PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Qbrexza (glycopyrronium)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Qbrexza is an anticholinergic agent initially approved by the FDA in 2018 for the treatment and management of primary axillary hyperhidrosis, or excessive sweating of the underarms. Hyperhidrosis is a dermatological skin disorder that is characterized by the presence of excess sweating whereas primary axillary hyperhidrosis refers to conditions that are idiopathic and involves regions of the palms, soles or face. This condition has been documented to negatively impact quality of life and impair daily activities. Glycopyrronium (Qbrexza) is a competitive inhibitor of acetylcholine receptors, which are present in the sweat gland, and have many roles, including the maintenance of secreting substances like sweat, tears, and saliva.

Qbrexza (glycopyrronium) will be considered for coverage when the following criteria are met:

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 primary axillary hyperhidrosis; AND
4. Chart notes include documentation of visible, excessive sweating for 6 months which significantly impairs daily activities and/or quality of life; AND
5. Member has had a 30-day trial and failure of **ONE** topical prescription-strength aluminum chloride (e.g. Xerac AC, Hypercare, Drysol); AND
6. Member does **NOT** have a medical condition that may be exacerbated by anticholinergic effects (e.g. glaucoma, Sjogren's syndrome, myasthenia gravis, ulcerative colitis).
7. **Dosage allowed/Quantity limit:** apply once daily to both axillae using a single cloth. Quantity limit: 30 pouches per 30 days.

If all the above requirements are met, the medication will be approved for 2 months.

For **reauthorization**:

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

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Qbrexza (glycopyrronium) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

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.
02/05/2024	Policy transferred to new template, added quality-of-life impact on diagnosis criteria, added examples of trial agents that may be used, included ulcerative colitis as medical condition members must not have a diagnosis of and removed urinary retention, removed that secondary causes of hyperhidrosis have been ruled out, shortened trial of aluminum chloride from 60 days to 30 days, updated references, simplified dosing, added primary into diagnosis criteria.

References:

1. Qbrexza [package insert]. Menlo Park, CA: Dermira, Inc.; 2022
2. Gelbard CM, Epstein H, Hebert A. Primary pediatric hyperhidrosis: a review of current treatment options. *Pediatr Dermatol.* 2008;25(6):591-598. doi:10.1111/j.1525-1470.2008.00782.x
3. Solish N, Bertucci V, Dansereau A, et al. A comprehensive approach to the recognition, diagnosis, and severity-based treatment of focal hyperhidrosis: recommendations of the Canadian Hyperhidrosis Advisory Committee. *Dermatol Surg.* 2007;33(8):908-923. doi:10.1111/j.1524-4725.2007.33192.x
4. Sammons JE, Khachemoune A. Axillary hyperhidrosis: a focused review. *J Dermatolog Treat.* 2017;28(7):582-590. doi:10.1080/09546634.2017.1309347
5. Lee KY, Levell NJ. Turning the tide: a history and review of hyperhidrosis treatment. *JRSM Open.* 2014;5(1):2042533313505511. Published 2014 Jan 7. doi:10.1177/2042533313505511
6. 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
7. 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
8. 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
9. 2021 Georgia Code Title 33 – Insurance Chapter 20A - Managed Health Care Plans Article 2 - Patient's Right to Independent Review § 33-20A-31 Definitions. Justia US Law. Accessed April 25, 2023. https://law.justia.com/codes/georgia/2021/title-33/chapter-20a/article-2/section-33-20a-31/.

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Revised date: 02/05/2024