

LEVOTHYROXINE PRODUCTS STEP THERAPY POLICY

- POLICY:** Levothyroxine Products Step Therapy Policy
- Ermeza™ (levothyroxine sodium 30 mcg/mL solution – Mylan)
 - Levothyroxine sodium tablets (generics)
 - Tirosint®-SOL (levothyroxine sodium solution [various strengths] – IBSA Pharma)
 - Thyquidity™ (levothyroxine sodium 20 mcg/mL solution – Azurity)

REVIEW DATE: 03/20/2024

OVERVIEW

All of the products contain levothyroxine sodium and are indicated for the following uses¹⁻⁴:

- **Hypothyroidism:** As replacement therapy in primary (thyroidal), secondary (pituitary), and tertiary (hypothalamic) congenital or acquired hypothyroidism.
- **Pituitary Thyrotropin (Thyroid-Stimulating Hormone, TSH) Suppression:** As an adjunct to surgery and radioiodine therapy in the management of thyrotropin-dependent well-differentiated thyroid cancer.

Labeling for all of the products additionally contains the following Limitations of Use:

- Not indicated for suppression of benign thyroid nodules and nontoxic diffuse goiter in iodine-sufficient patients.
- Not indicated for treatment of transient hypothyroidism during the recovery phase of subacute thyroiditis.

All of the products can be used in pediatric patients, including newborns (0 to 3 months of age).¹⁻⁴ Ermeza, Thyquidity, and Tirosint-SOL were approved under the 505(b)(2) pathway and relied on efficacy data from previously approved levothyroxine products.⁵⁻⁷ No new clinical efficacy studies were undertaken with any of the products.²⁻⁴ The labeling for Ermeza states that the product may have a different concentration from other levothyroxine oral solution products and to consider the total dosage in terms of mcg and not volume when converting between products.² All levothyroxine products are dosed based on the patient's weight (e.g., 1.6 mcg/kg/day for adults with hypothyroidism).¹⁻⁴ Table 1 shows the availability of each levothyroxine solution.

Table 1. Availability of Levothyroxine Solutions.²⁻⁴

Guidelines

The American Thyroid Association guidelines for the treatment of hypothyroidism (2014) state that levothyroxine has been considered the standard of care for this condition for many years.⁸ These guidelines do not address levothyroxine solutions.

POLICY STATEMENT

This program has been developed to encourage the use of a Step 1 Product prior to the use of a Step 2 Product. Approval for a Step 3 Product may be authorized if the patient has tried a Step 1 Product and a Step 2 Product. If the Step Therapy rule is not met for a Step 2 Product or a Step 3 Product at the point of service, coverage will be determined by the Step Therapy criteria below. All approvals are provided for 1 year in duration.

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Automation: A patient with a history of one Step 1 Product within the 130-day look-back period is excluded from Step Therapy for a Step 2 Product. Additionally, a patient with a of one Step 1 Product and one Step 2 Product within the 130-day look-back period is excluded from Step Therapy for a Step 3 Product.

Step 1: generic levothyroxine tablets

Step 2: Ermeza solution

Step 3: Thyquidity solution, Tirosint-SOL

CRITERIA

1. If the patient has tried one Step 1 Product, approve the Step 2 Product (Ermeza solution).
Note: If the patient has tried brand Synthroid (levothyroxine sodium tablet) or another brand of levothyroxine tablets, such as Levoxyl (levothyroxine sodium tablet), this would satisfy the criterion.
2. Approve the Step 2 Product (Ermeza solution) if the patient is unable to swallow or has difficulty swallowing tablets.
3. Approve either Step 3 Products (Thyquidity Solution or Tirosint-SOL) if the patient meets BOTH of the following criteria (A and B):
 - A) Patient meets one of the following criteria (i or ii):
 - i. Patient has tried one Step 1 Product; **OR**
Note: If the patient has tried brand Synthroid (levothyroxine sodium tablet) or another brand of levothyroxine tablets, such as Levoxyl (levothyroxine sodium tablet), this would satisfy the criteria for the Step 1 product.
 - ii. Patient is unable to swallow or has difficulty swallowing tablets; **AND**
 - B) Patient has tried the Step 2 Product (Ermeza solution).
4. No other exceptions are recommended.

REFERENCES

1. Levothyroxine sodium tablets [prescribing information]. Bridgewater, NJ: Amneal; September 2023.
2. Ermeza™ (levothyroxine sodium solution) [prescribing information]. Morgantown, WV: Mylan Specialty; April 2022.
3. Thyquidity™ (levothyroxine sodium solution) [prescribing information]. Woburn, MA: Azurity; February 2023.
4. Tirosint®-SOL (levothyroxine sodium solution) [prescribing information]. Parsippany, NJ: IBSA Pharma; November 2023.
5. FDA. Drugs@FDA. Ermeza approval letter. May 2022. Available at: [Ermeza \(levothyroxine sodium\) oral solution \(fda.gov\)](#). Accessed on March 11, 2024.
6. FDA. Drugs@FDA. Thyquidity approval letter. November 2020. Available at: [Thyquidity \(levothyroxine sodium\) oral solution \(fda.gov\)](#). Accessed on March 11, 2024.
7. FDA. Drugs@FDA. Tirosint-SOL approval letter. December 2016. Available at: [Tirosint-SOL \(levothyroxine sodium oral solution\) \(fda.gov\)](#). Accessed on March 11, 2024.
8. Jonklaas J, Bianco AC, Bauer AJ, et al. Guidelines for the treatment of hypothyroidism: prepared by the American Thyroid Association task force on thyroid hormone replacement. *Thyroid*. 2014;24(12):1670-751.