Pharmacy Policy Bulletin: J-0797 Primary Axillary Hyperhidrosis – Commercial and Healthcare Reform	
Number: J-0797	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial:** **Prior Authorization (1. or 2.):** **1.** Other Managed Prior Authorization = Yes w/ Prior Authorization [Qbrexza] **2.** Miscellaneous Specialty Drugs Oral = Yes w/ Prior Authorization [Sofdra] **Healthcare Reform:** Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** None
Version: J-0797-011	**Original Date:** 11/07/2018
Effective Date: 10/08/2025	**Review Date:** 09/17/2025

Drugs Product(s):	• Sofdra (sofpironium) • Qbrexza (glycopyrronium)
FDA-Approved Indication(s):	• Topical treatment of primary axillary hyperhidrosis in adults and pediatric patients 9 years of age and older.

Background:	• Sofdra and Qbrexza are anticholinergic agents that inhibit the action of acetylcholine on sweat glands, thereby reducing sweating. • Hyperhidrosis is a condition of extreme sweating and affects 4.8% of the U.S. population, or approximately 15.3 million individuals. Primary (idiopathic) hyperhidrosis is the most common form and involves excessive sympathetic stimulation in isolated or multiple areas such as the axillae, soles, palms, or face. Primary (idiopathic) hyperhidrosis is due to unknown causes and is not attributable to an underlying health condition (e.g., obesity, diabetes, hyperthyroidism, gout). • Severity of hyperhidrosis can be defined by the Hyperhidrosis Disease Severity Scale (HDSS): 1 - My sweating is never noticeable and never interferes with my daily activities 2 - My sweating is tolerable but sometimes interferes with my daily activities 3 - My sweating is barely tolerable and frequently interferes with my daily activities 4 - My sweating is intolerable and always interferes with my daily activities • HDSS scores of 1 or 2 indicate mild to moderate hyperhidrosis. Scores of 3 or 4 indicate severe hyperhidrosis. • The International Hyperhidrosis Society recommends starting treatment with topical, OTC "clinical strength" antiperspirants (active ingredient often zirconium salts) and then prescription products (active ingredient often aluminum chloride

	hexahydrate). Glycopyrronium cloth (or anticholinergics) can be a first-line alternative to topical antiperspirant therapy if excessive sweating is caused by anxiety-provoking situations (e.g., work presentations). • Acceptable prescription strength aluminum compounds include prescription and over-the-counter (OTC) antiperspirants. The maximum percentage the FDA allows in OTC antiperspirants is 25% aluminum. The only prescription option available is Drysol 20%. OTC antiperspirants with prescription strength include Xerac AC, Certain DRI, Secret Clinical Strength, Degree Clinical Antiperspirant, Dove Clinical Protection, Gillette Clinical, Odaban, Driclor, ZeroSweat, SweatBlock, DuraDry, and Carpe. • Prescribing Considerations: ○ Patients should be educated on Sofdra and Qbrexza regarding the application time and technique in order to maximize efficacy and minimize side effects. ○ Sofdra and Qbrexza should be used with caution in patients with a history of urinary retention. ○ Sofdra and Qbrexza are contraindicated in patients with medical conditions that can be exacerbated by anticholinergic effects (e.g., glaucoma, paralytic ileus, unstable cardiovascular status in acute hemorrhage, severe ulcerative colitis, toxic megacolon complicating ulcerative colitis, myasthenia gravis, and Sjogren's syndrome). ○ Patients should avoid use if they develop a generalized lack of sweating when exposed to hot or very warm temperatures. ○ Blurred vision may occur. Patients should be educated to avoid driving until the effects of Sofdra or Qbrexza are realized. ○ Sofdra or Qbrexza should not be used in combination with other anticholinergic-containing medications due to an increased risk of anticholinergic side effects.

Approval Criteria

I. Initial Authorization

When a benefit, coverage of Sofdra or Qbrexza may be approved when all of the following criteria are met **(A. through D.)**:

A. The member is 9 years of age or older.

B. The member has a diagnosis of primary axillary hyperhidrosis. (ICD-10: L74.510)

C. The member has a Hyperhidrosis Disease Severity Scale (HDSS) score of 3 or 4.

D. The member has experienced therapeutic failure, contraindication, or intolerance to at least one (1) plan-preferred topical aluminum chloride 20% product.

II. Reauthorization

When a benefit, reauthorization of Sofdra or Qbrexza may be approved when the following criterion is met **(A.)**:

A. The prescriber attests that the member has experienced a reduction in sweat production defined as a HDSS score of 2 or lower.

III. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

Limitations of Coverage

I. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.

II. For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

Initial Authorization

- Commercial and HCR Plans: If approved, up to a 6 month authorization may be granted. *Note*: For Delaware Commercial fully-insured and ACA members, a 12 month authorization must be granted pursuant to 18 Del. C. §§3376(a) and 3586(a) and market conduct examination docket #5467 (Exam Authority #53287-22-701).

Reauthorization

- Commercial and HCR Plans: If approved, up to a 12 month authorization may be granted.

Automatic Approval Criteria

None.

References:

1. Qbrexza [package insert]. Menlo Park, CA: Dermira; October 2022.
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5. Hyperhidrosis Disease Severity Scale. International Hyperhidrosis Society. Available at: https://www.sweathelp.org/pdf/HDSS.pdf. Accessed July 2, 2025.
6. Glaser DA, Hebert AA, Nast A, et al. Topical Glycopyrronium Tosylate for the Treatment of Primary Axillary Hyperhidrosis: Results from the ATMOS-1 and ATMOS-2 Phase 3 Randomized Controlled Trials. *Am Acad Dermatol*. 2018.
7. CFR-Code of Federal Regulations Title 21. FDA. Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=350&showFR=1. Accessed July 2, 2025.
8. Over the Counter Antiperspirants: A Brief Guide. Hyperhidrosis Network. Available at: https://hyperhidrosisnetwork.com/over-the-counter-antiperspirants-a-brief-guide/. Accessed July 2, 2025.