Hyperhidrosis Prior Authorization with Quantity Limit Program Summary

This program applies to FocusRx.

The BCBS MN Step Therapy Supplement also applies to this program for all Commercial/HIM lines of business.

POLICY REVIEW CYCLE

Effective Date
03-01-2024

Date of Origin
07-01-2019

FDA APPROVED INDICATIONS AND DOSAGE

Agent(s)	FDA Indication(s)	Notes	Ref#
Qbrexza® (glycopyrronium) Cloth	Topical treatment of primary axillary hyperhidrosis in adults and pediatric patients 9 years of age and older		1

See package insert for FDA prescribing information: https://dailymed.nlm.nih.gov/dailymed/index.cfm

CLINICAL RATIONALE

Hyperhidrosis	Hyperhidrosis is defined as overactive sweating that can be up to four to five times more than necessary, causing embarrassment, discomfort, and anxiety.(5) There are two types of hyperhidrosis, primary and secondary. Primary focal hyperhidrosis refers to excessive sweating that is not caused by another medical condition and usually affects the axillae, palms, soles, face, and head. Secondary generalized hyperhidrosis is defined as excessive sweating caused by another medical condition or as a side effect of medication(s).(6)
	
	Diagnosis of primary focal hyperhidrosis should be made only after excluding secondary causes of excessive sweating.(2,3) The following are recommended diagnosis criteria for primary focal hyperhidrosis:(2,6)
	
	• Focal, visible, excessive sweating of at least 6 months duration without apparent cause with at least two of the following characteristics:
	  ○ Bilateral and relatively symmetric
	  ○ Impairs daily activities
	  ○ Frequency of at least one episode per week
	  ○ Age of onset less than 25 years
	  ○ Positive family history
	  ○ Cessation of focal sweating during sleep
	
	The first line therapy for axillary hyperhidrosis is topical antiperspirants.(2,4) Treatment with prescription antiperspirants (e.g., 20% aluminum chloride hexahydrate) may provide adequate therapy for individuals who have failed to respond to nonprescription antiperspirants, though "clinical strength" 20% aluminum zirconium trichlorohydrex products are now available over-the-counter.(4) Second line therapy includes botulinum toxin injection, topical glycopyrronium, and microwave thermolysis.(2,4) For patients who cannot be managed with first or second lines of

	therapy, alternative therapies (suction curettage, followed by systemic agents, then endoscopic thoracic sympathectomy) may be considered.(4) Glycopyrronium cloth was studied in two randomized, vehicle-controlled, multicenter trials involving 697 patients. The co-primary endpoints were the proportion of subjects having at least a 4-point improvement from baseline in the weekly mean Axillary Sweating Daily Diary (ASDD) item #2 (a patient reported outcome instrument scored from 0 [no sweating] to 10 [worst possible sweating]) score at Week 4 and the mean absolute change from baseline in gravimetrically measured sweat production at Week 4. Both trials found that more patients in the glycopyrronium tosylate groups achieved the specified ASDD measure of response than in the vehicle groups; pooled response rates were 60 versus 28 percent. In the second trial, patients in the glycopyrronium tosylate group had a greater mean absolute change in sweat production compared with the vehicle group.(1)
Safety	Qbrexza is contraindicated in patients with medical conditions that can be exacerbated by the anticholinergic effect of Qbrexza (e.g., glaucoma, paralytic ileus, unstable cardiovascular status in acute hemorrhage, severe ulcerative colitis, toxic megacolon complicating ulcerative colitis, myasthenia gravis, Sjogren's syndrome).(1)

REFERENCES

Number	Reference
1	Qbrexza prescribing information. Journey Medical Corporation. November 2022.
2	Hornberger J, Grimes K, Naumann M, et al. Recognition, Diagnosis, and Treatment of Primary Focal Hyperhidrosis. J Am Acad Dermatol. 2004 Aug;51(2):274-286.
3	Diagnosis Guidelines. International Hyperhidrosis Society: Official Site. Available at: https://www.sweathelp.org/about-hyperhidrosis/diagnosis-guidelines.html.
4	Primary Focal Axillary Hyperhidrosis Clinical Guideline. International Hyperhidrosis Society: Official Site. Available at: https://www.sweathelp.org/treatments-hcp/clinical-guidelines/primary-focal-hyperhidrosis/primary-focal-axillary.html.
5	Defining Hyperhidrosis. International Hyperhidrosis Society: Official Site. Available at: https://www.sweathelp.org/home/defining-hyperhidrosis.html.
6	Two Types of Hyperhidrosis. International Hyperhidrosis Society: Official Site. Available at: https://www.sweathelp.org/home/types-of-hyperhidrosis.html.

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Qbrexza	Glycopyrronium Tosylate Pad 2.4% (Base Equivalent)	2.4 %	M ; N ; O ; Y	N		

POLICY AGENT SUMMARY QUANTITY LIMIT

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
Qbrexza	Glycopyrronium Tosylate Pad 2.4% (Base Equivalent)	2.4 %	30	Each	30	DAYS			

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Qbrexza	Glycopyrronium Tosylate Pad 2.4% (Base Equivalent)	2.4 %	FocusRx

CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Qbrexza	Glycopyrronium Tosylate Pad 2.4% (Base Equivalent)	2.4 %	FocusRx

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has a diagnosis of primary axillary hyperhidrosis defined by BOTH the following: A. Focal, visible, excessive sweating of at least 6 months duration without apparent cause **AND** B. TWO of the following characteristics: bilateral and relatively symmetric, impairs daily activities, frequency of at least one episode per week, age of onset less than 25 years, positive family history, cessation of focal sweating during sleep **AND** 2. ONE of the following: A. The patient has tried and had an inadequate response to 20% aluminum based topical antiperspirant (e.g., Drysol, OTC) **OR** B. The patient has an intolerance or hypersensitivity to 20% aluminum based topical antiperspirant **OR** C. The patient has an FDA labeled contraindication to 20% aluminum based topical antiperspirant **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that 20% aluminum based topical antiperspirant cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 3. If the patient has an FDA approved indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND**

Module	Clinical Criteria for Approval
	4. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 3 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. The patient has had clinical benefit with the requested agent **AND** 3. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL with PA	**Quantity Limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** 3. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** C. The prescriber has provided information in support of therapy with a higher dose for the requested indication **Length of Approval**: Initial: 3 months; Renewal: 12 months