STEP THERAPY CRITERIA

BRAND NAME
(generic)

QBREXZA
(glycopyrronium)

SOFDRA
(sofpironium)

Status: CVS Caremark® Criteria
Type: Initial Step Therapy with Quantity Limit;
Post Step Therapy Prior Authorization with Quantity Limit

POLICY

FDA-APPROVED INDICATIONS

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

Sofdra
Sofdra is indicated for the treatment of primary axillary hyperhidrosis in adults and pediatric patients 9 years of age and older.

INITIAL STEP THERAPY with QUANTITY LIMIT*

**Include Rx and OTC products unless otherwise stated.*

If the patient has filled a prescription for at least a 30-day supply of a topical antiperspirant within the past 120 days under a prescription benefit administered by CVS Caremark, then the requested drug will be paid under that prescription benefit. If the patient does not meet the initial step therapy criteria, then the claim will reject with a message indicating that a prior authorization (PA) is required. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.

**If the patient meets the initial step therapy criteria, then the initial limit criteria will apply. If the patient is requesting more than the initial quantity limit the claim will reject with a message indicating that a PA is required.

**INITIAL LIMIT QUANTITY

Limits should accumulate across all drugs and strengths up to highest quantity listed depending on the order the claims are processed. Accumulation does not apply if limit is coded for daily dose.

Drug	1 Month Limit*	3 Month Limit*
Qbrexza	30 cloths (1 carton) / 25 days	90 cloths (3 cartons) / 75 days
Sofdra	50 mL (1 multi dose metered pump containing 60 actuations) / 25 days	150 mL (3 multi dose metered pumps containing 180 actuations) / 75 days

**The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.*

COVERAGE CRITERIA

Primary Axillary Hyperhidrosis
Authorization may be granted when the requested drug is being prescribed for the topical treatment of primary axillary hyperhidrosis when ALL of the following criteria are met:

- The patient is 9 years of age or older
- The patient meets ONE of the following:
    - The patient has experienced an inadequate treatment response to a topical antiperspirant (e.g., aluminum chloride hexahydrate)
    - The patient has experienced an intolerance to a topical antiperspirant (e.g., aluminum chloride hexahydrate)
    - The patient has a contraindication that would prohibit a trial of a topical antiperspirant (e.g., aluminum chloride hexahydrate)

CONTINUATION OF THERAPY

Primary Axillary Hyperhidrosis
Authorization may be granted when the requested drug is being prescribed for the topical treatment of primary axillary hyperhidrosis when ALL of the following criteria are met:

- The patient is 9 years of age or older
- The patient has achieved or maintained a positive clinical response to the requested drug

QUANTITY LIMITS APPLY

Qbrexza: 30 cloths (1 carton) per 25 days* or 90 cloths (3 cartons) per 75 days*
Sofdra: 50 mL (1 multi dose metered pump containing 60 actuations) per 25 days* or 150 mL (3 multi dose metered pumps containing 180 actuations) per 75 days*
**The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.*

DURATION OF APPROVAL (DOA)

- 3187-E: DOA: 12 months

REFERENCES

1. Qbrexza [package insert]. Scottsdale, AZ: Journey Medical Corporation; December 2022.
2. Sofdra [package insert]. Wayne, PA: Botanix SB Inc.; June 2024.
3. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2023. https://online.lexi.com. Accessed November 29, 2023.
4. Lexicomp Online, Lexi-Drugs Online. Waltham, MA: UpToDate, Inc.; 2023. https://online.lexi.com. Accessed July 8, 2024.
5. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 07/08/2024).
6. Nawrocki S, Cha J. The etiology, diagnosis, and management of hyperhidrosis: A comprehensive review. *J Am Acad Dermatol* 2019;81(3):669-680.