

## PRIOR AUTHORIZATION POLICY

- POLICY:** Ophthalmology – Upneeq Prior Authorization Policy
- Upneeq™ (oxymetazoline hydrochloride 0.1% ophthalmic solution – Osmotica/RVL Pharmaceuticals)

**REVIEW DATE:** 08/19/2020

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### OVERVIEW

Upneeq, an alpha-adrenergic agonist, is indicated for the treatment of acquired blepharoptosis in adults.<sup>1</sup>

### Disease Overview and Clinical Efficacy

Blepharoptosis, also known as ptosis, is an abnormal low-lying upper eyelid margin, which can decrease or even completely occlude vision.<sup>2</sup> Two vehicle-controlled pivotal studies were conducted; results are not published at this time.<sup>3,4</sup> The primary outcome of change in Leicester Peripheral Field Test (a measurement of superior peripheral vision) was assessed up to Day 14. Statistically significant, but numerically small, improvements vs. vehicle were noted. As a secondary endpoint, marginal reflex distance of the upper lid (MRD<sub>1</sub>) was assessed up to Day 42. The relative improvement in MRD<sub>1</sub> was statistically significant favoring Upneeq over vehicle, but the treatment difference vs. vehicle was small (approximately 0.5 mm). Both pivotal trials were 6 weeks in duration; long-term efficacy beyond 6 weeks has not been evaluated.

### Guidelines

Upneeq is not addressed in guidelines. The American Academy of Ophthalmology issued a report in 2011 detailing functional indications for upper eyelid ptosis and blepharoplasty surgery.<sup>5</sup> Ptosis and upper eyelid blepharoplasty surgery were found to be functionally beneficial under the following circumstances:

- MRD<sub>1</sub> ≤ 2 mm measured in primary gaze; or
- Superior visual field loss of 12 degrees or 24%; or
- Down-gaze ptosis impairing reading documented by MRD<sub>1</sub> ≤ 2 mm measured in down gaze; or
- Self-reported functional impairment from upper eyelid droop; or
- Chin-up backward head tilt induced by visual field impairment caused by lids; or
- Interference with occupational duties and safety resulting from visual impairment caused by the upper lids; or
- Symptoms of discomfort, eye strain, or visual interference due to upper eyelid position.

### POLICY STATEMENT

Due to insufficient clinical efficacy data, **approval is not recommended** for Upneeq.

**Automation:** None.

### RECOMMENDED AUTHORIZATION CRITERIA

None.

### CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Upneeq is not recommended in the following situations:

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1. **Blepharoptosis.** Due to insufficient clinical efficacy data, approval is not recommended for Upneeq.
2. **Conjunctivitis.** A lower strength of oxymetazoline solution (0.025%) has been evaluated for treatment of allergic and non-infectious conjunctivitis and was previously marketed over-the-counter under the name Visine® Long Lasting (no longer marketed). Oxymetazoline solution 0.1% has not been evaluated for conjunctivitis. Other over-the-counter alpha-adrenergic agonists are available as eye drops, including Visine® (tetrahydrolozine hydrochloride 0.05%) and Naphcon-A® (naphazoline hydrochloride 0.025%).
3. **Cosmetic uses.** Coverage of Upneeq for cosmetic uses (i.e., blepharoptosis when functional limitation is absent) is not recommended as cosmetic uses are excluded from coverage in a typical pharmacy benefit.
4. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

## REFERENCES

1. Upneeq™ ophthalmic solution [prescribing information]. Bridgewater, NJ: Osmotica/RVL Pharmaceuticals; July 2020.
2. Shahzad B, Siccardi MA. Ptosis. StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; updated January 1, 2020. Available at: <https://www.ncbi.nlm.nih.gov/books/NBK546705/>. Accessed on July 17, 2020.
3. Slonim C, Silverberg M, Butler B, et al. RVL-1201 ophthalmic solution improves the superior field of vision in subjects with upper eyelid ptosis. Presented at: 2017ARVO Annual Meeting; Baltimore, MD: May 7-11, 2017.
4. Data on file. Osmotica Pharmaceutical US, LLC; received July 2020.
5. Cahill KV, Bradley EA, Meyer DR, et al. Functional indications for upper eyelid ptosis and blepharoplasty surgery: a report by the American Academy of Ophthalmology. *Ophthalmology*. 2011;118(12):2510-2517.

## HISTORY

| Type of Revision | Summary of Changes | Review Date |
|------------------|--------------------|-------------|
| New Policy       | --                 | 08/19/2020  |