

## azelaic acid 15% gel

**Disclaimer**

*Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.*

*Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.*

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## Summary

Azelaic acid gel is a topical agent used in the treatment of rosacea. Rosacea is a skin condition primarily affecting the face and can present as redness, swelling, inflammation that includes papules and pustules, dilated blood vessels that appear on the surface of the skin, and rhinophyma (characterized by an enlarged, red nose). Treatment of rosacea can vary depending on the symptoms involved. Rosacea is managed by non-pharmacological (e.g., avoiding triggers of flushing, gentle skin care, sun-protection), laser and light therapy, and pharmacological therapy such as topical brimonidine, topical antimicrobials, topical azelaic acid, topical oxymetazoline, and oral antibiotics. The first-line treatment for mild-to-moderate disease, including inflammatory papules and pustules, include topical agents such as metronidazole and azelaic acid gel.

## Definitions

“Papule” is a raised area of the skin, usually pink or red, that occurs in conditions such as rosacea and dermatitis.

“Pustule” is a bump on the skin that contains pus or liquid.

“Rosacea” is a skin condition primarily affecting the face and can present as redness, swelling, inflammation that includes papules and pustules, dilated blood vessels that appear on the surface of the skin, and rhinophyma (characterized by an enlarged, red nose).

“[s]” indicates state mandates may apply.

## Clinical Indications

### Medical Necessity Criteria for Clinical Review

#### Indication-Specific Criteria

##### Rosacea

The Plan considers azelaic acid 15% gel medically necessary when ALL of the following criteria are met:

1. The member is 18 years of age or older; *AND*
2. The member is using the requested medication for the treatment of inflammatory papules and pustules of mild to moderate rosacea (i.e., papulopustular rosacea); *AND*
3. The member is unable to use, or has adequately tried and failed topical metronidazole for a minimum one (1) month trial<sup>[s]</sup>.

If the above prior authorization criteria are met, the requested product will be approved for up to 36 months.<sup>[s]</sup>

### Experimental / Investigational, or unproven<sup>[s]</sup>

Azelaic acid 15% gel for any other indication is considered experimental, investigational, or unproven.

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#### Clinical Guideline Revision / History Information

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