glycopyrronium (Qbrexza™)

EOCCO POLICY

Policy Type: PA Pharmacy Coverage Policy: EOCCO035

Description

Glycopyrronium (Qbrexza) is an anticholinergic that works to reduce sweating by inhibiting the action of acetylcholine on sweat glands.

Length of Authorization

- Initial: Three months
- Renewal: 12 months

Quantity limits

Product Name	Dosage Form	Indication	Quantity Limit	DDID
glycopyrronium (Qbrexza)	Topical 2.4% single-use pre-moistened cloth	Primary axillary hyperhidrosis	30 cloths/30 days	203316 203275

Initial Evaluation

I. Glycopyrronium (Qbrexza) may be considered medically necessary when the following criteria below are met:
   A. Member is nine years of age or older; **AND**
   B. The medication is prescribed by or in consultation with a dermatologist; **AND**
   C. Member has a confirmed diagnosis of primary axillary hyperhidrosis; **AND**
   D. Member has a history of medical complications such as skin infections or significant functional impairments due to condition; **OR**
   E. Member has a significant impact to activities of daily living due to condition; **AND**
   F. Member has tried and failed or have a contraindication to both of the following:
      1. Over-the-counter topical antiperspirant therapy (e.g. Drysol Solution, Hypercare Solution, or Aluminum Chloride Hexahydrate 20% Solution); **AND**
      2. Oral anticholinergics (e.g. oxybutynin tablet, glycopyrrolate tablet)

Renewal Evaluation

I. Member has experienced a reduction in spontaneous axillary sweat production; **AND**
II. Member has experienced an improvement in activities of daily living.

Supporting Evidence

I. Glycopyrronium (Qbrexza) is the first topical anticholinergic agent FDA-approved for treatment of axillary hyperhidrosis. The drug was studied in two, phase III, randomized, double-blind, vehicle controlled, parallel group trials, ATMOS-1 (N=344) and ATMOS-2 (N=353) evaluating daily glycopyrronium (Qbrexza) application to each axilla over 4 weeks. ASDD responder rate at week 4 was significantly greater for glycopyrronium (Qbrexza) versus vehicle in both trials.
   - ATMOS-1: 52.8% vs 28.3%; *P*=<0.001
   - ATMOS-2: 66.1% vs 26.9%; *P*=<0.001

II. Safety and efficacy of glycopyrronium (Qbrexza) has been established in patients older than nine years of age.

III. Glycopyrronium (Qbrexza) is FDA approved in the setting of primary hyperhidrosis. Secondary causes of hyperhidrosis should be ruled out. Patients with generalized, secondary hyperhidrosis usually present as adults and report sweating that occurs both while awake and sleeping. Medications should be carefully reviewed, as many can cause generalized sweating

IV. Topical antiperspirants offer a localized treatment approach with a favorable side effect profile compared to other therapies. Although glycopyrronium (Qbrexza) is a topical formulation, it carries a similar side effect profile to oral anticholinergics (e.g. oxybutynin).

References

1. Qbrexza [prescribing information]. Menlo Park,CA: Dermira; June 2018.
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3. UpToDate, Inc. Primary focal hyperhidrosis. UpToDate [database online]. Waltham, MA. Updated January 16, 2018. Available at: http://www.uptodate.com/home/index.html. Accessed October 2, 2018.
4. Hornberger J, Grimes K, Naumann M, Glaser DA, Lowe NJ, Naver H, et al. Recognition, diagnosis, and treatment of primary focal hyperhidrosis. Journal of the American Academy of Dermatology. 2004;51(2):274–86.
5. Baumgartner, Fritz J. Hyperhidrosis [Internet]. London: BMJ Publishing Group Ltd. 2015. Available from: Best Practice. Accessed October 3, 2018
6. International Hyperhidrosis Society. Primary Axillary Hyperhidrosis Clinical Guidelines. Available at: https://www.sweathelp.org/pdf/IHhS%20Axillary%20Hh%20Treatment%20Algorithm%20Aug-2018.pdf. Accessed October 3, 2018

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Policy Implementation/Update:

Date Created	October 2018
Date Effective	November 2018
Last Updated	September 2019
Last Reviewed	09/2019

Action and Summary of Changes	Date
Transition from criteria to policy	09/2019
Criteria created	10/2018