Qbrexza™ (glycopyrronium)

Policy # 00660
Original Effective Date: 02/20/2019
Current Effective Date: 03/09/2020

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider Qbrexza™‡ (glycopyrronium) for the treatment of primary axillary hyperhidrosis to be **eligible for coverage**** when the patient selection criteria are met.

Patient Selection Criteria

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

- Patient has a diagnosis of primary axillary hyperhidrosis; AND
- Patient is 9 years of age or older.

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of Qbrexza (glycopyrronium) when the patient selection criteria are NOT met to be **investigational.***

Background/Overview

Qbrexza is an anticholinergic agent indicated for the topical treatment of primary axillary hyperhidrosis in adults and pediatric patients 9 years of age and older. It is supplied as a single-use

topical cloth pre-moistened with 2.4% glycopyrronium solution. Qbrexza should be applied once daily to both axillae using a single cloth.

Hyperhidrosis is defined as excessive sweating and can be classified as either primary or secondary. Primary hyperhidrosis is idiopathic and presents in a bilateral and symmetrical pattern on the axilla, palms, soles, and face. Underlying medical conditions or use of prescription medications is typically the cause of secondary hyperhidrosis. The exact ideology of hyperhidrosis is not known, however it has been observed that patients with hyperhidrosis have a higher expression of acetylcholine and alpha-7 neuronal nicotinic receptor subunits in the sympathetic ganglia as compared to controls. There are no formal guidelines for the treatment of hyperhidrosis, but the International Hyperhidrosis Society has a treatment algorithm available. First line recommendations include topical antiperspirants (e.g., Drysol™‡, topical aluminum chloride, etc.) followed by botulinum toxins if the antiperspirants are not effective. Botulinum toxins are effective, however require repeat treatment and multiple injections. Other agents (anticholinergics) have been used off-label, but often cause unwanted side effects. Medical treatment options also exist for this condition, however they will not be addressed in this policy.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Qbrexza is approved for the topical treatment of primary axillary hyperhidrosis in adults and pediatric patients 9 years of age and older.

Rationale/Source

Two randomized, vehicle-controlled multicenter trials, Trial 1 and Trial 2, were conducted in subjects 9 years of age or older with primary axillary hyperhidrosis. A method of efficacy measurement for these trials included the Axillary Sweating Daily Diary (ASDD) item #2, a patient reported outcome instrument scored from 0 (no sweating) to 10 (worst possible sweating). The median sweat production over 5 minutes at baseline was 122 mg in the Qbrexza arm and 113 mg in the vehicle arm in Trial 1, and 127 mg in the Qbrexza arm and 117 mg in the vehicle arm in Trial 2. The average weekly mean score on the ASDD item #2 at baseline was approximately 7.2 across both trials. Subjects were randomized to receive either Qbrexza or vehicle applied once daily to each axilla. The co-primary endpoints were the proportion of subjects having at least a 4-point improvement from baseline in the weekly mean ASDD item #2 score at week 4 and the mean

absolute change from baseline in gravimetrically measured sweat production at week 4. In Trial 1, 53% of subjects in the Qbrexza arm had at least a 4 point improvement in baseline in the weekly mean ASDD item #2 at week 4 vs. 28% in the placebo group. In Trial 2, 66% of subjects in the Qbrexza arm had at least a 4 point improvement in baseline in the weekly mean ASDD item #2 at week 4 vs. 27% in the placebo group. In Trial 1, subjects in the Qbrexza arm had a -81 mg/5 minutes change from baseline in sweat production at week 4 vs. the placebo group, which had a -66 mg/5 minutes change from baseline in sweat production at week 4. In Trial 2, subjects in the Qbrexza arm had a -79 mg/5 minutes change from baseline in sweat production at week 4 vs. the placebo group, which had a -58 mg/5 minutes change from baseline in sweat production at week 4.

References

1. Qbrexza [package insert]. Dermira, Inc. Menlo Park, California. Updated June 2018.
2. Qbrexza Drug Evaluation. Express Scripts. Updated July 2018.
3. Sammons JE, Khachemoune A. Axillary hyperhidrosis: a focused review. J Dermatolog Treat. 2017;28(7):582-290.
4. Hashmonai M, Cameron AEP, Connery CP, et al. The etiology of primary hyperhidrosis: a systematic review. Clin Auton Res. 2017;27:379-383.
5. International Hyperhidrosis Society. Primary axillary hyperhidrosis treatment algorithm. Updated May 29, 2014.

Policy History

Original Effective Date: 02/20/2019
Current Effective Date: 03/09/2020
02/07/2019 Medical Policy Committee review
02/20/2019 Medical Policy Implementation Committee approval. New policy.
02/06/2020 Medical Policy Committee review
02/12/2020 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
Next Scheduled Review Date: 02/2021

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*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.