Pharmacy Medical Necessity Guidelines: Qbrexza™ (glycopyrronium)

Effective: November 10, 2020

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM

These pharmacy medical necessity guidelines apply to the following:

Commercial Products

☒ Tufts Health Plan Commercial products – large group plans
☒ Tufts Health Plan Commercial products – small group and individual plans
☒ Tufts Health Freedom Plan products – large group plans
☒ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☐ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:

RXUM: 617.673.0988

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

Qbrexza is indicated for topical treatment of primary axillary hyperhidrosis in adult and pediatric patients 9 years of age and older.

COVERAGE GUIDELINES

The plan may authorize coverage of **Qbrexza** when all of the following criteria are met:

For members between the age of 9 and 17:

1. The member is at least 9 years of age

AND

2. The Member has a documented primary axillary hyperhidrosis

AND

3. The member has had a trial and failure with an aluminum chloride containing antiperspirant

For members age 18 and older:

1. The member is at least 9 years of age

AND

2. The Member has a documented primary axillary hyperhidrosis

AND

3. The member has had a trial and failure with an aluminum chloride containing antiperspirant

AND

4. The member has had a trial and failure with Botox

LIMITATIONS

1. Qbrexza will be limited to a quantity of 30 cloths per month.
2. Documentation of a Member having needle phobia does not qualify as a medically acceptable contraindication or clinical inappropriateness to Botox therapy.

CODES

None

REFERENCES

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4. 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):743-9.
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7. Glaser DA, Herbert AA, Nast A et al. Open-label study (ARIDO) evaluating long-term safety of topical glycopyrronium tosylate (GT) in patients with primary axillary hyperhidrosis. Poster presented at the 36th Fall Clinical Dermatology Conference. Las Vegas, NV; 2017 October 13.
8. Glaser DA, Hebert AA, Nast A et al. Topical Glycopyrronium tosylate for the treatment of primary axillary hyperhidrosis: results from the ATMOS-1 and ATMOS-2 phase 3 randomized controlled trials JAAD. In press.
9. International Hyperhidrosis Society (IHHS). Hyperhidrosis treatment overview. URL: sweathelp.org/hyperhidrosis-treatments/treatment-overview.html. Available from Internet. Accessed 2018 August 8.
10. Liu Y, Bahar R, Kalia S et al. Hyperhidrosis prevalence and demographical characteristics in dermatology outpatients in Shanghai and Vancouver. PLoS One. 2016; 11(4):e0153719.
11. Qbrexza (glycopyrronium) [package insert]. Dermira, Inc., Menlo Park, CA; June 2018

APPROVAL HISTORY

March 12, 2019: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- October 15, 2019: Effective January 1, 2020, added a limitation: Member having needle phobia does not qualify as a medically acceptable contraindication or clinical inappropriateness to Botox therapy. Administrative update: separated Commercial and Medicaid MNG.
- November 10, 2020: No changes.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.