Tirosint® Sol (levothyroxine sodium solution)

Policy # 00693
Original Effective Date: 10/09/2019
Current Effective Date: 11/09/2020

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 Tirosint®‡ Sol (levothyroxine sodium solution) for the treatment of certain thyroid conditions to be **eligible for coverage**** when the patient selection criteria are met.

Patient Selection Criteria

Coverage eligibility for Tirosint Sol (levothyroxine sodium solution) will be considered when the following criteria are met:

- 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 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 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 (levothyroxine sodium solution) when the patient does NOT have a gastrostomy tube (G-tube) or is otherwise able

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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.****

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 Tirosint Sol (levothyroxine sodium solution) for a non-FDA approved indication to be **investigational.***

Background/Overview

Tirosint Sol is approved as replacement therapy in primary (thyroidal), secondary (pituitary), and tertiary (hypothalamic) congenital or acquired hypothyroidism. It also carries 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, with the tablets being the most economically advantageous, yet equally efficacious version. Tirosint Sol should only be reserved for those that are not able to take other oral tablet or capsule dosage forms.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Tirosint Sol is approved as replacement therapy in primary (thyroidal), secondary (pituitary), and tertiary (hypothalamic) congenital or acquired hypothyroidism. It also carries approval as an adjunct to surgery and radioiodine therapy in the management of thyrotropin-dependent well-differentiated thyroid cancer.

Rationale/Source

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, and intravenous solution), with the tablets being the most economically advantageous, yet equally efficacious version. Tirosint Sol should only be reserved for those that are not able to take other oral tablet or capsule dosage forms.

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References

1. Tirosint Sol [package insert]. IBSA Pharma Inc. Pasippany, New Jersey. Updated June 2018.

Policy History

Original Effective Date: 10/09/2019
Current Effective Date: 11/09/2020
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.
Next Scheduled Review Date: 10/2021

*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 the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated 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.

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**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.

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.

‡ Indicated trademarks are the registered trademarks of their respective owners.

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.