Clinical Policy: Oxymetazoline (Upneeq)

Reference Number: ERX.NPA.149
Effective Date: 12.01.20
Last Review Date: 05.22
Line of Business: Commercial, Medicaid

Revision Log

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 congential 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

Indication	Dosing Regimen	Maximum Dose
Blepharoptosis	Instill one drop into one or both ptotic eye(s) once daily.	One drop/eye/day

VI. Product Availability

Ophthalmic solution, 0.1%: 0.3 mL (carton of 15 or 30 single patient use containers)

VII. References

1. Upneeq Prescribing Information. Bridgewater, NJ: RVL Pharmaceuticals, Inc.; May 2021. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/0212520s000lbl.pdf. Accessed January 13, 2022.
2. Slonim CB, Foster S, Jaros M, et al. Association of oxymetazoline hydrochloride, 0.1%, solution administration with visual field in acquired ptosis: a pooled analysis of 2 randomized clinical trials. JAMA Ophthalmol. 2020;138:1168–75.
3. Bacharach J, Lee WW, Harrison A, et al. A review of acquired blepharoptosis: prevalence, diagnosis, and current treatment options. Eye 2021. https://doi.org/10.1038/s41433-021-01547-5. Accessed January 13, 2022.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	08.25.20	11.20
4Q 2021 annual review: no significant changes; references reviewed and updated.	07.16.21	11.21
2Q 2022 annual review: no significant changes; references reviewed and updated.	01.13.22	05.22

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.