

## Pharmacy Policy Bulletin

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**Title:** Oxymetazoline (Upneeq™)

**Policy #:** Rx.01.240

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**Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, quantity, or formulary restrictions (ie limits on non-preferred drugs). Individual member benefits must be verified.**

**This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.**

**Members are advised to use participating pharmacies in order to receive the highest level of benefits.**

**Intent:**

The intent of this policy is to communicate the medical necessity criteria for **Oxymetazoline (Upneeq™)** as provided under the member's prescription drug benefit.

**Description:**

Blepharoptosis, or ptosis of the eyelid, refers to drooping of the upper eyelid that usually results from a congenital or acquired abnormality of the muscles that elevate the eyelid. Ptosis may be the presenting sign or symptom of serious neurologic disease. Depending on the degree of ptosis, presenting symptoms may range from an asymptomatic subtle cosmetic defect to significant visual deficits. Standard of care is surgery. While effective in improving visual function and quality-of-life measures, there are risks associated with surgical intervention. The Müller muscle, an accessory smooth muscle, maintains upper eyelid elevation and is innervated by the sympathetic nervous system. Therefore, the Müller muscle is a common surgical and pharmacological target.

Oxymetazoline is an alpha adrenoceptor agonist targeting a subset of adrenoceptors in Mueller's muscle of the eyelid. Oxymetazoline (Upneeq™) is indicated for the treatment of acquired blepharoptosis in adults.

Oxymetazoline (Upneeq™), when used solely to change the appearance of any portion of the face, without improving the physiologic functioning of that portion of the body, is considered cosmetic use.

**Policy:**

**INITIAL CRITERIA:** Oxymetazoline (Upneeq™) is approved when ALL of the following are met:

1. Diagnosis of acquired blepharoptosis; and
2. Request is not for an excluded benefit (i.e. cosmetic); and
3. Member has obstructed visual field in primary gaze or down gaze due to blepharoptosis; and
4. One of the following:
  - a. Marginal reflex distance-1 (MRD-1) is less than or equal to 2mm in primary gaze; or
  - b. Marginal reflex distance-1 (MRD-1) is less than or equal to 2mm in down gaze; or
  - c. Superior visual field loss of at least 12 degrees or 24 percent; and
5. Other treatable causes of blepharoptosis have been ruled out (e.g., recent botulinum toxin injection, myasthenia gravis); and
6. Prescribed by or in consultation with an ophthalmologist or optometrist

Initial authorization: 3 months

**REAUTHORIZATION CRITERIA:** Oxymetazoline (Upneeq™) is reapproved when BOTH of the following are met:

1. Documentation of positive clinical response to therapy (e.g., improvement in superior visual field, increase in Marginal reflex distance-1 [MRD-1]); and

2. One of the following:
  - a. Marginal reflex distance-1 (MRD-1) is less than or equal to 2mm in primary gaze; or
  - b. Marginal reflex distance-1 (MRD-1) is less than or equal to 2mm in down gaze; or
  - c. Superior visual field loss of at least 12 degrees or 24 percent

Reauthorization duration: 12 months

**Black Box Warning as shown in the drug Prescribing Information:**

N/A

**Guidelines:**

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

**BENEFIT APPLICATION**

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the prescription drug benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

**References:**

Upneeq™ (oxymetazoline hydrochloride ophthalmic solution) [prescribing information]. Bridgewater, NJ: RVL Pharmaceuticals, Inc; October 2020. Available from: <https://www.upneeq.com/Upneeq-PI.pdf>. Accessed February 23, 2021.

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 [published online ahead of print, 2020 Oct 1]. JAMA Ophthalmol. 2020;138(11):1168-1175. doi:10.1001/jamaophthalmol.2020.3812

Lee, MS. Overview of ptosis. UpToDate Web site. September 2018. www.uptodate.com. Accessed February 23, 2021.

**Applicable Drugs:**

Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

**Brand Name**

Upneeq™

**Generic Name**

Oxymetazoline hydrochloride

**Cross References:**

Rx.01.33 Off Label Use

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<b>Policy Version Number:</b>	1.00
<b>P&amp;T Approval Date:</b>	January 14, 2021
<b>Policy Effective Date:</b>	April 01, 2021
<b>Next Required Review Date:</b>	January 14, 2022

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The Policy Bulletins on this web site were developed to assist the Company in administering the provisions of the respective benefit programs, and do not constitute a contract. If you have coverage through the Company, please refer to your specific benefit program for the terms, conditions, limitations and exclusions of your coverage. Company does

not provide health care services, medical advice or treatment, or guarantee the outcome or results of any medical services/treatments. The facility and professional providers are responsible for providing medical advice and treatment. Facility and professional providers are independent contractors and are not employees or agents of the Company. If you have a specific medical condition, please consult with your doctor. The Company reserves the right at any time to change or update its Policy Bulletins.

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