PRIOR AUTHORIZATION POLICY

POLICY: Hyperhidrosis – Sofdra Prior Authorization Policy
- Sofdra™ (sofpironium 12.45% topical gel – Botanix)

REVIEW DATE: 07/03/2024

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 AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. 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.

CIGNA NATIONAL FORMULARY COVERAGE:

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.

- **Sofdra™ (sofpironium 12.45% topical gel – Botanix)**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

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 COVERED

- **Sofdra™ (sofpironium 12.45% topical gel – Botanix)**

is(are) considered experimental, investigational or unproven for ANY other use(s) 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.** The safety and efficacy of concurrent use of Sofdra and Qbrexza (glycopyrronium 2.4% cloth) have not been established.[1]

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.

HISTORY

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