

Dapsone 7.5% Topical Gel (Aczone)

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.

Summary

Acne vulgaris is a common chronic inflammatory skin condition affecting the pilosebaceous units, characterized by the presence of comedones, papules, pustules, and/or nodules. It primarily affects the face and trunk and can result in scarring and hyperpigmentation. Topical therapies, such as retinoids, benzoyl peroxide, antibiotics, and their combinations, are the mainstay of treatment for mild to moderate acne. Systemic therapies, such as oral antibiotics, hormonal agents, and isotretinoin, are often used for more severe or recalcitrant cases.

Aczone (dapsone) 7.5% gel is a topical medication FDA-approved for the treatment of acne vulgaris in those 9 years of age and older. It is applied as a thin layer to the entire face or other affected areas once daily.

- NOTE: members using Aczone gel should avoid concomitant use with topical benzoyl peroxide products to prevent temporary local yellow or orange discoloration of the skin and facial hair. If both agents are necessary for treatment, they should be applied at different times of the day.

Definitions

"Acne vulgaris" refers to a chronic inflammatory dermatologic condition primarily affecting the face and trunk, characterized by the presence of comedones, inflammatory papules, pustules, and nodules.

"Topical retinoid" is a class of medications derived from vitamin A that are applied to the skin for the treatment of acne, including tretinoin, adapalene, tazarotene, and trifarotene.

"Topical antibiotic" refers to antibacterial medications applied to the skin for the treatment of acne, such as clindamycin, erythromycin, and minocycline.

Medical Necessity Criteria for Authorization

The Plan considers Dapsone 7.5% Topical Gel (Aczone) medically necessary when ALL of the following criteria are met:

1. The member is 9 years of age or older; *AND*
2. The member has a diagnosis of acne vulgaris; *AND*
3. The member is unable to use, or has tried and failed ONE of the following:
 - a. One topical retinoid (e.g., tretinoin, adapalene); *and/or*
 - b. One topical antibiotic (e.g., clindamycin, erythromycin); *AND*
4. IF the member is concurrently using a topical benzoyl peroxide product, the prescriber attests that the member will avoid applying Dapsone 7.5% Topical Gel (Aczone) at the same time as the benzoyl peroxide product and instead will apply them at different times of the day.

If the above prior authorization criteria are met, the requested product will be authorized for up to 12 months.

Experimental or Investigational / Not Medically Necessary

Dapsone 7.5% Topical Gel (Aczone) for any other indication or use is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven.

References

1. Aczone 7.5% (dapsone) gel [prescribing information]. Malvern, PA: Almirall LLC; August 2021.
2. Dubina MI, Fleischer AB Jr. Interaction of topical sulfacetamide and topical dapsone with benzoyl peroxide. Arch Dermatol. 2009 Sep;145(9):1027-9. doi: 10.1001/archdermatol.2009.186.
3. Eichenfield LF, Lain T, Frankel EH, et al,. Efficacy and Safety of Once-Daily Dapsone Gel, 7.5% for Treatment of Adolescents and Adults With Acne Vulgaris: Second of Two Identically Designed, Large, Multicenter, Randomized, Vehicle-Controlled Trials. J Drugs Dermatol. 2016 Aug 1;15(8):962-9.
4. Reynolds RV, Yeung H, Cheng CE, Cook-Bolden F, Desai SR, Druby KM, Freeman EE, Keri JE, Stein Gold LF, Tan JKL, Tollefson MM, Weiss JS, Wu PA, Zaenglein AL, Han JM, Barbieri JS. Guidelines of care for the management of acne vulgaris. J Am Acad Dermatol. 2024

May;90(5):1006.e1-1006.e30. doi: 10.1016/j.jaad.2023.12.017. Epub 2024 Jan 30. PMID: 38300170.

5. Stein Gold LF, Jarratt MT, Bucko AD, et al,. Efficacy and Safety of Once-Daily Dapsone Gel, 7.5% for Treatment of Adolescents and Adults With Acne Vulgaris: First of Two Identically Designed, Large, Multicenter, Randomized, Vehicle-controlled Trials. J Drugs Dermatol. 2016 May 1;15(5):553-61.
6. Zaenglein AL, Pathy AL, Schlosser BJ, et al. Guidelines of care for the management of acne vulgaris. J Am Acad Dermatol. 2016;74(5):945-973.e33. doi:10.1016/j.jaad.2015.12.037

Clinical Guideline Revision / History Information

Original Date: 06/27/2024

Reviewed/Revised: 10/01/2025