Clinical Policy: Glycopyrronium (Qbrexza)

Reference Number: PA.CP.PMN.177
Effective Date: 08/2018
Last Review Date: 10/2024

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.PHARM.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.PHARM.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 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 July 30, 2024.
2. Clinical Pharmacology [database online]. Tampa, FL: Elsevier, Inc.; 2024. Available at: https://www.clinicalkey.com/pharmacology/. Accessed July 30, 2024.
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 30, 2024.
4. McConaghy JR, Fosselman D. Hyperhidrosis: Management Options. *Am Fam Physician.* 2018 Jun 1;97(11):729-734.
5. 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
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
4Q 2024 annual review: no significant changes; references reviewed and updated.	10/2024