LOUISIANA BLUE

Sofdra™ (sofpironium)

Policy # 00909
Original Effective Date: 01/01/2025
Current Effective Date: 01/01/2026

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 Sofdra™‡ (sofpironium) for the treatment of primary axillary hyperhidrosis to be **eligible for coverage**** when the patient selection criteria are met.

Patient Selection Criteria

Coverage eligibility for Sofdra (sofpironium) will be considered when the following criteria are met:

- Patient has a diagnosis of primary axillary hyperhidrosis; AND
- Patient is 9 years of age or older.

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 Sofdra (sofpironium) when the patient selection criteria are NOT met to be **investigational.***

Background/Overview

Sofdra is an anticholinergic indicated for the treatment of primary axillary hyperhidrosis in adults and pediatric patients 9 years of age and older. It is available as a topical gel that contains 12.45% of sofpironium. One pump of Sofdra should applied to each underarm once daily at bedtime.

Hyperhidrosis is defined as excessive sweating and can be classified as either primary or secondary. Primary hyperhidrosis is idiopathic and presents in a bilateral and symmetrical pattern on the axilla, palms, soles, and face. Underlying medical conditions or use of prescription medications is typically the cause of secondary hyperhidrosis. The exact ideology of hyperhidrosis is not known, however it has been observed that patients with hyperhidrosis have a higher expression of acetylcholine and alpha-7 neuronal nicotinic receptor subunits in the sympathetic ganglia as compared to controls. There are no formal guidelines for the treatment of hyperhidrosis, but the International Hyperhidrosis Society has a treatment algorithm available. First line recommendations include topical antiperspirants (e.g., Drysol™‡, topical aluminum chloride, etc.) or Qbrexza™‡, which is a cloth

formulation containing glycopyrronium, followed by botulinum toxins if the topical therapies are not effective. Botulinum toxins are effective, however require repeat treatment and multiple injections. Other agents (anticholinergics) have been used off-label, but often cause unwanted side effects. Medical treatment options also exist for this condition; however, they will not be addressed in this policy.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)
Sofdra is approved for the treatment of primary axillary hyperhidrosis in adults and pediatric patients 9 years of age and older.

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.

Two randomized, vehicle-controlled multicenter trials, CARDIGAN 1 and CARDIGAN 2, enrolled a total of 701 subjects 10 years of age or older with primary axillary hyperhidrosis. All subjects were to have symptoms of axillary hyperhidrosis for at least 6 months' duration, produce at least 50 mg of sweat in each axilla (underarm) with a combined total of at least 150 mg over a 5-minute period, and have a Hyperhidrosis Disease Severity Measure-Axillary, 7-item scale score (HDSM-Ax7) ≥ 3. Subjects 12 years of age and older were asked to rate their underarm sweating severity and frequency since waking on the previous day ("since you woke up yesterday") on the 11-item HDSM-Ax Adult version instrument. The HDSM-Ax-7 scale score was calculated by taking an average of 7 items, where the scale score ranges from 0 to 4 with a higher score representing greater underarm sweating severity. Subjects were randomized to receive either Sofdra or vehicle applied once daily at bedtime to each axilla. The co-primary endpoints were the proportion of subjects having at least a 2-point improvement in the HDSM-Ax-7 scale score from Baseline to Day 43, and the change in GSP from Baseline to Day 43. In CARDIGAN 1, 49% of patients treated with Sofdra had a ≥ 2 point improvement in the HDSM-Ax-7 score compared with 29% of patients given vehicle. In CARDIGAN 2, 64% of patients treated with Sofdra had a ≥ 2 point improvement in the HDSM-Ax-7 score compared with 48% of patients given vehicle. The mean change from baseline to Day 43 in GSP was -128 mg/5 minutes for patients treated with Sofdra and -100 mg/5 minutes for vehicle in CARDIGAN 1 and -143 mg/5 minutes for patients treated with Sofdra and -134 mg/5 minutes for vehicle in CARDIGAN 2, respectively.

References

1. Sofdra [package insert]. Botanix SB, Inc. Wayne, Pennsylvania. Updated June 2024.
2. Sofdra Drug Evaluation. Express Scripts. July 2024.

Policy History

Original Effective Date: 01/01/2025
Current Effective Date: 01/01/2026
12/05/2024 Medical Policy Committee review
12/11/2024 Medical Policy Implementation Committee approval. New policy.
12/04/2025 Medical Policy Committee review
12/10/2025 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
Next Scheduled Review Date: 12/2026

*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.

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.

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.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.