Drug Coverage Policy

Effective Date.....09/15/2024
Coverage Policy Number.....IP0074
Policy Title.....Qbrexza

Hyperhidrosis – Qbrexza

- Qbrexza™ (glycopyrronium cloth 2.4% for topical use – Journey Medical)

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment and have discretion in making individual coverage determinations. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Cigna Healthcare Coverage Policy

Overview

Qbrexza, an anticholinergic, is indicated for the topical treatment of **primary axillary** (i.e., underarm) **hyperhidrosis** in patients ≥ 9 years of age.[1] Qbrexza is applied topically using a single cloth once every 24 hours to clean dry skin on both of the underarm areas only; it is not for use on other body areas.

Guidelines

There are currently no guidelines for the treatment of hyperhidrosis published by a professional society. However, the International Hyperhidrosis Society, an independent, non-profit organization, provides an algorithm for the treatment of axillary hyperhidrosis (updated 2018).[2] Topical antiperspirant therapy or Qbrexza are both listed as initial treatment choices. It is noted in the

algorithm that typically aluminum chloride hexahydrate 20% topical solution is the most commonly prescribed agent.

Medical Necessity Criteria

Qbrexza is considered medically necessary when the following criteria are met:

FDA-Approved Indication

1. **Hyperhidrosis, Primary Axillary.** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
   - **A)** Patient is ≥ 9 years of age; AND
   - **B)** Hyperhidrosis is significantly interfering with the ability to perform age-appropriate activities of daily living; AND
   - **C)** The prescriber has excluded secondary causes of hyperhidrosis; AND
   - **D)** Patient meets ONE of the following (i or ii):
     - **i.** Patient has tried one prescription aluminum chloride-containing topical antiperspirant for at least 4 weeks and experienced inadequate efficacy; OR
       Note: Examples of prescription aluminum chloride-containing topical antiperspirants include Xerac AC (aluminum chloride 6.25% topical solution), Drysol (aluminum chloride 20% topical solution).
     - **ii.** According to the prescriber, the patient has experienced significant intolerance with an aluminum-containing topical antiperspirant.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Conditions Not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

1. **Hyperhidrosis, other than Primary Axillary.** Qbrexza is not intended for application to areas other than the axillae.[1]

2. **Concurrent Use with Sofdra (sofpironium 12.45% topical gel).** The safety and efficacy of concurrent use of Qbrexza and Sofdra have not been established.

References

1. Qbrexza™ cloth [prescribing information]. Scottsdale, AZ: Journey Medical; December 2023.
2. International Hyperhidrosis Society. Primary axillary hyperhidrosis treatment algorithm. Updated September 23, 2018. Available at: https://sweathelp.org/treatments-hcp/clinical-guidelines/primary-focal-hyperhidrosis/primary-focal-axillary.html. Accessed on April 26, 2024.

Revision Details

Type of Revision	Summary of Changes	Date
Annual Revision	**Hyperhidrosis, Primary Axillary:** Updated "Documentation of failure, contraindication or intolerance to at least ONE prescription aluminum chloride-containing topical antiperspirant applied for at least 4 weeks." to now read, "Patient meets one of the following (i or ii): i. Patient has tried one prescription aluminum chloride-containing topical antiperspirant for at least 4 weeks and experienced inadequate efficacy; OR ii. According to the prescriber, the patient has experienced significant intolerance with an aluminum-containing topical antiperspirant. Added "The prescriber has excluded secondary causes of hyperhidrosis."	7/1/2024
Selected Revision	**Updated** the title of the policy from ""Qbrexza" to "Hyperhidrosis – Qbrexza." **Conditions Not Covered**: **Added** concurrent use of Qbrexza with Sofdra (sofpironium 12.45% topical gel) to the Policy.	09/15/2024

The policy effective date is in force until updated or retired.