Drug Coverage Policy

Effective Date.....7/15/2025
Coverage Policy Number.....IP0703
Policy Title.....Sofdra

Hyperhidrosis – Sofdra

- Sofdra™ (sofpironium 12.45% topical gel – Botxanix)

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. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. 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

Sofdra, a topical anticholinergic, is indicated for the treatment of **primary axillary** (i.e., underarm) **hyperhidrosis** in patients ≥ 9 years of age.[1]

Sofdra is applied topically using a single actuation pump to clean dry skin applied to each of the underarm areas once daily at bedtime (2 pumps per day); it is not intended for use on other body areas.

Guidelines
There are currently no guidelines for the treatment of hyperhidrosis published by a professional society. However, the International Hyperhidrosis Society, an independent, non-profit organization, provides an algorithm for the treatment of axillary hyperhidrosis (updated 2025).[2] Topical antiperspirant therapy (aluminum and zirconium salts) is considered first line treatment for primary axillary hyperhidrosis. Sofdra, Qbrexza® (glycopyrronium 2.4% cloth), and botulinum toxin A injections are recommended as second line treatment options. It is noted that typically aluminum chloride hexahydrate 20% topical solution is the most commonly prescribed agent.

Coverage Policy

POLICY STATEMENT
Prior Authorization is required for benefit coverage of Sofdra. All approvals are provided for the duration noted below.

Sofdra is considered medically necessary when the following are met:

FDA-Approved Indication

1. **Hyperhidrosis, Primary Axillary.** Approve for 1 year if the patient meets ALL of the following (A, B, C, D, and E):
   - **A)** Patient is ≥ 9 years of age; AND
   - **B)** Hyperhidrosis is significantly interfering with the ability to perform age-appropriate activities of daily living; AND
   - **C)** The prescriber has excluded secondary causes of hyperhidrosis; AND
   - **D)** Patient meets ONE of the following (i or ii):
     - **i.** Patient has tried one prescription strength aluminum chloride-containing topical antiperspirant for at least 4 weeks and experienced inadequate efficacy; OR
       Note: Examples of prescription aluminum chloride-containing topical antiperspirants include Xerac AC (aluminum chloride 6.25% topical solution), Drysol (aluminum chloride 20% topical solution).
     - **ii.** According to the prescriber, the patient has experienced significant intolerance with an aluminum-containing topical antiperspirant; AND
   - **E)** Preferred product criteria is met for the product(s) as listed in the below table(s)

Employer Plans:

Product	Criteria
Sofdra (sofpironium 12.45% topical gel)	**Standard/Value/Legacy Drug Plans:** Patient has tried and, according to the prescriber, has experienced inadequate efficacy OR significant intolerance with Qbrexza [may require prior authorization].

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.

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

Conditions Not Covered

Sofdra for any other use is considered not medically necessary, including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

1. **Hyperhidrosis, other than Primary Axillary.** Sofdra is not intended for application to areas other than the axillae.[1]

2. **Concurrent Use with Qbrexza (glycopyrronium 2.4% cloth).** The safety and efficacy of concurrent use of Sofdra and Qbrexza have not been established.

References

1. Sofdra™ topical gel, 12.45% [prescribing information]. Wayne, PA: Botanix; August 2024.
2. International Hyperhidrosis Society. Primary axillary hyperhidrosis treatment algorithm. Updated February 2025. Available at: https://sweathelp.org/treatments-hcp/clinical-guidelines/primary-focal-hyperhidrosis/primary-focal-axillary.html. Accessed on May 8, 2025.

Revision Details

Type of Revision	Summary of Changes	Date
New	New policy	11/15/2024
Annual Revision	No criteria changes	07/15/2025

The policy effective date is in force until updated or retired.