Thalitone® (chlorthalidone 15 mg tablets)

Policy # 00777
Original Effective Date: 03/14/2022
Current Effective Date: 03/14/2022

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 Thalitone®‡ (chlorthalidone 15 mg tablets) to be **eligible for coverage**** when the patient selection criterion is met.

Patient Selection Criteria

Coverage eligibility for Thalitone (chlorthalidone 15 mg tablets) will be considered when the following criterion is met:

- There is clinical evidence or patient history that suggests the use of GENERIC chlorthalidone 25 mg and 50 mg tablets will be ineffective or cause an adverse reaction to the patient.

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of Thalitone (chlorthalidone 15 mg tablets) when the patient selection criterion is not met to be **not medically necessary.****

Background/Overview

Thalitone is a thiazide-like diuretic indicated for the treatment of hypertension. It is also indicated as adjunctive therapy in edema associated with heart failure, cirrhosis of the liver, and renal disease, including nephrotic syndrome. Thalitone is currently supplied as a 15 mg chlorthalidone tablet. The package insert notes a 25 mg tablet, however there is currently no availability. Other formulations of chlorthalidone tablets are regularly available in generic form in 25 mg and 50 mg strengths. Thalitone has the possibility of "potentially" producing fewer metabolic disturbances as compared to the other strengths of chlorthalidone tablets. Even though this carried statistical significance in

the clinical trials, it has yet to be seen if this holds clinical significance in real world settings. Blood pressure lowering was similar to the existing strengths of generic chlorthalidone tablets. Generic chlorthalidone 25 mg and 50 mg tablets offer an economically advantageous alternative to Thalitone.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Thalitone was approved in 2021 and is a thiazide-like diuretic indicated for the treatment of hypertension. It is also indicated as adjunctive therapy in edema associated with heart failure, cirrhosis of the liver, and renal disease, including nephrotic syndrome.

Rationale/Source

Two similarly designed, 12-week, double-blind, parallel group, placebo-controlled multicenter studies were conducted to compare Thalitone 15 mg to the standard chlorthalidone 25 mg in terms of reduction in blood pressure and metabolic disturbances. Collectively, a total of 222 patients with long-standing diastolic blood pressure between 90 and 104 mmHg were randomized to receive Thalitone 15 mg (N=71), standard chlorthalidone 25 mg (N=75), or placebo (N=76). Thalitone 15 mg helps meet the goal of lowering blood pressure in patients that respond to chlorthalidone therapy. Thalitone 15 mg has the advantage of demonstrating potentially fewer metabolic disturbances when compared to chlorthalidone 25 mg in clinical setting.

The purpose of this policy is to ensure that equally efficacious yet more cost effective medications are used for the conditions being treated.

References

1. Thalitone [package insert]. Casper Pharm, LLC. East Brunswick, New Jersey. Updated December 2019.

Policy History

Original Effective Date: 03/14/2022
Current Effective Date: 03/14/2022
02/03/2022 Medical Policy Committee review
02/09/2022 Medical Policy Implementation Committee approval. New policy.

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Next Scheduled Review Date: 02/2023

**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.