Prior Authorization Review Panel

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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: 05/01/2021**
Policy Number: PA.CP.PMN.192	**Effective Date: 04/2019** **Revision Date: 04/2021**
Policy Name: Brimonidine Tartrate (Mirvaso)	

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:

2Q 2021 annual review: added ivermectin 1% cream as an option for failure; references reviewed and updated.

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

Clinical Policy: Brimonidine Tartrate (Mirvaso)

Reference Number: PA.CP.PMN.192
Effective Date: 4.17.19
Last Review Date: 04/2021

Revision Log

Description
Brimonidine Tartrate (Mirvaso®) is an alpha-2 adrenergic agonist topical gel. It may reduce erythema through direct vasoconstriction.

FDA Approved Indication(s)
Mirvaso is indicated for the topical treatment of persistent (nontransient) facial erythema of rosacea in adults 18 years of age or older.

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 Mirvaso 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. Age ≥ 18 years;
3. If papules or pustules are present, 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, ivermectin cream, Finacea;
4. Dose does not exceed 30 mg (1 tube) per month.

Approval duration: 12 Months

B. 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): 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. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 30 mg (1 tube) per month.

Approval duration: 12 Months

B. 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

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%, Metrolotion® 0.75%)	Apply thin film topically to affected area QD for 1% and BID for 0.75%	No maximum dosage information is available.
azelaic acid 15% gel (Finacea®)	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)®	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
ivermectin cream 1% (Soolantra®)	Apply a pea-size amount to the affected areas of the face (forehead, chin, nose, each cheek) once daily. Spread as a thin layer, avoiding the eyes and lips.	4 oz/topical application

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

- Contraindication(s): hypersensitivity
- Boxed warning(s): 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.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
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

VI. Product Availability

Gel (30 gm tube or pump): 0.33%

VII. References

1. Mirvaso Prescribing Information. Fort Worth, TX: Galderma Laboratories; November 2016. Available at: www.fda.gov. Accessed January 22, 2021.
2. Thiboutot D, Anderson R, Cook-Bolden F, et al. Standard management options for rosacea: the 2019 update by the National Rosacea Society expert committee. *J Am Acad Dermatol*. 2020; 82(6): 1501-1510. doi: 10.1016/j.jaad.2020.01.077.
3. Shaller M, Almeida LMC, Bewley A, et al. Recommendations for rosacea diagnosis, classification and management: update from the global ROSacea COnsensus 2019 panel. *Br J Dermatol*. 2020; 182:1090-1091. doi: 10.1111/bjd.18420

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created. 2Q 2019 annual review: policy split from PA.CP.PMN.86 Brimonidine (Mirvaso), Oxymetazoline (Rhofade) into individual drug policies; added age limit; references reviewed and updated.	04.17.19	
2Q 2020 annual review: references reviewed and updated.	04/2020	
2Q 2021 annual review: added ivermectin 1% cream as an option for failure; references reviewed and updated.	04/2021	