

PHARMACY POLICY STATEMENT

Marketplace

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) 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.

PRIMARY AXILLARY HYPERHIDROSIS

For **initial** authorization:

1. Member must be 9 years of age or older; AND
2. Medication must be prescribed by or in consultation with a dermatologist; AND
3. Member has a diagnosis of severe axillary hyperhidrosis, including documentation in the chart notes of visible, excessive sweating of at least 6 months duration which significantly impairs daily activities; AND
4. Secondary causes of hyperhidrosis (e.g., hyperthyroidism) have been ruled out; AND
5. Member has tried and failed topical prescription-strength aluminum chloride (e.g. Xerac) for at least 60 days; AND
6. Member does not have a medical condition that may be exacerbated by anticholinergic effects (e.g. glaucoma, urinary retention, Sjogren's syndrome, myasthenia gravis).
7. **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 2 months.

For **reauthorization**:

1. Chart notes must document clinically significant decreased severity of sweating.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 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.
09/22/2020	Reordered the criteria, matched wording to Botox policy, removed sweat quantification measure, removed HDSS score, summarized the list of exclusions, removed the mental health issue piece, removed trial of Botox per IHS guideline, changed the reauth criteria, extended reauth duration per long term efficacy study, changed Drysol to Xerac and extended trial period to be 60 days, changed initial auth duration to 2 months instead of 1.
11/17/2021	Annual review, no changes

References:

1. Qbrexza [package insert]. Menlo Park, CA: Dermira, Inc. June, 2018.
2. ClinicalTrials.gov. Identifier: NCT02530281. Study of Glycopyrronium in Axillary Hyperhidrosis. Available at: <https://clinicaltrials.gov/ct2/show/NCT02530281?term=NCT02530281&rank=1>.
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. JRSO Open. 2014 Jan; 5(1):2042533313505511.
12. Primary Focal Axillary - International Hyperhidrosis Society: Official Site. Primary Focal Axillary - International Hyperhidrosis Society | Official Site. <https://www.sweathelp.org/treatments-hcp/clinical-guidelines/primary-focal-hyperhidrosis/primary-focal-axillary.html>. Published September 23, 2018. Accessed September 23, 2020.
13. Hornberger J, Grimes K, Naumann M, et al. Recognition, diagnosis, and treatment of primary focal hyperhidrosis. J Am Acad Dermatol. 2004;51(2):274-286. doi:10.1016/j.jaad.2003.12.029
14. Glaser DA, Hebert AA, Nast A, et al. Topical glycopyrronium tosylate for the treatment of primary axillary hyperhidrosis: Results from the ATMOS-1 and ATMOS-2 phase 3 randomized controlled trials. J Am Acad Dermatol. 2019;80(1):128-138.e2. doi:10.1016/j.jaad.2018.07.002
15. Glaser DA, Hebert AA, Nast A, et al. A 44-Week Open-Label Study Evaluating Safety and Efficacy of Topical Glycopyrronium Tosylate in Patients with Primary Axillary Hyperhidrosis. Am J Clin Dermatol. 2019;20(4):593-604. doi:10.1007/s40257-019-00446-6

Effective date: 01/01/2022

Revised date: 11/17/2021