
Title: Glycopyrronium Topical (Qbrexza™)

Policy #: Rx.01.214

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, quantity, or formulary restrictions (ie limits on non-preferred drugs). Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Intent:

The intent of this policy is to communicate the medical necessity criteria for **glycopyrronium (Qbrexza™)** as provided under the member's prescription drug benefit.

Description:

Hyperhidrosis, defined as the secretion of sweat in amounts greater than physiologically necessary to maintain thermoregulation, can adversely affect an individual's social and emotional well-being and overall daily function. It commonly involves the axillae, palms, and soles, but may also affect the face, groin, or any area of the body. Prescription antiperspirants such as aluminum chloride hexahydrate 20% (Drysol®) and topical glycopyrronium (Qbrexza™) are first line options for the treatment of hyperhidrosis. Second line treatment options include onabotulinumtoxin A injections and microwave thermolysis.

Glycopyrronium (Qbrexza™) is a competitive inhibitor of acetylcholine receptors that are located on certain peripheral tissues, including sweat glands. In hyperhidrosis, glycopyrronium inhibits the action of acetylcholine on sweat glands, reducing sweating.

Glycopyrronium (Qbrexza™) is indicated for the topical treatment of primary axillary hyperhidrosis in adults and pediatric patients 9 years of age and older.

Policy:

INITIAL CRITERIA: Qbrexza™ (glycopyrronium) is approved when ALL of the following are met:

1. Diagnosis of primary axillary hyperhidrosis for at least 6 months; and
2. Member is 9 years of age or greater; and
3. Prescribed by or in consultation with a dermatologist; and
4. Hyperhidrosis Disease Severity Scale grade 3 or 4; and
5. Documentation of an inadequate response or inability to tolerate aluminum chloride (e.g. Drysol)

Initial authorization: 2 years

REAUTHORIZATION CRITERIA: Qbrexza™ (glycopyrronium) is re-approved when there is positive clinical response to therapy.

Reauthorization: 2 years

Black Box Warning as shown in the drug Prescribing Information:

N/A

Guidelines:

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the prescription drug benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

References:

Qbrexza™ (glycopyrronium) [prescribing information]. Menlo Park, CA. Dermira., Inc. June 2018. Available at: <http://pi.dermira.com/QbrexzaPI.pdf>. Accessed March 24, 2021

Smith CC, Pariser D. Primary focal hyperhidrosis. UpToDate Web site. Updated January 2, 2020. www.uptodate.com. Accessed March 24, 2021.

Wade R, Rice S, Llewellyn A, et al. Interventions for hyperhidrosis in secondary care: a systematic review and value-of-information analysis. *Health Technol Assess.* 2017;21(80):1-280.

Applicable Drugs:

Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Brand Name

Qbrexza™

Generic Name

Glycopyrronium

Cross References:

Off-Label Use Rx.01.33

Quantity Level Limits for Pharmaceuticals Covered Under the Prescription Drug Benefit Rx.01.76

Policy Version Number:	3.00
P&T Approval Date:	March 18, 2021
Policy Effective Date:	July 1, 2021
Next Required Review Date:	March 18, 2022

The Policy Bulletins on this web site were developed to assist the Company in administering the provisions of the respective benefit programs, and do not constitute a contract. If you have coverage through the Company, please refer to your specific benefit program for the terms, conditions, limitations and exclusions of your coverage. Company does not provide health care services, medical advice or treatment, or guarantee the outcome or results of any medical services/treatments. The facility and professional providers are responsible for providing medical advice and treatment. Facility and professional providers are independent contractors and are not employees or agents of the Company. If you have a specific medical condition, please consult with your doctor. The Company reserves the right at any time to change or update its Policy Bulletins.