Policy and Procedure	
PHARMACY PRIOR AUTHORIZATION POLICY AND CRITERIA ORPTCTOP033.0625	**TOPICAL PRODUCTS** **UPNEEQ®** (oxymetazoline 0.1% ophthalmic solution)
Effective Date: 8/1/2025	**Review/Revised Date**: 04/21, 05/22, 05/23, 05/24, 05/25 (JEF)
Original Effective Date: 02/21	**P&T Committee Meeting Date**: 12/20, 06/21, 06/22, 06/23, 06/24, 06/25
Approved by: Oregon Region Pharmacy and Therapeutics Committee	

SCOPE:
Providence Health Plan and Providence Health Assurance as applicable (referred to individually as "Company" and collectively as "Companies").

APPLIES TO:
Commercial
Medicaid

POLICY CRITERIA:

COVERED USES:
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

REQUIRED MEDICAL INFORMATION:
For initial authorization all the following criteria must be met:
1. Documentation of acquired blepharoptosis,
2. Documentation of a superior visual field deficit [such as inability to detect at least 8 of 17 points in the top two rows on the Leicester Peripheral Field Test (LPFT)],
3. Marginal reflex distance 1 (MRD-1) of less than or equal to 2 mm.

Reauthorization requires documentation of improvement in visual field deficit

EXCLUSION CRITERIA:
- Congenital ptosis
- Horner syndrome
- Myasthenia gravis
- Mechanical ptosis
- Visual field loss from any cause other than ptosis

AGE RESTRICTIONS: N/A

PRESCRIBER RESTRICTIONS:
Must be prescribed by, or in consultation with, an ophthalmologist

PHARMACY PRIOR AUTHORIZATION POLICY AND CRITERIA ORPTCTOP033	TOPICAL PRODUCTS UPNEEQ® (oxymetazoline 0.1% ophthalmic solution)

COVERAGE DURATION:
Initial authorization will be approved for six months. Reauthorization will be approved for twelve months.

QUANTITY LIMIT:
Two dropperettes per day

Requests for indications that were approved by the FDA within the previous six (6) months may not have been reviewed by the health plan for safety and effectiveness and inclusion on this policy document. These requests will be reviewed using the New Drug and or Indication Awaiting P&T Review; Prior Authorization Request ORPTCOPS047.

Requests for a non-FDA approved (off-label) indication requires the proposed indication be listed in either the American Hospital Formulary System (AHFS), Drugdex, or the National Comprehensive Cancer Network (NCCN) and is considered subject to evaluation of the prescriber's medical rationale, formulary alternatives, the available published evidence-based research and whether the proposed use is determined to be experimental/investigational.

Coverage for Medicaid is limited to a condition that has been designated a covered line item number by the Oregon Health Services Commission listed on the Prioritized List of Health Care Services.

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case.

INTRODUCTION:
Oxymetazoline is an alpha adrenoceptor agonist that targets a subset of adrenoreceptors in Mueller's muscle of the eyelid. The dosage is one drop daily into the affected eye; each single-use vial can be used to dose both eyes and should be discarded after.

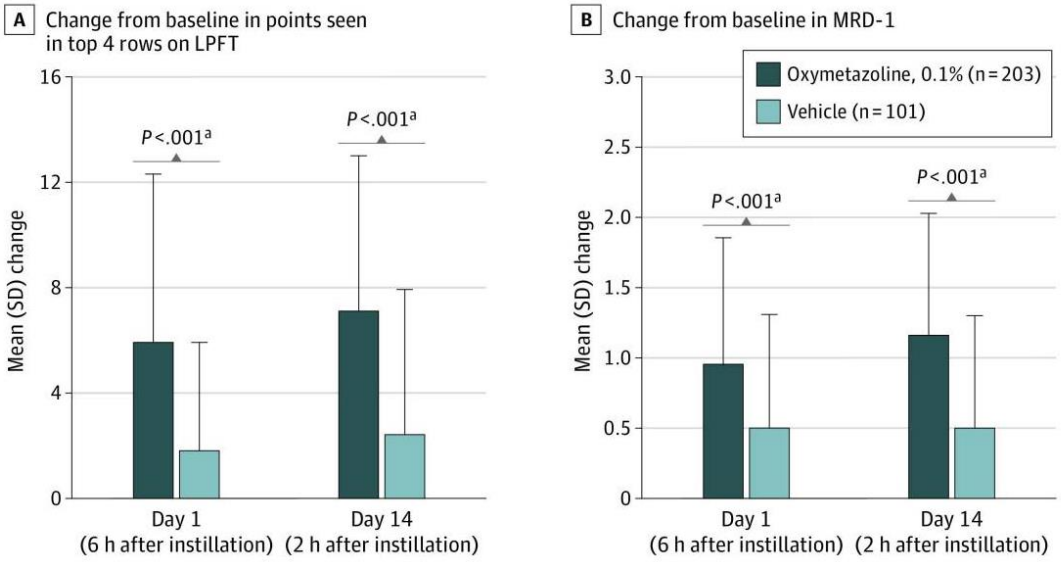
FDA APPROVED INDICATIONS:
Treatment of acquired blepharoptosis in adults

POSITION STATEMENT:
Diseases State info

- Blepharoptosis refers to drooping of the upper lid, which can be a congenital for acquired condition. Acquired conditions may be related to disorders affecting the muscle tendon, muscle, neuromuscular junction, or nerve
- This condition may result in visual field loss
- Surgery is indicated for patients with visual field loss

Clinical Evidence
Slonim et al. (PubMed ID #33001144)

- Pooled analysis of 2 R, PC, double-masked clinical trials
- Study Duration: Patients self-administered for 42 days, but primary efficacy endpoint was analyzed on day 14
- Patient population: Patients (N= 304) aged nine years or older with acquired ptosis and a superior visual field deficit in at least one eye at screening (3-7 days before treatment day one) and baseline (treatment day one).
    - Key exclusion criteria: Congenital ptosis, Horner syndrome, myasthenia gravis, mechanical ptosis, or visual field loss from any cause other than ptosis. Participants with pseudoptosis or substantial dermatochalasis (redundant eyelid skin occurring within 3 mm of the upper eyelid margin) in the study eye were also excluded.
- Intervention: Randomized 2:1 to receive oxymetazoline, 0.1%, or vehicle, self-administered as a single drop per eye, once daily, for 42 days.
- Primary endpoint: Change from baseline in the number of points seen on the Leicester Peripheral Field Test (LPFT), a test to detect superior visual field deficits due to ptosis, on days one (six hours after instillation) and 14 (two hours after instillation).
- Results: Baseline characteristics similar across groups
    - Efficacy: At baseline, mean points seen on LPFT were similar between groups. Treatment with oxymetazoline showed a statistically significant improvement in number of points seen on LPFT



    - Safety: A similar number of patients experienced adverse events in the treatment group (63, 31%) vs placebo (36, 35.6%)

    - Two participants (1.0%) receiving oxymetazoline [0.1% reported serious TEAEs (hyperparathyroidism; cerebrovascular accident)], and 1 participant (1.0%) receiving vehicle had a serious TEAE (lower gastrointestinal hemorrhage). No serious TEAE was suspected of being treatment related, and all were resolved.
- GRADE evidence rating: C
    - Strengths: Study completion rates and treatment compliance was high
    - Limitations: small study size, pooled analysis, placebo-controlled, surrogate endpoint (LPFT), short study duration

REFERENCE/RESOURCES:

1. Upneeq. Bridgewater, NJ: RVL Pharmaceuticals; 2024 May.
2. oxymetazoline In: DRUGDEX® System [Internet database]. Greenwood Village, Colo: Thomson Reuters (Healthcare) Inc. Updated periodically. Accessed May 08, 2024.
3. oxymetazoline In: Lexi-Drugs Online [Internet database]. Hudson, OH: Lexi-Comp, Inc. Updated periodically. Accessed May 08, 2024.
4. Farber SE, Codner MA. Evaluation and management of acquired ptosis. Plast Aesthet Res 2020;7:20.
5. Slonim, C. B., Foster, S., Jaros, M., Kannarr, S. R., Korenfeld, M. S., Smyth-Medina, R., & Wirta, D. L. (2020). Association of Oxymetazoline Hydrochloride, 0.1%, Solution Administration With Visual Field in Acquired Ptosis: A Pooled Analysis of 2 Randomized Clinical Trials. JAMA ophthalmology, e203812. Advance online publication. https://doi.org/10.1001/jamaophthalmol.2020.3812