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.

Program specific denial language for prerequisite step therapy component does not apply. Instead, supplemental program denial language will apply.

**FDA APPROVED INDICATIONS AND DOSAGE**

<table>
<thead>
<tr>
<th>Agent</th>
<th>Indication</th>
<th>Dosage &amp; Administration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Qbrexza™ (glycopyrronium) 2.4% cloth</td>
<td>Topical treatment of primary axillary hyperhidrosis in adults and pediatric patients 9 years of age and older</td>
<td>Apply once daily to both axillae using a single cloth</td>
</tr>
</tbody>
</table>

**CLINICAL RATIONALE**

Hyperhidrosis is defined as overactive sweating that can be up to four to five times more than necessary, causing embarrassment, discomfort, and anxiety. 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 medications or another medical condition.

Diagnosis of primary focal hyperhidrosis should be made only after excluding secondary causes of excessive sweating. The following are recommended diagnosis criteria for primary focal hyperhidrosis:

- 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. 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 are now available over-the-counter. Second line therapy includes botulinum toxin injection, topical glycopyrronium, and microwave thermolysis. 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.

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:

<table>
<thead>
<tr>
<th></th>
<th>Trial 1</th>
<th></th>
<th>Trial 2</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Qbrelza 2.4% N=229</td>
<td>Vehicle N=115</td>
<td>Qbrelza 2.4% N=234</td>
<td>Vehicle N=119</td>
</tr>
<tr>
<td><strong>ASDD Item #2 Response at Week 4:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Proportion of subjects with at least a 4-point improvement from baseline in the weekly mean ASDD item #2 at Week 4</td>
<td>53%</td>
<td>28%</td>
<td>66%</td>
<td>27%</td>
</tr>
<tr>
<td><strong>Change from Baseline in Sweat Production at Week 4 (mg/5 minutes):</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median</td>
<td>-81</td>
<td>-66</td>
<td>-79</td>
<td>-58</td>
</tr>
<tr>
<td>25th percentile, 75th percentile</td>
<td>-149, -40</td>
<td>-106, -28</td>
<td>-144, -45</td>
<td>-122, -21</td>
</tr>
</tbody>
</table>

**Safety**
Qbrelza has no black box warnings but is contraindicated in the following:
- Patients with medical conditions that can be exacerbated by the anticholinergic effect of Qbrelza (e.g., glaucoma, paralytic ileus, unstable cardiovascular status in acute hemorrhage, severe ulcerative colitis, toxic megacolon complicating ulcerative colitis, myasthenia gravis, Sjogren’s syndrome)

**REFERENCES**
Hyperhidrosis Prior Authorization with Quantity Limit

TARGET AGENT(S)
Qbrexza™ (glycopyrronium cloth)

<table>
<thead>
<tr>
<th>Brand (generic)</th>
<th>GPI</th>
<th>Multisource Code</th>
<th>Quantity Limit Per Day</th>
</tr>
</thead>
<tbody>
<tr>
<td>Qbrexza (glycopyrronium)</td>
<td>90970030204320</td>
<td>M, N, O, Y</td>
<td>1 cloth</td>
</tr>
</tbody>
</table>

PRIOR AUTHORIZATION WITH QUANTITY LIMIT CRITERIA FOR APPROVAL

Initial Evaluation

Target Agent(s) will be approved when ALL of the following are met:

1. The patient is 9 years of age or over

2. The patient has a diagnosis of primary axillary hyperhidrosis defined by the following:
   a. Focal, visible, excessive sweating of at least 6 months duration without apparent cause with at least TWO of the following characteristics:
      i. Bilateral and relatively symmetric
      ii. Impairs daily activities
      iii. Frequency of at least one episode per week
      iv. Age of onset less than 25 years
      v. Positive family history
      vi. Cessation of focal sweating during sleep

3. 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 a documented intolerance, FDA labeled contraindication, or hypersensitivity to 20% aluminum based topical antiperspirant

4. The patient does NOT have any FDA labeled contraindications to the requested agent

5. ONE of the following:
   a. The requested quantity (dose) does NOT exceed the program quantity limit
      OR
   b. ALL of the following:
      i. The requested quantity (dose) is greater than the program quantity limit
         AND
      ii. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose
         AND
      iii. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit
      OR
   c. ALL of the following:
      i. The requested quantity (dose) is greater than the program quantity limit
         AND
      ii. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication
         AND
iii. The prescriber has submitted information in support of therapy with a higher dose for the requested indication

**Length of Initial Approval:** 3 months

**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 for the requested agent **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 **AND**
4. ONE of the following:
   a. The requested quantity (dose) does NOT exceed the program quantity limit **OR**
   b. ALL of the following:
      i. The requested quantity (dose) is greater than the program quantity limit **AND**
      ii. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND**
      iii. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit **OR**
   c. ALL of the following:
      i. The requested quantity (dose) is greater than the program quantity limit **AND**
      ii. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication **AND**
      iii. The prescriber has submitted information in support of therapy with a higher dose for the requested indication

**Length of Renewal Approval:** 12 months
Step Therapy Supplement

This program applies to FlexRx Closed, FlexRx Open, GenRx Closed, GenRx Open, Health Insurance Marketplace, FocusRx and KeyRx formularies.

Please note, this does not include or apply to quantity limit questions.

STEP THERAPY SUPPLEMENT

OBJECTIVE

The intent of the Step Therapy Supplement is to provide additional questions, to ensure compliance to MN Statute 62Q.184. These questions will apply if the step therapy component within a Prior Authorization or Step Therapy program is not able to be approved.

CONDITIONS FOR APPROVAL

The requested agent will be approved when ONE of the following are met:

1. The patient is currently being treated with the requested agent as indicated by ALL of the following:
   a. A statement by the prescriber that the patient is currently taking the requested agent
      AND
   b. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent
      AND
   c. The prescriber states that a change in therapy is expected to be ineffective or cause harm

   OR

2. The patient’s medication history include the required prerequisite/preferred agent(s) as indicated by:
   a. Evidence of a paid claim(s) within the past 999 days
   OR
   b. The prescriber has stated that the patient has tried the required prerequisite/preferred agent(s) in the past 999 days AND the required prerequisite/preferred agent(s) was discontinued due to lack of effectiveness or an adverse event

   OR

3. The prescriber has provided documentation that the required prerequisite/preferred agent(s) 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

Length of Approval: As per program specific criteria