Clinical Policy: Glycopyrronium (Qbrexza)

Reference Number: ERX.NPA.106
Effective Date: 12.01.18
Last Review Date: 11.22
Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

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.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ 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:
Commercial – Length of Benefit
Medicaid – 12 months

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
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:
Commercial – Length of Benefit
Medicaid – 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 – ERX.PA.01 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. Menlo Parh, CA: Dermira, Inc.; June 2018. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/210361lbl.pdf. Accessed July 20, 2022.
2. Clinical Pharmacology [database online]. Philadelphia, PA: Elsevier, Inc.; 2022. Available at: http:// https://www.clinicalkey.com/pharmacology/. Accessed July 20, 2022.

3. International Hyperhidrosis Society. Primary Focal Axillary Clinical Guidelines. 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	08.14.18	11.18
4Q 2019 annual review: no significant changes; added Medicaid line of business with 12 month approval durations; references reviewed and updated.	09.10.19	11.19
4Q 2020 annual review: no significant changes; references reviewed and updated.	07.20.20	11.20
4Q 2021 annual review: no significant changes; references reviewed and updated.	08.09.21	11.21
4Q 2022 annual review: no significant changes; references reviewed and updated.	07.20.22	11.22

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.