



Kansas City

An Independent Licensee of the Blue Cross and Blue Shield Association

# Qbrexza (glycopyrronium cloth 2.4%)

**Policy Number:** 5.01.677

**Last Review:** 02/2019

**Origination:** 02/2019

**Next Review:** 02/2020

## **Policy**

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Blue Cross and Blue Shield of Kansas City (Blue KC) will provide coverage for **Qbrexza (glycopyrronium cloth 2.4%)** when it is determined to be medically necessary because the criteria shown below are met.

## **When Policy Topic is covered**

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**Qbrexza (glycopyrronium cloth 2.4%)** may be considered **medically necessary** when all of the following criteria are met:

### **FDA-Approved Indications**

- 1) Hyperhidrosis, Primary Axillary.** Approve for 1 year if (a and b):
  - a) Patient is  $\geq 9$  years of age; AND
  - b) Patient is unresponsive or unable to tolerate topical aluminum chloride (e.g. Drysol) or other prescription strength antiperspirants

## **When Policy Topic is not covered**

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Qbrexza (glycopyrronium cloth 2.4%) is considered **not medically necessary** when the above criteria is not met and **investigational** for all other uses, including:

- 1. Hyperhidrosis, other than Primary Axillary.** Qbrexza is not intended for application to areas other than the axillae.<sup>1</sup>
- 2.** Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

## **Considerations**

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Qbrexza (glycopyrronium cloth 2.4%) requires prior authorization through the Clinical Pharmacy Department.

This Blue Cross and Blue Shield of Kansas City policy statement was developed using available resources such as, but not limited to: Food and Drug Administration (FDA) approvals, Facts and Comparisons, National specialty guidelines, local medical policies of other health plans, Medicare (CMS), local providers.

## **Description of Procedure or Service**

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Qbrexza, an anticholinergic, is indicated for the topical treatment of primary axillary hyperhidrosis in adult and pediatric patients  $\geq 9$  years of age.<sup>1</sup> Qbrexza is a competitive inhibitor of acetylcholine receptors, which are located on peripheral tissues, including sweat glands. Qbrexza inhibits the action of acetylcholine on sweat glands in hyperhidrosis, thereby reducing sweating. Qbrexza is applied topically once every 24 hours to clean dry skin on the underarm areas only; it is not for use on other body areas. It is administered by a single-use pre-moistened cloth supplied in an individual pouch. One single cloth should be used to apply Qbrexza to both underarms. Hands should be washed immediately with soap and water after applying and discarding the Qbrexza cloth. If Qbrexza comes in contact with the eyes it may cause temporary pupil dilation and blurred vision; avoid transfer of Qbrexza to the periocular area. Qbrexza should not be applied to broken skin or used with occlusive dressings.

## **Disease Overview**

Hyperhidrosis is a skin disorder in which sweat is produced in excess of what is required to maintain normal body temperature.<sup>2</sup> It is categorized as either primary or secondary. Primary hyperhidrosis is idiopathic and presents in a bilateral and symmetrical pattern on the axilla, palms, soles, and face.<sup>3</sup> An underlying medical condition or use of a prescription medication generally results in secondary hyperhidrosis. Currently, the estimated prevalence of hyperhidrosis in the US is 4.8% (approximately 15.3 million people); 65% of these patients have axillary hyperhidrosis (equating to 3.12% of the US population or 9.9 million people).<sup>2-3</sup> Hyperhidrosis can range in severity with approximately 70% of patients with hyperhidrosis reporting severe excessive sweating in at least one part of the body.<sup>2</sup> This may result in restrictions in work and social relationships, limitations in physical and leisure activities, and emotional and mental health impairments. Low self-esteem and interpersonal difficulties have been reported to have a negative impact on daily activities; patients may also have impaired performance and productivity at work.<sup>3</sup> The exact etiology of hyperhidrosis is not completely understood.<sup>3-4</sup> However, it has been observed that patients with hyperhidrosis have a higher expression of acetylcholine and alpha-7 neuronal nicotinic receptor subunit in the sympathetic ganglia compared with controls.<sup>4</sup> Therefore, it has been hypothesized that excess sweating is caused by overstimulation of eccrine glands by sympathetic postganglionic nerve fibers releasing acetylcholine. The goal of the management of axillary hyperhidrosis is to decrease sweat production and sweat glands in an effort to ameliorate symptoms and improve quality of life.<sup>4-</sup>  
<sup>5</sup> There are some treatment options available in addition to modifications such as wearing lightweight clothing, replacing electrolytes lost in sweat, and maintaining a cold environment. Topical antiperspirants are first-line therapy for axillary

hyperhidrosis. Over-the-counter (OTC) [e.g., aluminum zirconium tetrachlorohydrate gly] and prescription options (e.g., aluminum chloride hexahydrate 20% solution [Drysol™, generics]; Hypercare™ [aluminum chloride hexahydrate 15% solution], Xerac™ AC [aluminum chloride hexahydrate 6.25% solution]) are available. These agents work by blocking the openings of the sweat ducts. They are easy to use, but treatment with the prescription products is often limited by skin irritation. Other topical treatments have included topical anticholinergics (used off-label prior to the approval of Qbrexza) and topical botulinum toxin type A.

### **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 (2014).<sup>6</sup> Topical antiperspirant therapy is recommended initially, followed by either Botox injections or microwave thermolysis (if available). This algorithm has not been updated to include Qbrexza.

### **Rationale**

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Prior authorization is required to ensure the safe, clinically appropriate and cost effective use of Qbrexza (glycopyrronium cloth 2.4%) while maintaining optimal therapeutic outcomes.

### **References**

1. Qbrexza™ cloth [prescribing information]. Menlo Park, CA: Dermira, Inc.; June 2018.
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3. Hashmonai M, Cameron AEP, Connery CP, et al. The etiology of primary hyperhidrosis: a systematic review. *Clin Auton Res*. 2017;27:379-383.
4. Grabell DA, Hebert AA. Current and emerging medical therapies for primary hyperhidrosis. *Dermatol Ther (Heidelb)*. 2017;7:25-36.
5. Doolittle J, Walker P, Mills T, et al. Hyperhidrosis: an update on prevalence and severity in the United States. *Arch Dermatol Res*. 2016;308(10):743-749.
6. International Hyperhidrosis Society. Primary axillary hyperhidrosis treatment algorithm. Updated May 29, 2014. Accessed on July 11, 2018.

### **Billing Coding/Physician Documentation Information**

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N/A	Pharmacy benefit
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### **Additional Policy Key Words**

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N/A

### **Policy Implementation/Update Information**

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02/2019	New policy titled Qbrexza (glycopyrronium cloth 2.4%)
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State and Federal mandates and health plan contract language, including specific provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The medical policies contained herein are for informational purposes. The medical policies do not constitute medical advice or medical care. Treating health care providers are independent contractors and are neither employees nor agents Blue KC and are solely responsible for diagnosis, treatment and medical advice. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, photocopying, or otherwise, without permission from Blue KC.