

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.

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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.
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