**Clinical Policy: Oxymetazoline (Upneeq)**

Reference Number: ERX.NPA.149  
Effective Date: 12.01.20  
Last Review Date: 11.20  
Line of Business: Commercial, Medicaid

See **Important Reminder** at the end of this policy for important regulatory and legal information.

**Description**

Oxymetazoline ophthalmic solution (Upneeq™) is an alpha-2 adrenergic receptor agonist.

**FDA Approved Indication(s)**

Upneeq is indicated for the treatment of acquired blepharoptosis in adults.

**Policy/Criteria**

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

*Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.*

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Upneeq is **medically necessary** when the following criteria are met:

**I. Initial Approval Criteria**

**A. Acquired Blepharoptosis (must meet all):**

1. Diagnosis of acquired blepharoptosis/ptosis (e.g., aponeurotic, neurologic ptosis);
2. Prescribed by or in consultation with an optometrist or ophthalmologist;
3. Age ≥ 13 years;
4. Member does not have congenital or mechanical ptosis;
5. Documentation of baseline visual peripheral field test (e.g., Leicester peripheral field test [LPFT]) demonstrating visual field loss;
6. Documentation of baseline marginal reflex distance 1 (MRD-1) ≤ 2 mm;
7. Dose does not exceed 1 carton (30 single use containers) per affected eye per month.

**Approval duration: 12 months**

**B. Other diagnoses/indications**

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

**II. Continued Therapy**

**A. Acquired Blepharoptosis (must meet all):**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. Member is responding positively to therapy as evidenced by, including but not limited to, improvement in visual peripheral field test (e.g., LPFT) or MRD-1;
3. Dose does not exceed 1 carton (30 single use containers) per affected eye per month.

**Approval duration: 12 months**

**B. Other diagnoses/indications (must meet 1 or 2):**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.

**Approval duration: Duration of request or 12 months (whichever is less); or**
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:
   A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information
   Appendix A: Abbreviation/Acronym Key
   FDA: Food and Drug Administration
   LPFT: Leicester peripheral field test
   MRD: marginal reflex distance

   Appendix B: Therapeutic Alternatives
   Not applicable

   Appendix C: Contraindications/Boxed Warnings
   None reported

   Appendix D: General Information
   • The Phase 3 clinical trials of Upneeq excluded patients with congenital ptosis and mechanical ptosis (e.g., ptosis due to excess weight on the upper lid possibly from infections, inflammation, and eyelid tumors).

V. Dosage and Administration

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<thead>
<tr>
<th>Indication</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
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</thead>
<tbody>
<tr>
<td>Blepharoptosis</td>
<td>Instill one drop into one or both ptotic eye(s) once daily.</td>
<td>One drop/eye/day</td>
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</tbody>
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VI. Product Availability
   Ophthalmic solution, 0.1%: 0.3 mL (carton of 15 or 30 single patient use containers)

VII. References

Reviews, Revisions, and Approvals

<table>
<thead>
<tr>
<th>Reviews, Revisions, and Approvals</th>
<th>Date</th>
<th>P&amp;T Approval Date</th>
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<tbody>
<tr>
<td>Policy created</td>
<td>08.25.20</td>
<td>11.20</td>
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Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional
medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.

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