Clinical Policy: Glycopyrronium (Qbrexza)

Reference Number: LA.PMN.177
Effective Date: 06.01.23
Last Review Date: 02.01.24~~4.23~~
Line of Business: Medicaid

Revision Log

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

****Please note: This policy is for medical benefit****

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~~/enrollee~~ has met all approval criteria.

It is the policy of Louisiana Healthcare Connections 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 (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255.
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to LA.PMN.53.

II. Continued Therapy

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A. Primary Axillary Hyperhidrosis (must meet all)**:**
1. Member~~/enrollee~~ meets one of the following (a or b):
   a. Currently receiving medication via Louisiana Healthcare Connections benefit or member~~/enrollee~~ has previously met initial approval criteria;
   b. Member~~/enrollee~~ is currently receiving medication and is enrolled in a state and product with continuity of care regulations
2. Member~~/enrollee~~ 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. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to LA.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 policies – refer to LA.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

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- 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 Park, CA: Dermira, Inc.; June 2018.~~Scottsdale, AZ: Journey Medical Corporation; October 2022. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/~~2018/210361lbl~~2022/210361Orig1s005lbl.pdf. Accessed ~~July 20, 2022~~August 11, 2023.
2. Clinical Pharmacology [database online]. ~~Philadelphia, PA: Elsevier. 2022.~~Tampa, FL: Gold Standard, Inc.; 2023. Available at: https://www.clinicalkey.com/pharmacology~~.~~/. Accessed ~~July 20, 2022~~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~~August 11, 2023.
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	~~Revision~~ Date	LDH Approval Date
Converted Corporate to LHCC policy.	04.23	6.21.23
Annual review: no significant changes; references reviewed and updated.	02.01.24	

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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. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable LHCC administrative policies and procedures.

This clinical policy is effective as of the date determined by LHCC. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. LHCC retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. 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. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom LHCC has no control or right of control. Providers are not agents or employees of LHCC.

This clinical policy is the property of LHCC. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their

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