Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 11/01/2020**
Policy Number: PA.CP.PMN.86	**Effective Date: 01/2020** **Revision Date: 10/2020**
Policy Name: Oxymetazoline (Rhofade, Upneeq)	

Type of Submission – Check all that apply:

- ☐ **New Policy**
- ✓ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ☐ **Statewide PDL** - *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

Added Upneeq to policy with new criteria for blepharoptosis.

Name of Authorized Individual (Please type or print): **Auren Weinberg, MD**	**Signature of Authorized Individual:** 

CLINICAL POLICY
Oxymetazoline

Clinical Policy: Oxymetazoline (Rhofade, Upneeq)

Reference Number: PA.CP.PMN.86
Effective Date: 4.17.19
Last Review Date: 11.20

Revision Log

Description
Oxymetazoline (Rhofade™) is a topical alpha-1a adrenoreceptor agonist.

Oxymetazoline ophthalmic solution (Upneeq™) is an alpha-2 adrenergic receptor agonist.

FDA Approved Indication(s)
Rhofade is indicated for the topical treatment of persistent facial erythema associated with rosacea in adults.

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.

It is the policy of health plans affiliated with PA Health & Wellness® that Rhofade is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Facial Erythema Associated with Rosacea (must meet all)**:**
1. Diagnosis of persistent facial erythema associated with rosacea;
2. Request is for Rhofade;
3. Age ≥ 18 years;
4. If papules or pustules are present, a failure of or concomitant treatment with any of the following agents, unless clinically significant adverse effects are experienced or all are contraindicated: topical metronidazole, oral doxycycline or Finacea;
5. Dose does not exceed 30 mg (1 tube) per month.

Approval duration: 12 months

B. Acquired Blepharoptosis (must meet all)**:**
1. Diagnosis of acquired blepharoptosis/ptosis (e.g., aponeurotic, neurologic ptosis);
2. Request is for Upneeq;
3. Prescribed by or in consultation with an optometrist or ophthalmologist;
4. Age ≥ 13 years;
5. Member does not have congenital or mechanical ptosis;
6. Documentation of baseline visual peripheral field test (e.g., Leicester peripheral field test [LPFT]) demonstrating visual field loss;
7. Documentation of baseline marginal reflex distance 1 (MRD-1) ≤ 2 mm;
8. Dose does not exceed 1 carton (30 single use containers) per affected eye per month.

Approval duration: 12 months

C. Other diagnoses/indications:

Commented [NVB1]: Consider adding requirement for MRD-1 ≤ 2 mm
- It was required in both pivotal trials
- MRD-1 is an objective measure to identify and measure severity of ptosis – per 2020 AAO oculofacial plastic and orbital surgery textbook, "MRD-1 is the single most important measurement in describing the amount of ptosis"
- The LPFT study in your references notes "We have defined ptosis as MRD of 2 mm or less"
- When LPFT is reported, is it reported by eye? I couldn't figure that out. If it's not, having MRD-1 would be useful because that is reported for each eye so we'd know how many eyes are affected
- We would have a baseline to compare to for the positive response reqt

I realize that if they have visual field loss, it probably shouldn't matter what MRD-1 is. But I'm thinking it's easier to be more strict now, then we can always be more lenient later. At the least, maybe we could show the policy to the specialists with this reqt in and see if they flag it as inappropriate.

Commented [NMN2R1]: I initially didn't include MRD-1 because it's somewhat of a surrogate measure, but it's probably doesn't hurt to include since guideline and trial would support it. Based on the machine used to perform the LPFT (humphrey visual field analyzer), I believe it is performed on each eye

Commented [NMN3]: Per PI, despite trial allowing patients down to 9 years

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Facial Erythema Associated with Rosacea (must meet all)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Request is for Rhofade;
3. Member is responding positively to therapy;
4. If request is for a dose increase, new dose does not exceed 30 mg (1 tube) per month.

Approval duration: 12 months

B. Acquired Blepharoptosis (must meet all)**:**

5. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
1. Reqeust is for Upneeq;
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

C. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53 for Medicaid.

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 – PA.CP.PMN.53 for Medicaid 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

Commented [NMN4]: Asking specialist what is considered clinically significant and if appropriate to require for continued authorization

Commented [NVB5R4]: I agree with including specific reqts for LPFT/MRD for continued auth – if specialists support it and we keep it, not sure we should allow length of benefit auth for commercial since we'd want to check on these measures

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
metronidazole (Metrocream® 0.75%, Metrogel® 1%, Metrolotion® 0.75%)	**Rosacea** Apply thin film topically to affected area QD for 1% and BID for 0.75%	No maximum dosage information is available
Finacea® (15% gel) (azelaic acid)	**Rosacea** Apply in a thin film topically to the affected area BID Reassess if no improvement in 12 weeks.	No maximum dosage information is available
doxycycline (Oracea)®	**Rosacea** Lesions (papules and pustules): 40 mg PO once daily in the morning (1 hour before or 2 hours after a meal)	300 mg/day; 40 mg/day for Oracea

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- None reported

Appending D: General Information

- Tetracycline agents, including doxycycline and minocycline exhibit anti-inflammatory activities at doses < 50 mg. Anti-inflammatory dose doxycycline does not exert antibiotic selection pressure and thus does not induce antibiotic resistance; its mechanism of action in rosacea appears to relate to the anti-inflammatory and biological activities of doxycycline.
- 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

Drug Name	Indication	Dosing Regimen	Maximum Dose
Oxymetazoline cream (Rhofade)	Facial erythema associated with rosacea	Apply a pea-size amount topically QD to each of the five areas of the face (forehead, chin, nose, each cheek) avoiding the eyes and lips.	One application/day
Oxymetazoline ophthalmic solution (Upneeq)	Blepharoptosis	Instill one drop into one or both ptotic eye(s) once daily.	One drop/eye/day

VI. Product Availability

Drug Name	Availability
Oxymetazoline cream (Rhofade)	Cream (30 gm tube): 1%
Oxymetazoline ophthalmic solution (Upneeq)	Ophthalmic solution, 0.1%: 0.3 mL (carton of 15 or 30 single patient use containers)

VII. References

1. Rhofade Prescribing Information. Irvine, CA: Allergan; January 2017. Available at: www.rhofade.com. Accessed Accessed February 7, 2020.
2. Micromedex® Healthcare Series [database online]. Greenwood Village, Colorado: Thomson Healthcare. Updated periodically. Accessed February 7, 2020.
3. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2016. Available at: http://www.clinicalpharmacology-ip.com. Accessed February 7, 2020.
4. National Rosacea Society. Rosacea treatment algorithms. Available at: https://www.rosacea.org/physicians/treatmentalgorithms. Accessed February 7, 2020.
5. Schaller M, et al. Rosacea treatment update: Recommendations from the global ROSacea Consensus (ROSCO) panel. Br J Dermatol 2016. Epub ahead of print. doi: 10.1111/bjd.15173.
6. Schaller M, Almeida LMC, Bewley A, et al. Recommendations for rosacea diagnosis, classification and management: update from the global ROSacea COnsensus 2019 (ROSCO) panel. Br J Dermatol 2019. Epub ahead of print. doi: 10.1111/bjd.18420.
7. Upneeq Prescribing Information. Bridgewater, NJ: RVL Pharmaceuticals, Inc.; July 2020. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/0212520s000lbl.pdf. Accessed July 27, 2020.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	04.17.19	
2Q 2020 annual review: references reviewed and updated	04/2020	
Added Upneeq to policy with new criteria for blepharoptosis.	07/2020	11/2020