MEDICAL MUTUAL®

Drug Policy

Policy:	**Qbrexza (glycopyrronium cloth 2.4%)** **Sofdra (sofpironium topical gel)**	**Annual Review Date: 08/15/2024** **Last Revised Date: 08/15/2024**

OVERVIEW

Qbrexza and Sofdra, anticholinergics, are indicated for the topical treatment of primary axillary hyperhidrosis in patients ≥ 9 years of age.

POLICY STATEMENT

This policy involves the use of Qbrexza and Sofdra. Prior authorization is recommended for pharmacy benefit coverage of Qbrexza and Sofdra. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

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

1. **Initial - Hyperhidrosis, Primary Axillary.**
   a) The patient is ≥ 9 years of age; AND
   b) Symptomatic hyperhidrosis occurs more than once weekly and symptoms cease at night; AND
   c) Qbrexza will ONLY be applied to the axillae (underarms) [documentation required]: AND
   d) Patient has tried and failed a clinical strength topical antiperspirant for one month (such as: 20% aluminum chloride hexahydrate, 15% aluminum chloride hexahydrate) unless a contraindication exists [documentation required]; AND
   e) Hyperhidrosis Disease Severity Scale (HDSS) of 3 or 4 [documentation required].

2. **Continuation of Therapy - Hyperhidrosis, Primary Axillary.**
   a) The patient is ≥ 9 years of age; AND
   b) Qbrexza will ONLY be applied to the axillae (underarms) [documentation required]; AND
   c) The patient's HDSS score has improved by at least two points since starting treatment with glycopyrronium [documentation required].

MEDICAL MUTUAL®

Drug Policy

Initial Approval/ Extended Approval.
A) *Initial Approval:* 60 days
B) *Extended Approval:* 1 year

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Qbrexza has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. **Hyperhidrosis, other than Primary Axillary.** Qbrexza and Sofdra are not intended for application to areas other than the axillae.

2. **Primary Focal Hyperhidrosis.** Qbrexza and Sofdra are not intended for application to other areas other than the axillae.

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

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Qbrexza™ cloth [prescribing information]. Menlo Park, CA: Dermira, Inc.; June 2018.
2. Sofdra [prescribing information]. Wayne, PA: Botanix SB Inc.; June 2024
3. Sammons JE, Khachemoune A. Axillary hyperhidrosis: a focused review. *J Dermatolog Treat*. 2017;28(7):582-290.
4. Hashmonai M, Cameron AEP, Connery CP, et al. The etiology of primary hyperhidrosis: a systematic review. *Clin Auton Res*. 2017;27:379-383.
5. Grabell DA, Hebert AA. Current and emerging medical therapies for primary hyperhidrosis. *Dermatol Ther (Heidelb)*. 2017;7:25-36.
6. Doolittle J, Walker P, Mills T, et al. Hyperhidrosis: an update on prevalence and severity in the United States. *Arch Dermatol Res*. 2016;308(10):743-749.
7. International Hyperhidrosis Society. Primary axillary hyperhidrosis treatment algorithm. Updated May 29, 2014. Accessed on July 11, 2018.
8. Smith CC, Pariser D. et al. Primary focal hyperhidrosis. UptoDate. October 11, 2018.
9. Kowalski et al. Validity and reliability of the hyperhidrosis disease severity scale (HDSS). J Am Acad Dermatol. 50(3):P51,2004.

10. Glycopyrronium tosylate. In: DRUGDEX [online database]. Truven Health Analytics; Greenwood Village, CO. Last updated 17 April 2019. Accessed on 14 September 2019.