BlueCross BlueShield of Arizona
An Independent Licensee of the Blue Cross and Blue Shield Association

PHARMACY COVERAGE GUIDELINES	
SECTION: DRUGS	
ORIGINAL EFFECTIVE DATE:	**11/17/16**
LAST REVIEW DATE:	**11/16/17**
LAST CRITERIA REVISION DATE:	**11/16/17**
ARCHIVE DATE:	

MIRVASO® (brimonidine tartrate) external gel

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. All requested data must be provided. Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

MIRVASO® (brimonidine tartrate) external gel (cont.)

Description:

Mirvaso (brimonidine) topical gel is indicated for the topical treatment of moderate to severe persistent (non-transient) facial erythema of rosacea in adults.

Brimonidine is a relatively selective alpha-2 adrenergic agonist, topical application of the gel may reduce erythema through direct vasoconstriction.

Rosacea:

- Rosacea is a chronic facial dermatologic disorder that is characterized by intermittent periods of exacerbation and remission
  - The condition primarily affects the center of the face including the cheeks, nose, chin and central forehead
  - Ocular manifestations may also be present

- Clinical signs of rosacea include central facial erythema, coarseness of the skin, inflammatory lesions (papules and pustules) resembling acne, and telangiectasias
  - Rosacea is distinguished from acne vulgaris by the absence of comedones and by its confinement to flush areas

- The underlying cause of rosacea is unknown
  - Major pathogenic components appear to include chronic inflammatory, vascular changes, hormonal, and neural processes

- There are 4 subtypes of rosacea:
  - Erythematotelangiectatic
  - Papulopustular
  - Phymatous
  - Ocular

- The most common clinical presentations of rosacea include erythematotelangiectatic and the inflammatory (papulopustular) subtypes
  - Features of both subtypes are primarily localized on the central face
  - Persistent facial redness, recurrent facial flushing, telangiectasias, skin dryness and sensitivity are common features of erythematotelangiectatic rosacea
  - Lesions of papulopustular rosacea closely resemble inflammatory acne

- The less common phymatous form of rosacea may demonstrate marked skin thickening and distortion of facial contours, there may be severe disfigurement as a result
  - Other areas such as the chin, cheeks, and ears may also be affected

- Ocular rosacea is not uncommon in patients with cutaneous rosacea
  - Clinical presentations of ocular rosacea include conjunctivitis, blepharitis, stye formation and keratitis

MIRVASO® (brimonidine tartrate) external gel (cont.)

- Facial redness is a common cutaneous finding that may occur as a normal feature or as a consequence of cutaneous or systemic disorders
    - Examples of conditions that may lead to facial redness include inflammatory skin disease, photosensitive disorders, autoimmune disorders, vascular reactions, and infections

- Treatment:
    - Topical metronidazole is effective for the treatment of inflammatory papules and pustules, but may also contribute to improvement in facial erythema
    - Similar to metronidazole, azelaic acid improves papular and pustular lesions, and may also reduce erythema
    - The efficacy of sulfacetamide-sulfur are limited, but a vehicle-controlled trial and an open-label study reported benefit of this agent for inflammatory lesions and erythema
    - Topical application of alpha agonists (brimonidine and oxymetazoline) have shown efficacy for persistent facial erythema in rosacea
    - Oral tetracyclines are useful for improving inflammatory papules and pustules and may reduce erythema

Rosacea subtypes and variants and their characteristics	
Sub-type	**Characteristics**
Erythematotelangiectatic	Flushing and persistent central facial erythema with or without telangiectasia
Papulopustular	Persistent central facial erythema with transient, central facial papules or pustules or both, may resemble acne vulgaris but it is without comedones, facial edema may be present
Phymatous	Thickening skin, irregular surface nodules may occur on the nose, chin, forehead, cheeks, or ears, rhinophyma is present
Ocular	Foreign body sensation in the eye, burning or stinging, dryness, itching, ocular photosensitivity, blurred vision, telangiectasia of the sclera or other parts of the eye, or periorbital edema
Variants	
Granulomatous	Non-inflammatory; hard; brown, yellow, or red cutaneous papules; or nodules of uniform size
Rosacea fulminans	Sudden appearance of papules, pustules, and nodules, along with fluctuating and draining sinuses that may be interconnecting

MIRVASO® (brimonidine tartrate) external gel (cont.)

Mirvaso (brimonidine tartrate) topical

Medication class:
Alpha-2 adrenergic agonist

FDA-approved indication(s):
- Topical treatment of persistent (nontransient) erythema of rosacea in adults 18 years and older

Recommended Dose:
- Apply a pea-size amount once daily as a thin layer across the entire face covering the central forehead, chin, nose, and each cheek while avoiding the eyes and lips

Maximum dosage
- Not stated

Available Dosage Forms:
- 0.33% gel as 30 g tube or 30 g pump bottle

Warnings and Precautions:
- Avoid application to irritated skin or to open wounds
- Avoid use following any laser procedure
- Woman who is breast feeding an infant or child should stop breast feeding
- It is not indicated for phymatous rosacea, ocular rosacea, granulomatous rosacea, or rosacea fulminans
- Use of combined topical alpha agonists (topical brimonidine and topical oxymetazoline) has not been studied

Criteria:

- **Criteria for initial therapy:** Mirvaso (brimonidine tartrate) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Individual is 18 years of age or older

  2. A confirmed diagnosis of moderate to severe persistent (non-transient) facial erythema of rosacea

  3. Individual has failure, contraindication or intolerance to use **two** of the following:
     - topical azeleic acid 15%
     - topical metronidazole 0.75% or 1%
     - topical sodium sulfacetamide/sulfur generic 10%/5%

  4. There are **NO** contraindications:
     - Contraindications include:
       - Known hypersensitivity to any component of Mirvaso topical gel

  Initial approval duration: 6 months

MIRVASO® (brimonidine tartrate) external gel (cont.)

- **Criteria for continuation of coverage (renewal request):** Mirvaso (brimonidine tartrate) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

1. Individual's condition responded while on therapy
    - Response is defined as:
        - Facial erythema improved over baseline from moderate-severe to mild
            - Described as **any** of the following:
                - No redness, very mild redness, or mild redness
                - Clear skin with no erythema, almost clear with slight erythema, or mild erythema with definite redness

2. Individual has been adherent with the medication

3. Individual has not developed any contraindications or other significant level 4 adverse drug effects that may exclude continued use
    - Contraindications as listed in the criteria for initial therapy section

Renewal duration: 12 months

Resources:

Mirvaso. Package Insert. Revised by manufacturer 7/2016. Accessed 9/16/16.

Wilkin J, Dahl M, Detmar M, et al.: Standard classification of rosacea: Report of the National Rosaceas Society Expert Committee on the Classification and staging of Rosacea. J Am Acad Dermatol 2002; 46 (4):584-587

UpToDate: Rosacea: Pathogenesis, clinical feature, and diagnosis. Current through Sep 2017. https://www-uptodate-com.mwu.idm.oclc.org/contents/rosacea-pathogenesis-clinical-features-and-diagnosis?source=search_result&search=erythema%20of%20rosacea&selectedTitle=2~150

UpToDate: Management of rosacea. Current through Sep 2017. https://www-uptodate-com.mwu.idm.oclc.org/contents/management-of-rosacea?source=search_result&search=erythema%20of%20rosacea&selectedTitle=1~150

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Fax completed prior authorization request form to 602-864-3126 or email to pharmacyprecert@azblue.com.
Call 866-325-1794 to check the status of a request.
All requested data must be provided. **Incomplete forms or forms without the chart notes will be returned.**
Pharmacy Coverage Guidelines are available at www.azblue.com/pharmacy.

Pharmacy Prior Authorization Request Form

Do not copy for future use. Forms are updated frequently.
REQUIRED: Office notes, labs, and medical testing relevant to the request that show medical justification are required.

Member Information

Member Name (first & last):	Date of Birth:	Gender:	BCBSAZ ID#:
Address:	City:	State:	Zip Code:

Prescribing Provider Information

Provider Name (first & last):	Specialty:	NPI#:	DEA#:
Office Address:	City:	State:	Zip Code:
Office Contact:	Office Phone:	Office Fax:	

Dispensing Pharmacy Information

Pharmacy Name:	Pharmacy Phone:	Pharmacy Fax:

Requested Medication Information

Medication Name:	Strength:		Dosage Form:
Directions for Use:	Quantity:	Refills:	Duration of Therapy/Use:

☐ Check if requesting **brand** only ☐ Check if requesting **generic**

☐ Check if requesting continuation of therapy (prior authorization approved by BCBSAZ expired)

Turn-Around Time For Review

☐ Standard ☐ Urgent. Sign here: _____ ☐ Exigent (requires prescriber to include a written statement)

Clinical Information

1. **What is the diagnosis? Please specify below.**

   ICD-10 Code: _____ **Diagnosis Description:** _____

2. ☐ Yes ☐ No **Was this medication started on a recent hospital discharge or emergency room visit?**

3. ☐ Yes ☐ No **There is absence of ALL contraindications.**

4. **What medication(s) has the individual tried and failed for this diagnosis? Please specify below.**
Important note: Samples provided by the provider are not accepted as continuation of therapy or as an adequate trial and failure.

Medication Name, Strength, Frequency	Dates started and stopped or Approximate Duration	Describe response, reason for failure, or allergy

5. **Are there any supporting labs or test results? Please specify below.**

Date	Test	Value

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Pharmacy Prior Authorization Request Form

6. Is there any additional information the prescribing provider feels is important to this review? Please specify below.
For example, explain the negative impact on medical condition, safety issue, reason formulary agent is not suitable to a specific medical condition, expected adverse clinical outcome from use of formulary agent, or reason different dosage form or dose is needed.

Signature affirms that information given on this form is true and accurate and reflects office notes

Prescribing Provider's Signature: Date:

Please note: Some medications may require completion of a drug-specific request form.

Incomplete forms or forms without the chart notes will be returned.

Office notes, labs, and medical testing relevant to the request that show medical justification are required.