

PHARMACY POLICY STATEMENT

Kentucky Medicaid

DRUG NAME	Qbrexza (glycopyrronium) cloth, 2.4%
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) Alternative preferred product includes Botox QUANTITY LIMIT— carton of 30 pouches for 30 days
LIST OF DIAGNOSES CONSIDERED NOT MEDICALLY NECESSARY	Click Here

Qbrexza (glycopyrronium) cloth, 2.4% is a **non-preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

AXILLARY HYPERHIDROSIS

For **initial** authorization:

1. Member has diagnosis of severe primary axillary hyperhidrosis, with resting sweat production of 50 mg per axilla measured over 5 minutes at room temperature documented in chart notes; AND
2. Documentation of Hyperhidrosis Disease Severity Scale (HDSS) rating of 3 or 4 must be submitted with chart notes; AND
3. Member is 9 -17 years of age; OR
4. Member ≥ 18 years old AND has tried and failed Botox (prior authorization required) for 30 days unless contraindicated or clinically significant adverse effects are experienced; AND
5. Medication must be prescribed by or in consultation with a dermatologist AND prescribing physician has documented the members hyperhidrosis is causing social anxiety, depression, or similar mental health related issues that impact daily life; AND
6. Member has tried and failed to respond to treatment with Drysol for ≥ 1 month, unless contraindicated or clinically significant adverse effects are experienced; AND
7. Secondary causes of hyperhidrosis (e.g., hyperthyroidism) have been evaluated and, if necessary, treated; AND
8. Member does not have ANY of the following:
 - a) History of Sjögren's syndrome or Sicca syndrome;
 - b) History of glaucoma, inflammatory bowel disease, toxic megacolon, or febrile illness;
 - c) Men with a history of urinary retention requiring catheterization due to prostatic hypertrophy or severe obstructive symptoms of prostatic hypertrophy;
 - d) History or presence of ventricular arrhythmias, atrial fibrillation, atrial flutter.
9. **Dosage allowed:** Qbrexza cloth (one cloth per pouch) is used topically once daily to both axillae using a single cloth.

If member meets all the requirements listed above, the medication will be approved for 4 weeks.

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided that show the member has shown a two level improvement in HDSS score.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 6 months.

CareSource considers Qbrexza (glycopyrronium) cloth, 2.4% not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Hyperhidrosis of palms/hands, soles (feet), forehead and other regions

DATE	ACTION/DESCRIPTION
11/27/2018	New policy for Qbrexza created.

References:

1. Obrexza [package insert]. Menlo Park, CA: Dermira, Inc. June, 2018.
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3. ClinicalTrials.gov. Identifier: NCT02530294. Study of Glycopyrronium in Subjects With Axillary Hyperhidrosis. Available at: <https://clinicaltrials.gov/ct2/show/NCT02530294?term=NCT02530294&rank=1>.
4. Doolittle, J., Walker, P., Mills, T. et al. Arch Dermatol Res (2016) 308: 743. <https://doi.org/10.1007/s00403-016-1697-9> Hyperhidrosis: an update on prevalence and severity in the United States
5. Gelbard, Christina M. MD, et al. "Primary pediatric hyperhidrosis: a review of current treatment options". Pediatric Dermatology 25:6 (2008): 591-598.
6. Guidance for Industry: Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims. FDA, 2009.
7. Kowalski et. al., Validity and Reliability of the Hyperhidrosis Disease Severity Scale (HDSS). J Am Acad Dermatol. 50(3): P51, 2004. [https://www.jaad.org/article/S0190-9622\(03\)03534-5/fulltext](https://www.jaad.org/article/S0190-9622(03)03534-5/fulltext)
8. A Comprehensive Approach to the Recognition, Diagnosis, and Severity-Based Treatment of Focal Hyperhidrosis: Recommendations of the Canadian Hyperhidrosis Advisory Committee, Dermatologic Surgery, August 2007, pages 908-923.
9. IPD Analytics. New Drug Approval. Qbrexza (glycopyrronium). Available at: <http://www.ipdanalytics.com/>.
10. Sammons JE, et al. Axillary hyperhidrosis: a focused review. J Dermatolog Treat. 2017 Nov;28(7):582-590.
11. Lee KY, et al. Turning the tide: a history and review of hyperhidrosis treatment. JRSM Open. 2014 Jan; 5(1):2042533313505511.

Effective date: 12/13/2018

Revised date: 11/27/2018