

Blue Cross Blue Shield Association 750 9th St NW, Suite 900 Washington, D.C. 20001 1-800-624-5060 Fax 1-877-378-4727

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| Last Review Da | ato. | December 13, 2024 | | |
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| Subsection: | Topical Products | | Original Policy Date: | November 8, 2018 |
| Section: | Prescription | n Drugs | Effective Date: | January 1, 2025 |

Qbrexza

Description

Qbrexza (glycopyrronium)

Background

Qbrexza (glycopyrronium) is a competitive inhibitor of acetylcholine receptors that are located on certain peripheral tissues, including sweat glands. In hyperhidrosis, Qbrexza inhibits the action of acetylcholine on sweat glands, which reduces sweating (1).

Regulatory Status

FDA-approved indication: Qbrexza is an anticholinergic indicated for topical treatment of primary axillary hyperhidrosis in adults and pediatric patients 9 years of age and older (1).

Qbrexza should be used with caution in patients with a history or presence of documented urinary retention. Prescribers and patients should be alert for signs and symptoms of urinary retention (e.g., difficulty passing urine, distended bladder), especially in patients with prostatic hypertrophy or bladder-neck obstruction. Patients should be instructed to discontinue use immediately and consult a physician should any of these signs or symptoms develop (1).

In the presence of high ambient temperature, heat illness (hyperpyrexia and heat stroke due to decreased sweating) can occur with the use of anticholinergic drugs such as Qbrexza. Patients using Qbrexza should be advised to watch for generalized lack of sweating when in hot or very warm environmental temperatures and to avoid use if not sweating under these conditions (1).

Transient blurred vision may occur with use of Qbrexza. If blurred vision occurs, the patient should discontinue use until symptoms resolve. Patients should be warned not to engage in

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activities that require clear vision such as operating a motor vehicle or other machinery or performing hazardous work until the symptoms have resolved (1).

The safety and efficacy of Qbrexza have not been established in pediatric patients under 9 years of age (1).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Qbrexza may be considered medically necessary if the conditions indicated below are met.

Qbrexza may be considered investigational for all other indications.

Prior-Approval Requirements

Age 9 years of age and older

Diagnosis

Patient must have the following:

Primary axillary hyperhidrosis

AND ALL of the following:

- 1. Inadequate treatment response, intolerance, or contraindication to **ALL** of the following:
 - a. **ONE** over the counter topical antiperspirant (e.g., Bromi-lotion)
 - b. **ONE** legend aluminum chloride-containing topical antiperspirants (e.g., Drysol, Hypercare, Xerac AC)
- 2. Documented baseline evaluation of the condition using a scoring tool, such as the Hyperhidrosis Disease Severity Scale (HDSS) (*e.g., https://www.sweathelp.org/pdf/HDSS.pdf*)

AND NONE of the following:

- 1. Glaucoma
- 2. Paralytic ileus

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- 3. Unstable cardiovascular status in acute hemorrhage
- 4. Severe ulcerative colitis
- 5. Toxic megacolon complicating ulcerative colitis
- 6. Myasthenia gravis
- 7. Sjogren's syndrome

Prior – Approval Renewal Requirements

Age 9 years of age and older

Diagnosis

Patient must have the following:

Primary axillary hyperhidrosis

AND the following:

 Documented improvement from baseline using a scoring tool such as the Hyperhidrosis Disease Severity Scale (HDSS) (e.g., https://www.sweathelp.org/pdf/HDSS.pdf)

AND NONE of the following:

- 1. Glaucoma
- 2. Paralytic ileus
- 3. Unstable cardiovascular status in acute hemorrhage
- 4. Severe ulcerative colitis
- 5. Toxic megacolon complicating ulcerative colitis
- 6. Myasthenia gravis
- 7. Sjogren's syndrome

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 90 cloths per 90 days

Duration 12 months

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Prior – Approval Renewal Limits

Same as above

Rationale

Summary

Qbrexza (glycopyrronium) is a competitive inhibitor of acetylcholine receptors that are located on certain peripheral tissues, including sweat glands. In hyperhidrosis, Qbrexza inhibits the action of acetylcholine on sweat glands, which reduces sweating. The safety and efficacy of Qbrexza have not established in pediatric patients under 9 years of age (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Qbrexza while maintaining optimal therapeutic outcomes.

References

Dell's al l'acte

1. Qbrexza [package insert]. Scottsdale, AZ: Journey Medical Corporation; November 2022.

| Policy History | |
|----------------|--|
| Date | Action |
| May 2019 | New addition |
| June 2019 | Annual review. Revised continuation criteria to include documented improvement in symptoms |
| September 2020 | Annual review |
| September 2021 | Annual review and reference update. Per MQA, added requirements: patient needs to have a documented baseline score such as HDSS and improvement in score for renewal. Per MQA, revised initiation requirement from t/f of two OTC antiperspirants to t/f one OTC and one legend aluminum chloride-containing topical antiperspirants |
| September 2022 | Annual review |
| September 2023 | Annual review and reference update |
| September 2024 | Annual review |
| December 2024 | Annual review |

Keywords

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This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 13, 2024 and is effective on January 1, 2025.