Anticholinergics, Topical

Goal(s):

- Promote coverage in evidence-supported conditions and in people with severe symptoms that interfere with daily activities.
- Allow case-by-case review for members covered under the EPSDT program.

Length of Authorization:

Up to 12 months

Requires PA:

- Topical anticholinergics (e.g., sofpironium, glycopyrronium)

Covered Alternatives:

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

Table 1. Topical anticholinergics approved by the FDA

Drug	Age	Indication
Glycopyrronium	≥ 9 years	Primary axillary hyperhidrosis
Sofpironium	≥ 9 years	Primary axillary hyperhidrosis

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code.	
2. Is the request for renewal of a product previously approved by FFS?	**Yes:** Go to **Renewal Criteria**	**No:** Go to #3
3. Is the diagnosis funded by OHP?	**Yes:** Go to #5	**No:** If not eligible for EPSDT review: Pass to RPh. Deny; not funded by the OHP If eligible for EPSDT review: Go to #4.
4. Is there documentation that the diagnosis detrimentally impacts at least one of the following? a. disability or health impairment (e.g., complications, comorbidities, etc) b. age-appropriate growth or development c. independence in self-care or activities of daily living d. ability to live and work in the setting of the patient's choice	**Yes:** Go to #5	**No:** Pass to RPh; Deny; medical necessity

Approval Criteria		
5. Is there documentation of severe symptoms which interfere with daily activities more than once per week as indicated by one of the following: • Hyperhidrosis Disease Severity Scale (HDSS) ≥ 3 • Hyperhidrosis Disease Severity Measure-Axillary (HDSM-Ax) ≥ 3 • Axillary Sweating Daily Diary – item 2 (sweating severity) ≥ 4 on a 0-10 point scale Note: these same assessments should be evaluated for continuation of treatment.	**Yes:** Go to #6	**No:** Pass to RPh. Deny; medical necessity
6. Is this an FDA approved age and indication (**Table 1**)? Note: secondary axillary hyperhidrosis related to comorbid conditions and non-axillary hyperhidrosis are not FDA-approved.	**Yes**: Go to #7	**No:** Pass to RPh. Deny; medical appropriateness
7. Is the requested product prescribed by, or in consultation with, a dermatologist?	**Yes:** Go to #8	**No:** Pass to RPh. Deny; medical appropriateness
8. Is there documentation indicating lack of adequate response with non-pharmacologic lifestyle management (e.g., trigger identification and avoidance, clothing modification, use of topical antiperspirants)?	**Yes**: Go to #9	**No:** Pass to RPh. Deny; medical appropriateness
9. Has the patient had lack of benefit, inadequate response, intolerance or contraindication to preferred therapy options for hyperhidrosis (e.g., botulinum toxins)?	**Yes**: Approve for 3 months	**No:** Pass to RPh. Deny; medical appropriateness

Renewal Criteria		
1. Is there documentation of symptom improvement from baseline as assessed by the prescribing provider? Note: the following are described as clinically relevant responses to therapy: • Total score ≤ 2 on the Hyperhidrosis Disease Severity Scale (HDSS) or Hyperhidrosis Disease Severity Measure-Axillary (HDSM-Ax) • ≥ 4 point improvement on the Axillary Sweating Daily Diary – item 2 (a 10 point scale assessing sweating severity)	**Yes**: Approve for 12 months	**No:** Pass to RPh. Deny; medical appropriateness

P&T/DUR Review: 4/25 (SS)
Implementation: 5/12/25