

MEDICATION COVERAGE POLICY

PHARMACY AND THERAPEUTICS ADVISORY COMMITTEE

POLICY	Thyroid Disorders	P&T DATE:	12/11/2018
THERAPEUTIC CLASS	Endocrine Disorders	REVIEW HISTORY (MONTH/YEAR)	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 9/2018)

Generic Name or Brand Name	Available Strengths	Formulary Limits	Average Cost per Rx*
ANTI-THYROID MEDICATIONS			
Methimazole	5, 10 mg tablets	-	\$14.02
Propylthiouracil	50 mg tablet	-	\$38.54
THYROID MEDICATIONS			
Armour Thyroid	15, 30, 60, 90, 120, 180, 240, 300 mg tablets	-	\$31.13
Levothyroxine sodium	25, 50, 75, 88, 100, 112, 125, 137, 150, 175, 200, 300 mcg tablets	-	\$10.44
Levoxyol	25, 50, 75, 88, 100, 112, 125, 137, 150, 175, 200 mcg tablets	NF	\$30.20
Liothyronine sodium	5, 25, 50 mcg tablets	-	\$24.89
Nature-Throid	48.75, 65, 81.25, 97.5, 113.75, 130, 146.25, 162.5, 195, 260, 325 mg tablets	NF	\$7.57
NP Thyroid	15, 30, 60, 90 mg tablets	-	\$11.08
Synthroid	25, 50, 75, 88, 100, 112, 125, 137, 150, 175, 200, 300 mcg tablets	NF	\$34.73
Tirosint	13, 25, 50, 75, 88, 100, 112, 125, 137, 150 mcg capsules	NF	\$119.68
WP Thyroid	16.25, 32.5, 48.75, 65, 81.25, 97.5, 113.75, 130 mg tablets	NF	--
THYROID FUNCTION DIAGNOSTIC AGENT			
Thyrogen	1.1 mg vial	PA ; SP	\$3,139.71

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>

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

Thyroid Agents

Armour Thyroid, Levothyroxine sodium, Liothyronine sodium, NP Thyroid, Synthroid, Tirosint

Armour Thyroid, Levothyroxine sodium, Liothyronine sodium, NP Thyroid

- Coverage Criteria:** *None*
- Limits:** None
- Required Information for Approval:** N/A
- Other Notes:** None
- Non-Formulary:** Brand name Synthroid, Tirosint

Thyroid Agents

Thyrotropin alfa (Thyrogen)

- Coverage Criteria:** Approval is determined by medical necessity criteria.
- Limits:** None
- Required Information for Approval:** N/A
- 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

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