# Clinical Policy: Glycopyrronium (Qbrexza)

Reference Number: PA.CP.PMN.177
Effective Date: 08/2018
Last Review Date: 10/2023 Revision Log

**Description**
Glycopyrronium tosylate (Qbrexza®)) is a competitive inhibitor of acetylcholine receptors that are located on certain peripheral tissues, including sweat glands.

**FDA Approved Indication(s)**
Qbrexza is indicated for topical treatment of primary axillary hyperhidrosis in adults and pediatric patients 9 years of age and older.

**Policy/Criteria**
*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of PA Health & Wellness® that Qbrexza is **medically necessary** when the following criteria are met:

**I. Initial Approval Criteria**

**A. Primary Axillary Hyperhidrosis** (must meet all):

1. Diagnosis of primary axillary hyperhidrosis;
2. Prescribed by or in consultation with a dermatologist;
3. Age ≥ 9 years;
4. Failure of a 3-month trial of topical aluminum chloride unless contraindicated or clinically significant adverse effects are experienced;
5. Dose does not exceed a single cloth per day.

**Approval duration:** 12 months

**B. Other diagnoses/indications**

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

**II. Continued Therapy**

**A. Primary Axillary Hyperhidrosis** (must meet all)**:**

1. Currently receiving medication via PA Health & Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed a single cloth per day.

**Approval duration:** 12 months

**B. Other diagnoses/indications** (must meet 1 or 2)**:**
1. Currently receiving medication via PA Health & Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies.
   **Approval duration: Duration of request or 12 months (whichever is less)**; or
2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

## III. Diagnoses/Indications for which coverage is NOT authorized:

**A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – PA.CP.PMN.53 or evidence of coverage documents.

## IV. Appendices/General Information

*Appendix A: Abbreviation/Acronym Key*
FDA: Food and Drug Administration

*Appendix B: Therapeutic Alternatives*
*This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.*

| Drug Name | Dosing Regimen | Dose Limit/ Maximum Dose |
|---|---|---|
| Xerac™ AC (aluminum chloride hexahydrate) | Apply solution sparingly to affected area, as directed. Use QHS for up to 1 week, or as directed; then decrease application frequency to every other night or 1 to 2 times per week, PRN. | Adults: 1 application per day to affected area(s) |
| Drysol™ (aluminum chloride hexahydrate) | | |

*Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.*

*Appendix C: Contraindications/Boxed Warnings*

- Contraindication(s): Qbrexza is contraindicated in patients with medical conditions that can be exacerbated by the anticholinergic effect of Qbrexza. Examples include:
  - Glaucoma
  - Paralytic ileus
  - Unstable cardiovascular status in acute hemorrhage
  - Severe ulcerative colitis
  - Toxic megacolon complicating ulcerative colitis
  - Myasthenia gravis
  - Sjogren's syndrome
- Boxed warning(s): none reported

## V. Dosage and Administration

| Indication | Dosing Regimen | Maximum Dose |
|---|---|---|
| Primary Axillary Hyperhidrosis | Apply QD to both axillae using a single cloth | A single cloth per day (one cloth used for both axillae) |

## VI. Product Availability

Pre-moistened cloth: 2.4% (30 pouches in 1 box)

## VII. References

1. Qbrexza Prescribing Information. Scottsdale, AZ: Journey Medical Corporation; October 2022. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/210361Orig1s005lbl.pdf. Accessed August 11, 2023.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2023. Available at: https://www.clinicalkey.com/pharmacology/. Accessed August 11, 2023.
3. International Hyperhidrosis Society. Primary Focal Axillary Hyperhidrosis Clinical Guidelines. Last updated September 23, 2018. Available at: https://www.sweathelp.org/treatments-hcp/clinical-guidelines/primary-focal-hyperhidrosis/primary-focal-axillary.html. Accessed July 20, 2022.
4. Nawrocki S and Cha J. The etiology, diagnosis, and management of hyperhidrosis: A comprehensive review: Therapeutic options. J Am Acad Dermatol 2019; 81(3): 669-680. https://0-doi.org.pacificatclassic.pacific.edu/10.1016/j.jaad.2018.11.066.

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|---|---|---|
| Policy created | 10/2018 | |
| 4Q 2019 annual review: No changes per Statewide PDL implementation 01-01-2020 | 10/2019 | |
| 4Q 2020 annual review: References reviewed and updated | 07/2020 | |
| 4Q 2021 annual review: no significant changes; references reviewed and updated. | 10/2021 | |
| 4Q 2022 annual review: no significant changes; references reviewed and updated. | 10/2022 | |
| 4Q 2023 annual review: no significant changes; references reviewed and updated. | 10/2023 | |