
5.90.049

Section:	Prescription Drugs	Effective Date:	April 1, 2026
Subsection:	Topical products	Original Policy Date:	September 24, 2021
Subject:	Aczone	Page:	1 of 3

Last Review Date: March 6, 2026

Aczone

Description

Aczone (dapsone)

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).

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.

Section:	Prescription Drugs	Effective Date:	April 1, 2026
Subsection:	Topical Products	Original Policy Date:	September 24, 2021
Subject:	Aczone	Page:	2 of 3

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)

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	

5.90.049

Section:	Prescription Drugs	Effective Date:	April 1, 2026
Subsection:	Topical Products	Original Policy Date:	September 24, 2021
Subject:	Aczone	Page:	3 of 3

Duration 6 months

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
September 2024	Annual review
March 2025	Annual review
March 2026	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 6, 2026 and is effective on April 1, 2026.