



Commercial/Healthcare Exchange PA Criteria

Effective: May 8th, 2019

Prior Authorization: Tirosint-Sol

Products Affected: Tirosint-Sol (levothyroxine sodium) oral solution

Medication Description: Thyroid hormones exert their physiologic actions through control of DNA transcription and protein synthesis. Triiodothyronine (T3) and L-thyroxine (T4) diffuse into the cell nucleus and bind to thyroid receptor proteins attached to DNA. This hormone nuclear receptor complex activates gene transcription and synthesis of messenger RNA and cytoplasmic proteins. The physiological actions of thyroid hormones are produced predominantly by T3, the majority of which (approximately 80%) is derived from T4 by deiodination in peripheral tissues. Oral levothyroxine sodium is a synthetic T4 hormone that exerts the same physiologic effect as endogenous T4, thereby maintaining normal T4 levels when a deficiency is present.

Covered Uses:

1. Replacement therapy in primary (thyroidal), secondary (pituitary), and tertiary (hypothalamic) congenital or acquired hypothyroidism
2. Pituitary Thyrotropin (ThyroidStimulating Hormone, TSH) Suppression

Exclusion Criteria:

1. Hypersensitivity to glycerol, the inactive ingredient in Tirosint-Sol
2. Uncorrected adrenal insufficiency
3. Suppression of benign thyroid nodules and nontoxic diffuse goiter in iodine-sufficient patients
4. Treatment of transient hypothyroidism during the recovery phase of subacute thyroiditis

Required Medical Information:

1. Diagnosis
2. Previous therapies tried/failed
3. Medical history

Age Restrictions: N/A

Prescriber Restrictions: N/A

Coverage Duration: 12 months

Other Criteria:

Hypothyroidism

- A. Patient has a diagnosis of primary (thyroidal), secondary (pituitary), or tertiary (hypothalamic) congenital or acquired hypothyroidism; AND
- B. The patient is unable to ingest generic levothyroxine oral tablets due to one of the following:
 - a. Oral/motor difficulties; OR
 - b. Dysphagia

Last Res. December 20th, 2019



Confidential Information

This document is confidential and proprietary to ConnectiCare. Unauthorized use and distribution are prohibited.

Pituitary Thyrotropin (Thyroid-Stimulating Hormone, TSH) suppression

- A. Patient has a diagnosis of thyrotropin-dependent well-differentiated thyroid cancer (either papillary carcinoma OR follicular carcinoma); AND
- B. Patient requires surgical intervention and radioiodine therapy for treatment; AND
- C. The patient is unable to ingest generic levothyroxine oral tablets due to one of the following:
 - a. Oral/motor difficulties; OR
 - b. Dysphagia

References:

1. American Thyroid Association. Available at: <http://www.thyroid.org>. Accessed on March 7, 2019.
2. Garber JR, Cobin RH, Gharib H, Hennessey JV, Klein I, Mechanick JI, Pessah-Pollack R, Singer PA, Woeber KA. Clinical practice guidelines for hypothyroidism in adults: cosponsored by the American Association of Clinical Endocrinologists and the American Thyroid Association. *Endocr Pract.* 2012; 18: 988-1028. Accessed on March 7, 2019.
3. Haugen BR, Alexander EK, Bible KC, et al. 2015 American Thyroid Association Management Guidelines for Adult Patients with Thyroid Nodules and Differentiated Thyroid Cancer: The American Thyroid Association Guidelines Task Force on Thyroid Nodules and Differentiated Thyroid Cancer. *Thyroid.* 2016; 26: 1-133. Accessed on March 7, 2019.
4. Tirosint-SOL [prescribing information]. Pambio-Noranco, Switzerland: Institut Biochimique SA (IBSA); December 2016.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	5/8/2019
2	Revision	Aligned with EH	All	12/20/2019

Last Res. December 20th, 2019

