



An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINES  
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 11/17/2016  
LAST REVIEW DATE: 11/18/2021  
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## MIRVASO® (brimonidine tartrate) external gel

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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.

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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](http://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](mailto:Pharmacyprecert@azblue.com). **Incomplete forms or forms without the chart notes will be returned.**

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### 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. Prescriber is a physician specializing in the patient's diagnosis or is in consultation with a Dermatologist
2. Individual is 18 years of age or older
3. A confirmed diagnosis of moderate to severe persistent (non-transient) facial erythema of rosacea
4. Individual has failure, contraindication per FDA label or intolerance to use **two** of the following:
  - a. Topical azelaic acid 15%
  - b. Topical metronidazole 0.75% or 1%
  - c. Topical sodium sulfacetamide/sulfur generic 10%/5%

**Initial approval duration:** 6 months

- **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 continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with a Dermatologist
2. Individual's condition responded while on therapy
  - a. Response is defined as:
    - i. Facial erythema improved over baseline from moderate-severe to mild
      1. Described as **BOTH** of the following:
        - a. Patient self-assessment, **ONE** of the following:
          - i. No redness
          - ii. Very mild redness
          - iii. Mild redness
        - b. Clinical Erythema Assessment, **ONE** of the following:
          - i. Clear skin with no erythema
          - ii. Almost clear with slight erythema
          - iii. Mild erythema with definite redness
3. Individual has been adherent with the medication

**Renewal duration:** 12 months

- Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

1. **Off-Label Use of a Non-cancer Medications**

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### 2. Off-Label Use of a Cancer Medication for the Treatment of Cancer without a Specific Coverage Guideline

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#### **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

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- Clinical presentations of ocular rosacea include conjunctivitis, blepharitis, stye formation and keratitis
- 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

<b>Rosacea subtypes and variants and their characteristics</b>	
<b>Sub-type</b>	<b>Characteristics</b>
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
<b>Variants</b>	
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



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Score	Clinical Erythema Assessment (CEA)	Patient Self-Assessment (PSA)
0 = Clear	Clear skin with no signs of erythema	No redness
1 = Almost clear	Almost clear, slight redness	Very mild redness
2 = Mild	Mild erythema, definite redness	Mild redness
3 = Moderate	Moderate erythema, marked redness	Moderate redness
4 = Severe	Severe erythema, fiery redness	Severe redness

Fowler L, Jarratt M, Moore A, et al.: Once daily topical brimonidine tartrate gel 0.05% is a novel treatment for moderate to severe facial erythema of rosacea: results of two multicenter, randomized and vehicle controlled studies. Br J Derm 2012; 166 (3)633-641

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### **Resources:**

Mirvaso (brimonidine) product information, revised by Gladerma Laboratories LP 08-2021. Available at DailyMed <http://dailymed.nlm.nih.gov>. Accessed September 15, 2021.

Maier LE. Management of rosacea. In: UpToDate, Owen C, Ofori AO (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at <http://uptodate.com>. Accessed September 15, 2021.

Maier LE, Helfrich YR. Rosacea: Pathogenesis, clinical features, and diagnosis. In: UpToDate, Dellavalle RP, Owen C, Ofori AO (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at <http://uptodate.com>. Accessed September 15, 2021.

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