

Clinical Policy: Oxymetazoline (Rhofade, Upneeq)

Reference Number: CP.PMN.86

Effective Date: 11.16.16

Last Review Date: 11.20

Line of Business: Commercial, HIM*, Medicaid

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

Oxymetazoline cream (Rhofade™) is an alpha-1a adrenoreceptor agonist.

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

**For Health Insurance Marketplace (HIM), if request is through pharmacy benefit, Rhofade is non-formulary and should not be approved using these criteria; refer to the formulary exception policy, HIM.PA.103.*

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 Centene Corporation[®] that Rhofade and Upneeq are **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:**Medicaid** – 12 months**HIM** – refer to HIM.PA.103**Commercial** – Length of Benefit**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) \leq 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:

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): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

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

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
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:

Medicaid – 12 months

Commercial – Length of Benefit

B. Acquired Blepharoptosis (must meet all):

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Request is for Upneeq;
3. 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;
4. 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 Centene benefit and documentation supports positive response to therapy.

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): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and 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 policies –

CP.CPA.09 for commercial for commercial, HIM.PHAR.21 for health insurance marketplace, and 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

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%, Metro lotion [®] 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

Appendix 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 congenital 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 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
2Q 2019 annual review: policy split from CP.PMN.86 Brimonidine (Mirvaso), Oxymetazoline (Rhofade) into individual drug policies; added age limit; references reviewed and updated.	02.05.19	05.19
2Q 2020 annual review: no significant changes; references reviewed and updated	02.07.20	05.20

Reviews, Revisions, and Approvals	Date	P&T Approval Date
RT2: added Upneeq to policy with new criteria set for blepharoptosis; added HIM line of business.	07.27.20	11.20

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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Note:

For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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