Select Levothyroxine Products

Policy # 00693
Original Effective Date: 10/09/2019
Current Effective Date: 08/14/2023

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider select levothyroxine products, including, but not limited to Tirosint®‡ Sol, Tirosint capsules, brand Levothyroxine capsules, Thyquidity™‡, and Ermeza™‡ for the treatment of certain thyroid conditions to be **eligible for coverage**** when the patient selection criteria are met for the requested drug.

Patient Selection Criteria

Coverage eligibility for select levothyroxine products, including, but not limited to Tirosint Sol, Tirosint capsules, brand Levothyroxine capsules, Thyquidity, and Ermeza will be considered when the following criteria are met for the requested drug:

- For Tirosint Sol, Thyquidity, and Ermeza requests:
  - Patient has a diagnosis of hypothyroidism OR patient is using the requested drug for pituitary thyrotropin suppression in the management of thyroid cancer; AND
  - Patient has a gastrostomy tube (G-tube) or is otherwise unable to swallow tablets and/or capsules; AND
    *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*
  - Patient is NOT taking any other medications in tablet and/or capsule form.
    *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*
- For Tirosint capsule and brand Levothyroxine capsule requests:
  - Patient has a diagnosis of hypothyroidism OR patient is using the requested drug for pituitary thyrotropin suppression in the management of thyroid cancer; AND

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- Patient has tried and failed (e.g. intolerance or inadequate response) TWO of the following products: GENERIC levothyroxine tablets, GENERIC levoxyl tablets, GENERIC unithroid tablets, GENERIC euthyrox tablets, GENERIC levo-t tablets, or BRAND Synthroid®‡ tablets unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the member.
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of Tirosint Sol, Thyquidity, and Ermeza when the patient does NOT have a gastrostomy tube (G-tube) or is otherwise able to swallow tablets and/or capsules OR when the patient is taking any other medications in tablet and/or capsule form to be **not medically necessary.****

Based on review of available data, the Company considers the use of Tirosint capsules or brand Levothyroxine capsules when the patient has NOT tried and failed TWO of the following products: GENERIC levothyroxine tablets, GENERIC levoxyl tablets, GENERIC unithroid tablets, GENERIC euthyrox tablets, GENERIC levo-t tablets, or BRAND Synthroid tablets to be **not medically necessary.****

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of select levothyroxine products, including, but not limited to Tirosint Sol, Tirosint capsules, brand Levothyroxine capsules, Thyquidity, and Ermeza for non-FDA approved indications to be **investigational.***

Background/Overview

Tirosint Sol, Tirosint capsules, brand Levothyroxine capsules, Thyquidity, and Ermeza are all approved as replacement therapy in primary (thyroidal), secondary (pituitary), and tertiary

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(hypothalamic) congenital or acquired hypothyroidism. They also carry approval as an adjunct to surgery and radioiodine therapy in the management of thyrotropin-dependent well-differentiated thyroid cancer. There are various dosage forms of levothyroxine (tablets, capsules, oral solution, and intravenous solution), with the tablets being the most economically advantageous, yet equally efficacious version. Tirosint Sol, Thyquidity, and Ermeza which are liquid dosage forms, should only be reserved for those who are not able to take oral tablet or capsule dosage forms. Tirosint capsules and brand Levothyroxine capsules have similar kinetics as the tablet version of levothyroxine, however they are a higher cost option without substantial benefits versus using levothyroxine tablets with close monitoring of TSH (thyroid stimulating hormone) levels.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Tirosint Sol, Tirosint capsules, brand Levothyroxine capsules, Thyquidity, and Ermeza are all approved as replacement therapy in primary (thyroidal), secondary (pituitary), and tertiary (hypothalamic) congenital or acquired hypothyroidism. They also carry approval as an adjunct to surgery and radioiodine therapy in the management of thyrotropin-dependent well-differentiated thyroid cancer.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

The purpose of this policy is to ensure that the appropriate patient has access to the appropriate dosage form of levothyroxine. There are various dosage forms of levothyroxine (tablets, capsules, oral solution, and intravenous solution), with the tablets being the most economically advantageous, yet equally efficacious version. Tirosint Sol, Thyquidity, and Ermeza should only be reserved for those patients who are not able to take oral tablet or capsule dosage forms. Tirosint capsules and brand Levothyroxine capsules should be reserved for patients who have tried and failed tablet versions of levothyroxine.

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References

1. Tirosint Sol [package insert]. IBSA Pharma Inc. Pasippany, New Jersey. Updated June 2018.
2. Thyquidity [package insert]. Vertice Specialty Group. Largo, Florida. Updated February 2021.
3. Tirosint [package insert]. IBSA Pharma, Inc. Parsippany, New Jersey. Updated June 2018.
4. Levothyroxine Capsules [package insert]. Lannet Company, Inc. Philadelphia, Pennsylvania. Updated April 2020.
5. Treatment of Primary Hypothyroidism in Adults. UpToDate. Accessed August 2021.
6. Ermeza [package insert]. Mylan Specialty L.P. Morgantown, West Virginia. Updated April 2022.

Policy History

Original Effective Date: 10/09/2019
Current Effective Date: 08/14/2023

10/03/2019	Medical Policy Committee review
10/09/2019	Medical Policy Implementation Committee approval. New policy.
10/01/2020	Medical Policy Committee review
10/07/2020	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
05/06/2021	Medical Policy Committee review
05/12/2021	Medical Policy Implementation Committee approval. Changed title from “Tirosint Sol (levothyroxine sodium solution)” to “Levothyroxine Oral Solution Products”. Added a new product, Thyquidity, to the policy.
09/02/2021	Medical Policy Committee review
09/08/2021	Medical Policy Implementation Committee approval. Changed the title of the policy from Levothyroxine Oral Solution Products to Select Levothyroxine Products. Added Tirosint capsules and criteria to the policy. Updated the background and rationale sections of the policy.
10/07/2021	Medical Policy Committee review
10/13/2021	Medical Policy Implementation Committee approval. Added brand Levothyroxine capsules to the list of targeted medications in the policy.
10/06/2022	Medical Policy Committee review
10/11/2022	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

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07/06/2023 Medical Policy Committee review
07/12/2023 Medical Policy Implementation Committee approval. Added Ermeza to the targeted list of medications in the policy.
Next Scheduled Review Date: 07/2024

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

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For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

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