



Effective Date..... 5/1/2023  
Next Review Date..... 5/1/2024  
Coverage Policy Number ..... IP0060

# Thyroid Hormone Supplements

## Table of Contents

Overview ..... 1  
Initial Approval Criteria.....2  
Continuation of Therapy .....4  
Authorization Duration .....4  
Conditions Not Covered.....4  
Background.....4  
References .....6

## Related Coverage Resources

### INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

## Overview

This policy supports medical necessity review for the following thyroid hormone supplement products:

- **Armour<sup>®</sup> Thyroid** (thyroid, porcine tablet)
- **Adthyza<sup>™</sup> Thyroid** (levothyroxine and liothyronine oral tablet)
- **Cytomel** (liothyronine tablet)
- **Ermeza<sup>™</sup>** (levothyroxine sodium oral solution)
- **Levothyroxine capsule** (generic for Tirosint)
- **Synthroid** (levothyroxine tablet)
- **Thyquidity<sup>™</sup>** (levothyroxine sodium oral solution)
- **Tirosint<sup>®</sup>** (levothyroxine sodium capsule)
- **Tirosint<sup>®</sup>-SOL** (levothyroxine sodium oral solution)
- **Unithroid** (levothyroxine tablet)
- **WP Thyroid<sup>®</sup>** (thyroid, porcine tablet)

Coverage for thyroid hormone supplement products varies across plans and requires the use of preferred products in addition to the criteria listed below. Refer to the customer's benefit plan document for coverage details. Receipt of sample product does not satisfy any criteria requirements for coverage.

Receipt of sample product does not satisfy any criteria requirements for coverage.

## Initial Approval Criteria

Coverage criteria are listed for products in below table:

Non-Covered Product	Criteria
<p><b>Armour Thyroid</b> (15 mg, 30 mg, 60 mg, 90 mg, 120 mg, 180mg, 240mg, 300mg thyroid, desiccated porcine tablet)</p>	<p><b>Armour Thyroid (thyroid, desiccated porcine tablets) is considered medically necessary when the individual meets ONE of the following:</b></p> <ol style="list-style-type: none"> <li>1. <b>Inadequate response or intolerance to Nature-Throid</b> (16.25 mg, 32.5 mg, 48.75 mg, 65 mg, 81.25 mg, 97.5mg, 130 mg, 146.25 mg, 195 mg, 260 mg, 325 mg)</li> <li>2. <b>Inadequate response or intolerance to NP Thyroid</b> (15 mg, 30 mg, 60 mg, 90 mg, 120 mg)</li> <li>3. <b>Inadequate response or intolerance to Westhroid</b> (32.5 mg, 65 mg, 97.5 mg, 130 mg, 195 mg)</li> <li>4. Has <b>ONE</b> of the following conditions:               <ol style="list-style-type: none"> <li>a. Congenital hypothyroidism in children 3 years of age or younger</li> <li>b. Diagnosis of thyroid cancer</li> <li>c. Pregnancy</li> </ol> </li> </ol>
<p><b>Adthyza Thyroid</b> (levothyroxine and liothyronine 16.25 mg, 32.5 mg, 65 mg, 97.5 mg, 130 mg oral tablet)</p>	<p><b>Adthyza Thyroid (levothyroxine and liothyronine tablet) is considered medically necessary when the individual meets ONE of the following:</b></p> <ol style="list-style-type: none"> <li>1. <b>Inadequate response or intolerance to Nature-Throid</b> (16.25 mg, 32.5 mg, 48.75 mg, 65 mg, 81.25 mg, 97.5 mg, 130 mg, 146.25 mg, 195 mg, 260 mg, 325 mg)</li> <li>2. <b>Inadequate response or intolerance to NP Thyroid</b> (15 mg, 30 mg, 60 mg, 90 mg, 120 mg)</li> <li>3. <b>Inadequate response or intolerance to Westhroid</b> (32.5 mg, 65 mg, 97.5 mg, 130 mg, 195 mg)</li> <li>4. Has <b>ONE</b> of the following conditions:               <ol style="list-style-type: none"> <li>a. Congenital hypothyroidism in children 3 years of age or younger</li> <li>b. Diagnosis of thyroid cancer</li> <li>c. Pregnancy</li> </ol> </li> </ol>
<p><b>Cytomel</b> (liothyronine)</p>	<p><b>Cytomel (liothyronine) is considered medically necessary when the individual meets the ONE following criteria:</b></p> <ol style="list-style-type: none"> <li>1. Documentation that individual has tried <b>liothyronine (generic for Cytomel)</b> AND cannot take due to a formulation difference in the inactive ingredient(s) [for example, difference in dyes, fillers, preservatives] between the brand and the bioequivalent generic product which, per the prescribing physician, would result in a significant allergy or serious adverse reaction</li> <li>2. Has <b>ONE</b> of the following conditions:               <ol style="list-style-type: none"> <li>a. Congenital hypothyroidism in children 3 years of age or younger</li> <li>b. Diagnosis of thyroid cancer</li> <li>c. Pregnancy</li> </ol> </li> </ol>
<p><b>Ermeza</b> (levothyroxine sodium oral solution)</p>	<p><b>Ermeza (levothyroxine sodium oral solution) is considered medically necessary when the individual meets ONE of the following criteria:</b></p> <ol style="list-style-type: none"> <li>1. Inability to swallow generic levothyroxine sodium tablet</li> <li>2. Has <b>ONE</b> of the following conditions:               <ol style="list-style-type: none"> <li>a. Congenital hypothyroidism in children 3 years of age or younger</li> <li>b. Diagnosis of thyroid cancer</li> <li>c. Pregnancy</li> </ol> </li> </ol>

Non-Covered Product	Criteria
<b>Thyquidity</b> (levothyroxine sodium oral solution)	<b>Thyquidity (levothyroxine sodium oral solution) is considered medically necessary when the individual meets ONE of the following criteria:</b> <ol style="list-style-type: none"> <li>1. Inability to swallow generic levothyroxine sodium tablet</li> <li>2. Has <b>ONE</b> of the following conditions:               <ol style="list-style-type: none"> <li>a. Congenital hypothyroidism in children 3 years of age or younger</li> <li>b. Diagnosis of thyroid cancer</li> <li>c. Pregnancy</li> </ol> </li> </ol>
<b>Tirosint</b> (levothyroxine sodium capsule)	<u><b>Standard/Performance/ Value/Advantage/ Cigna Total Savings:</b></u> <b>Tirosint (levothyroxine sodium capsule) is considered medically necessary when the individual meets ONE of the following criteria:</b> <ol style="list-style-type: none"> <li>1. Inability to swallow generic levothyroxine sodium tablet</li> <li>2. Has <b>ONE</b> of the following conditions:               <ol style="list-style-type: none"> <li>a. Congenital hypothyroidism in children 3 years of age or younger</li> <li>b. Diagnosis of thyroid cancer</li> <li>c. Pregnancy</li> </ol> </li> </ol>
<b>levothyroxine</b> (generic for Tirosint capsule)	<u><b>Standard/Performance/ Value/Advantage/ Cigna Total Savings:</b></u> <b>Levothyroxine capsule (generic for Tirosint) is considered medically necessary when the individual meets ONE of the following criteria:</b> <ol style="list-style-type: none"> <li>1. Inability to swallow levothyroxine sodium tablet</li> <li>2. Has <b>ONE</b> of the following conditions:               <ol style="list-style-type: none"> <li>a. Congenital hypothyroidism in children 3 years of age or younger</li> <li>b. Diagnosis of thyroid cancer</li> <li>c. Pregnancy</li> </ol> </li> </ol>
<b>Synthroid</b> (levothyroxine)	<b>Synthroid (levothyroxine) is considered medically necessary when the individual meets ONE the following criteria:</b> <ol style="list-style-type: none"> <li>1. Documentation that individual has tried <b>levothyroxine (generic for Synthroid)</b> AND cannot take due to a formulation difference in the inactive ingredient(s) [for example, difference in dyes, fillers, preservatives] between the brand and the bioequivalent generic product which, per the prescribing physician, would result in a significant allergy or serious adverse reaction</li> <li>2. Has <b>ONE</b> of the following conditions:               <ol style="list-style-type: none"> <li>a. Congenital hypothyroidism in children 3 years of age or younger</li> <li>b. Diagnosis of thyroid cancer</li> <li>c. Pregnancy</li> </ol> </li> </ol>
<b>Tirosint-SOL</b> (levothyroxine sodium oral solution)	<u><b>Standard/Performance/ Value/Advantage/ Cigna Total Savings:</b></u> <b>Tirosint-SOL (levothyroxine sodium oral solution) is considered medically necessary when the individual meets ONE of the following criteria:</b> <ol style="list-style-type: none"> <li>1. Inability to swallow generic levothyroxine sodium tablet</li> <li>2. Has <b>ONE</b> of the following conditions:               <ol style="list-style-type: none"> <li>a. Congenital hypothyroidism in children 3 years of age or younger</li> <li>b. Diagnosis of thyroid cancer</li> <li>c. Pregnancy</li> </ol> </li> </ol>
<b>Unithroid</b> (levothyroxine)	<b>Unithroid (levothyroxine) is considered medically necessary when the individual meets ONE the following criteria:</b> <ol style="list-style-type: none"> <li>1. Documentation that individual has tried <b>levothyroxine (generic for Unithroid)</b> AND cannot take due to a formulation difference in the inactive ingredient(s) [for example, difference in dyes, fillers, preservatives] between the brand and the bioequivalent generic product which, per the prescribing physician, would result in a significant allergy or serious adverse reaction</li> <li>2. Has <b>ONE</b> of the following conditions:               <ol style="list-style-type: none"> <li>a. Congenital hypothyroidism in children 3 years of age or younger</li> <li>b. Diagnosis of thyroid cancer</li> </ol> </li> </ol>

Non-Covered Product	Criteria
<b>WP Thyroid</b> (16.25 mg, 32.5 mg, 48.75 mg, 65 mg, 81.25 mg, 97.5 mg, 113.75 mg, 130 mg thyroid, desiccated porcine tablet)	c. Pregnancy  <b>WP Thyroid (thyroid, desiccated porcine tablets) is considered medically necessary when the individual meets ONE of the following:</b> <ol style="list-style-type: none"> <li>1. Inadequate response or intolerance to <b>ONE</b> of the following:               <ol style="list-style-type: none"> <li>a. Nature-Throid (16.25 mg, 32.5 mg, 48.75 mg, 65 mg, 81.25 mg, 97.5 mg, 130 mg, 146.25 mg, 195 mg, 260 mg, 325 mg)</li> <li>b. NP Thyroid (15 mg, 30 mg, 60 mg, 90 mg, 120 mg)</li> <li>c. Westroid (32.5 mg, 65 mg, 97.5 mg, 130 mg, 195 mg)</li> </ol> </li> <li>2. Has <b>ONE</b> of the following conditions:               <ol style="list-style-type: none"> <li>a. Congenital hypothyroidism in children 3 years of age or younger</li> <li>b. Diagnosis of thyroid cancer</li> <li>c. Pregnancy</li> </ol> </li> </ol>

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

## Continuation of Therapy

Thyroid hormone supplement products are considered medically necessary for continued use when initial criteria are met **AND** documentation of beneficial response.

## Authorization Duration

For pregnancy, authorization duration is for the pregnancy term.

For all other diagnosis, initial approval and reauthorization duration is 12 months.

## Conditions Not Covered

Any other use is considered not medically necessary.

## Background

### Overview

Armour Thyroid tablets are a natural preparation derived from porcine thyroid glands. They provide 38 mcg levothyroxine (T4) and 9 mcg liothyronine (T3) per grain of thyroid. T3 liothyronine is approximately four times as potent as T4 levothyroxine on a microgram for microgram basis.<sup>1</sup>

Armour Thyroid tablets are indicated:

- As replacement or supplemental therapy in patients with hypothyroidism of any etiology, except transient hypothyroidism during the recovery phase of subacute thyroiditis. This category includes cretinism, myxedema, and ordinary hypothyroidism in patients of any age (children, adults, the elderly), or state (including pregnancy); primary hypothyroidism resulting from functional deficiency, primary atrophy, partial or total absence of thyroid gland, or the effects of surgery, radiation, or drugs, with or without the presence of goiter; and secondary (pituitary), or tertiary (hypothalamic) hypothyroidism.
- As pituitary TSH suppressants, in the treatment or prevention of various types of euthyroid goiters, including thyroid nodules, subacute or chronic lymphocytic thyroiditis (Hashimoto's), multinodular goiter, and in the management of thyroid cancer.<sup>1</sup>

Thyquidity, Tirosint (levothyroxine sodium) oral capsule and Tirosint-SOL (levothyroxine sodium) oral solution contain levothyroxine (T4). Levothyroxine (T4) is an oral and parenteral synthetically derived levorotatory isomer of thyroxine (T4), a hormone secreted by the thyroid gland. Tirosint capsules are specifically indicated in adults and pediatric patients 6 years and older, while the solution does not have a limitation on pediatric age. All 3 products are indicated for the following:

- 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

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<sup>2,3,10,11</sup>

All thyroid hormone supplement products contain a similar boxed warning relating to the use of thyroid supplements for obesity/weight loss.<sup>1-5,10,11</sup>

**WARNING: NOT FOR TREATMENT OF OBESITY or FOR WEIGHT LOSS**

- Thyroid hormones should not be used for the treatment of obesity or for weight loss.
- Doses beyond the range of daily hormonal requirements may produce serious or even life threatening manifestations of toxicity.

Typically, dosing of thyroid supplement products is individualized according to clinical response and serum thyroid-stimulating hormone (TSH) and/or free T<sub>4</sub> concentrations. It is recommended for all of the thyroid hormone supplement products to administer consistently in the morning on an empty stomach, at least 30 to 60 minutes before food. Alternatively, they may be consistently administered at night 3 to 4 hours after the last meal. They are not to be administered within 4 hours of calcium- or iron-containing products, bile acid sequestrants, or other medications which could interfere with absorption.<sup>1-5,10,11</sup>

**Guidelines/Scientific Statements**

According to the American Thyroid Association Task Force on Thyroid Hormone Replacement, levothyroxine products are preferred over naturally-derived desiccated thyroid hormones from animal glands. Because of considerable variations in levothyroxine (T4) and liothyronine (T3) content, desiccated thyroid hormone extracts have been largely replaced in clinical medicine by the preferred use of synthetic levothyroxine (T4), which has a more reliable hormonal content, providing consistent gastrointestinal absorption, once-daily dosing, and provision of clinically stable serum levels of both T4 and T3. There is scientific and clinical evidence that the majority of the biologically active T3 hormone is generated from T4 in the human body. The replacement of thyroid hormone using synthetic levothyroxine (T4) is alone sufficient in most individuals with hypothyroidism, including pediatric and pregnant patients, and is the preferred replacement therapy for routine use. Other thyroid replacement hormones offer no discernable safety and efficacy advantage over levothyroxine and the effects during dosage titration are more predictable due to the standardized hormonal content of levothyroxine products.<sup>6</sup> Almost all patients receiving levothyroxine alone will become euthyroid; there are few individuals who need T3 supplementation in addition to T4 to treat symptoms or biochemical imbalance.<sup>6</sup> Levothyroxine is also the preferred agent when used as a diagnostic agent in TSH suppression tests as an aid in detecting hyperthyroidism, and as an adjunct agent in the treatment of well-differentiated thyroid cancer.<sup>7,8</sup> Levothyroxine has been used clinically since the 1950s; marketed products are governed by modern FDA approval processes for safety, efficacy, purity, potency, and bioequivalence.<sup>9</sup> Desiccated thyroid hormone extracts have been in clinical use since 1939, but carry a marketing status of “unapproved” and hence does not fall under the modern FDA approval processes.

## References

1. Armour Thyroid (thyroid tablets, USP) [prescribing information]. St. Louis, MO: Forest Pharmaceuticals; June, 2018.
2. Adthyza [prescribing information]. 2023; Azurity Pharmaceuticals, Inc. <https://adthyza.com/hcp/media/pdf/ADTHYZA-PI.pdf>
3. Tirosint (levothyroxine sodium) capsules, for oral use [prescribing information]. Cranford, NJ: IBSA Pharma Inc.; April, 2017.
4. Tirosint -SOL (levothyroxine sodium) oral solution [prescribing information]. Parsippany, NJ: IBSA Pharma Inc. June, 2018.
5. Levothyroxine Sodium. Drug Facts and Comparisons. Facts & Comparisons® eAnswers [online]. Available from Wolters Kluwer Health, Inc. Accessed August, 2020.
6. Thyroid Desiccated Oral. Drug Facts and Comparisons. Facts & Comparisons eAnswers [online]. Available from Wolters Kluwer Health, Inc. Accessed August, 2020.
7. Jonklaas J, Bianco AC, Bauer AJ, et al and the American Thyroid Association Task Force on Thyroid Hormone Replacement. Guidelines for the treatment of hypothyroidism: prepared by the American Thyroid Association Task Force on Thyroid Hormone Replacement. *Thyroid*. 2014; 24:1670-1751.
8. 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. Review.
9. Ross DS, Burch HB, Cooper DS, et al. 2016 American Thyroid Association guidelines for diagnosis and management of hyperthyroidism and other causes of thyrotoxicosis. *Thyroid* 2016; 26:1343-1421.
10. Dong BJ, Hauck WW, Gambertoglio JG, et al. Bioequivalence of generic and brand-name levothyroxine products in the treatment of hypothyroidism. *JAMA* 1997; 277:1205-13.
11. Thyquidity (levothyroxine sodium) oral solution [prescribing information]. Largo, FL: VistaPharm, Inc. November, 2020.
12. Ermeza (levothyroxine sodium) oral solution [prescribing information]. San Antonio, TX: DPT Laboratories, Ltd. April, 2022.

---

“Cigna Companies” refers to operating subsidiaries of Cigna Corporation. All products and services are provided exclusively by or through such operating subsidiaries, including Cigna Health and Life Insurance Company, Connecticut General Life Insurance Company, Evernorth Behavioral Health, Inc., Cigna Health Management, Inc., and HMO or service company subsidiaries of Cigna Health Corporation. © 2023 Cigna.