

Market Applicability						
Market	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X

Upneeq (oxymetazoline ophthalmic solution)

Override(s)	Approval Duration
Prior Authorization	Initial Approval Duration: 3 months
Quantity Limit	Continuation Approval Duration: 1 year

Medications	Quantity Limit
Upneeq (oxymetazoline ophthalmic solution)	May be subject to quantity limit

APPROVAL CRITERIA

Initial requests for Upneeq (oxymetazoline ophthalmic solution) may be approved if the following criteria are met:

- I. Individual has a diagnosis of acquired blepharoptosis; **AND**
- II. Individual has a loss of visual field confirmed by (NCT 02436759):
 - A. Loss of 8 or more points on the top two rows of a Leicester Peripheral Field Test (LPFT); **AND**
 - B. Marginal reflex distance 1 (MRD1; the distance from the central pupillary light reflex to the central margin of the upper lid) of less than or equal to 2 mm.

Continuation requests for Upneeq (oxymetazoline ophthalmic solution) may be approved if the following criterion is met (NCT 02436759, NCT 03565887):

- I. There is documentation of clinically significant improvement in visual field on the Leicester Peripheral Field Test (LPFT) or on marginal reflex distance 1 (MRD1).

Upneeq (oxymetazoline ophthalmic solution) may not be approved for the following (NCT 02436759, NCT 03565887):

- I. Blepharoptosis that is cosmetic and does not impair the visual field; **OR**
- II. Congenital blepharoptosis; **OR**
- III. Horner syndrome; **OR**
- IV. Myasthenia gravis; **OR**
- V. Mechanical blepharoptosis (including blepharoptosis due to orbital or lid tumor).

Key References:

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New Program Date 09/18/2020

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: July 13, 2020.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Ho SF, Morawski A, Sampath R, et. al. Modified visual field test for ptosis surgery (Leicester Peripheral Field Test). *Eye (Lond)*. 2011;25(3):365-369.
4. Lee MS. Overview of ptosis. Last updated: September 18, 2018. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed: July 13, 2020.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.
6. RVL Pharmaceuticals, Inc. Study of Safety and Efficacy of RVL-1201 in the Treatment of Blepharoptosis. NLM Identifier: NCT 03565887. Last updated: May 4, 2020. Available at: <https://clinicaltrials.gov/ct2/show/NCT03565887?term=RVL1201&draw=2&rank=3>. Accessed: July 13, 2020.
7. RVL Pharmaceuticals, Inc. Study of the Safety and Efficacy of RVL-1201 in the Treatment of Acquired Blepharoptosis. NLM Identifier: NCT 02436759. Last updated: December 7, 2016. Available at: <https://clinicaltrials.gov/ct2/show/NCT02436759?term=RVL1201&draw=2&rank=2>. Accessed: July 13, 2020.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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