

5.90.049

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<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	April 1, 2024
<b>Subsection:</b>	Topical products	<b>Original Policy Date:</b>	September 24, 2021
<b>Subject:</b>	Aczone	<b>Page:</b>	1 of 3

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**Last Review Date:** March 8, 2024

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## Aczone

### Description

#### Aczone (dapsonsone)

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#### Background

Aczone gel is a topical sulfone antimicrobial. In an oral formulation the mechanism of sulfones is like that of sulfonamides: competitive antagonism of paraaminobenzoic acid and disruption of folic acid synthesis. It is unknown how Aczone works to treat acne vulgaris topically, but it may work on neutrophils to reduce inflammation (1).

#### Regulatory Status

Aczone gel is indicated for the topical treatment of acne vulgaris (1).

The safety and effectiveness of Aczone gel in pediatric patients under 9 years old have not been established (1).

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#### Related policies

Isotretinoin, Tazarotene, Tretinoin, Winlevi

### Policy

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.*

Aczone gel may be considered **medically necessary** if the conditions indicated below are met.

Aczone gel may be considered **investigational** for all other indications.

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**Prior-Approval Requirements**

**Age** 9 years of age and older

**Diagnoses**

Patient must have the following:

- 1. Acne vulgaris
  - a. Comedones
  - b. Cysts (eruptive vellus hair cyst, cystic acnes)
  - c. Papules
  - d. Pustules

**AND** the following:

- 1. Inadequate treatment response, intolerance, or contraindication to at least **ONE** topical generic acne product (e.g., benzoyl peroxide, clindamycin topical, erythromycin topical, or sodium sulfacetamide)

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**Prior-Approval *Renewal* Requirements**

Same as above

[Policy Guidelines](#)

**Pre-PA Allowance**

None

**Prior-Approval Limits**

**Quantity**

Drug	Quantity per 90 days
Aczone (dapson) 5% gel	180 grams
Aczone (dapson) 7.5% gel	

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**Duration** 6 months

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## Prior-Approval *Renewal* Limits

Same as above

### Rationale

#### Summary

Aczone is a topical product for the treatment of acne vulgaris. Aczone is a sulfone antibiotic and its exact mechanism of action in the treatment of acne vulgaris is unknown (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Aczone while maintaining optimal therapeutic outcomes.

#### References

1. Aczone [package insert]. Exton, PA: Almirall, LLC.; September 2019.

### Policy History

Date	Action
September 2021	Removal of Aczone from Topical Antifungals Antibiotics to its own policy
December 2021	Annual review
March 2022	Annual review
June 2022	Annual review
March 2023	Annual review. Changed policy number to 5.90.049
March 2024	Annual review

### Keywords

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**This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.**