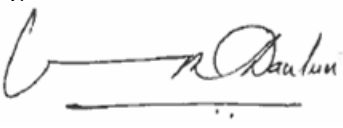


## Prior Authorization Review Panel

### CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.  
Policies submitted without this form will not be considered for review.

<b>Plan: PA Health &amp; Wellness</b>	<b>Submission Date: 11/01/2022</b>
<b>Policy Number: PA.CP.PMN.177</b>	<b>Effective Date: 01/2020</b> <b>Revision Date: 10/2022</b>
<b>Policy Name: Glycopyrronium (Qbrexza)</b>	
<p><b>Type of Submission – <u>Check all that apply:</u></b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> New Policy</li> <li><input checked="" type="checkbox"/> Revised Policy*</li> <li><input type="checkbox"/> Annual Review - No Revisions</li> <li><input type="checkbox"/> <b>Statewide PDL</b> - <i>Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.</i></li> </ul>	
<p><b>*All revisions to the policy <u>must</u> be highlighted using track changes throughout the document.</b></p> <p><b>Please provide any changes or clarifying information for the policy below:</b></p> <p>4Q 2022 annual review: no significant changes; references reviewed and updated.</p>	
<b>Name of Authorized Individual (Please type or print):</b>  Venkateswara R. Davuluri, MD	<b>Signature of Authorized Individual:</b>  

## Clinical Policy: Glycopyrronium (Qbrexza)

Reference Number: PA.CP.PMN.177

Effective Date: 08/2018

Last Review Date: 10/2022

[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  $\geq$  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. Menlo Park, CA: Dermira, Inc.; June 2018. Available at: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2018/210361lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/210361lbl.pdf). Accessed July 20, 2022.
2. Clinical Pharmacology [database online]. Philadelphia, PA: Elsevier. 2022. Available at: <https://www.clinicalkey.com/pharmacology>. Accessed July 20, 2022.
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	