

PRIOR AUTHORIZATION POLICY

POLICY: Hyperhidrosis – Sofdra Prior Authorization Policy

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

REVIEW DATE: 07/03/2024

OVERVIEW

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

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 2018).² Sofdra is not in the current treatment algorithm. Topical antiperspirant therapy or Qbrexza® (glycopyrronium 2.4% cloth) are both listed as initial treatment choices. It is noted in the algorithm that typically aluminum chloride hexahydrate 20% topical solution is the most commonly prescribed agent.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Sofdra. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Sofdra is recommended in those who meet the following criteria:

FDA-Approved Indication

- 1. Hyperhidrosis, Primary Axillary.** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
 - 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.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Sofdra is not recommended in the following situations:

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.
3. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Sofdra™ topical gel, 12.45% [prescribing information]. Wayne, PA: Botanix; June 2024.
2. International Hyperhidrosis Society. Primary axillary hyperhidrosis treatment algorithm. Updated September 23, 2018. Available at: <https://sweathelp.org/treatments-hcp/clinical-guidelines/primary-focal-hyperhidrosis/primary-focal-axillary.html>. Accessed on June 26, 2024.
- 3.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	07/03/2024