezza (teprotumumab-trbw)	500 mg vials	See criteria below	--
THYROID FUNCTION DIAGNOSTIC AGENT			
Thyrogen	1.1 mg vial	PA; SP	\$3,474.49

Bolded items = Brand name drug cost/utilization; PA = Prior Authorization Required; NF = Non-formulary; SP = Restricted to Specialty Pharmacy

⊞ EVALUATION CRITERIA FOR APPROVAL/EXCEPTION

CONSIDERATION

Below are the coverage criteria and required information for each agent. These coverage criteria have been reviewed & approved by the HPSJ Pharmacy & Therapeutics (P&T) Advisory Committee. For conditions not covered under this Coverage Policy, HPSJ will make the determination based on Medical Necessity as described in HPSJ Medical Review Guidelines (UM06).

Anti-Thyroid Agents
<i>Methimazole, Propylthiouracil</i>
<input type="checkbox"/> Coverage Criteria: <i>None</i> <input type="checkbox"/> Limits: <i>None</i> <input type="checkbox"/> Required Information for Approval: <i>N/A</i> <input type="checkbox"/> Other Notes: <i>None</i>

Thyroid Agents
<i>Armour Thyroid, Cytomel, Euthyrox, Levothyroxine sodium, Levoxyl, Liothyronine sodium, Nature-Throid, NP Thyroid, Synthroid, Tirosint, Unithroid, Westhroid, WP Thyroid</i>
Armour Thyroid, Levothyroxine sodium, Liothyronine sodium, NP Thyroid
<input type="checkbox"/> Coverage Criteria: <i>None</i> <input type="checkbox"/> Limits: <i>None</i> <input type="checkbox"/> Required Information for Approval: <i>N/A</i> <input type="checkbox"/> Other Notes: <i>None</i> <input type="checkbox"/> Non-Formulary: Brand name Cytomel, Euthyrox, Levoxyl, Nature-Throid, Synthroid, Tirosint, Unithroid, Westhroid, WP Thyroid

Thyroid Agents
<i>Teprotumumab-trbw (Tepezza)</i>
<input type="checkbox"/> Coverage Criteria: Tepezza is reserved for patients with the following: <ul style="list-style-type: none"> ○ 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.
<input type="checkbox"/> Limits: Fill limit of 8 for a total of 8 doses. Must be prescribed by an endocrinologist/ophthalmologist.
<input type="checkbox"/> Required Information for Approval: Prescription history or medical authorization history showing at least a 4-week trial of glucocorticoids except if intolerable or contraindicated.
<input type="checkbox"/> 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
<i>Thyrotropin alfa (Thyrogen)</i>
<input type="checkbox"/> Coverage Criteria: Approval is determined by medical necessity criteria. <input type="checkbox"/> Limits: <i>None</i> <input type="checkbox"/> Required Information for Approval: <i>N/A</i> <input type="checkbox"/> Other Notes: Medication is to be dispensed by HPSJ's designated Specialty Pharmacy.

⊞ **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.

⊞ **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

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