

Clinical Policy: Dapsone (Aczone Gel)

Reference Number: CP.PCH.32

Effective Date: 12.01.18

Last Review Date: 11.21

Line of Business: Commercial, HIM

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

Dapsone (Aczone[®] Gel) is a sulfone.

FDA Approved Indication(s)

Aczone Gel is indicated for the topical treatment of acne vulgaris. The 7.5% strength is specifically indicated in patients 9 years of age and older

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation[®] that Aczone Gel is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Acne Vulgaris (must meet all):

1. Diagnosis of acne vulgaris;
2. Age \geq 9 years;
3. Failure of TWO preferred topical anti-acne agents (e.g., topical adapalene, tretinoin, benzoyl peroxide/erythromycin, clindamycin, benzoyl peroxide/clindamycin phosphate, erythromycin, sulfacetamide/sulfur) unless clinically significant adverse effects are experienced or all are contraindicated;
4. Dose does not exceed 1 tube or pump per month.

Approval duration:

Commercial – Length of Benefit

HIM – 3 months

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial and HIM.PA.154 for health insurance marketplace.

II. Continued Therapy

A. Acne Vulgaris (must meet all):

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;

2. Member is responding positively to therapy;
3. If request is for a dose increase, dose does not exceed 1 tube or pump per month.

Approval duration:

Commercial – Length of Benefit

HIM – 12 months

B. Other diagnoses/indications (must meet 1 or 2):

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.

Approval duration: Duration of request or 12 months (whichever is less); or

2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial and HIM.PA.154 for health insurance marketplace.

III. Diagnoses/Indications for which coverage is NOT authorized:

- A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial and HIM.PA.154 for health insurance marketplace, or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Topical Retinoids		
adapalene (Differin®)	Lotion, Cream: 0.1%; Gel: 0.1%, 0.3% Apply topically QD	Not applicable
tretinoin (Retin-A®, Retin-A Micro®)	Cream: 0.025%, 0.05%, 0.1%; Gel: 0.01%, 0.025%, 0.05% Microsphere Gel: 0.04%, 0.1% Apply topically QD	Not applicable
Topical Antibiotics		
benzoyl peroxide-erythromycin (Benzamycin®)	Gel: 5% benzoyl peroxide/3% erythromycin Apply topically QD-BID	Not applicable
clindamycin (Cleocin T®, Clindagel®, Clindamax®)	Solution, Gel, Lotion 1%: Apply topically BID Foam 1%: Apply topically QD	Not applicable

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
benzoyl peroxide/ clindamycin phosphate (Duac [®] , Neuac, Benzaclin)	Duac, Neuac: 1.2% clindamycin/5% benzoyl peroxide: Apply topically QD BenzaClin: 1% clindamycin/5% benzoyl peroxide: Apply topically BID	Not applicable
erythromycin (Erygel [®])	Solution: 2%; Gel: 2% Apply topically BID	Not applicable
sulfacetamide/sulfur	Various strengths Apply topically QD to TID	Not applicable

Therapeutic alternatives are listed as Brand name[®] (generic) when the drug is available by brand name only and generic (Brand name[®]) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

None reported

Appendix D: General Information

Per the Aczone gel prescribing information, if there is no improvement after 12 weeks, treatment with Aczone should be reassessed.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Acne vulgaris	5%: Apply a pea-sized amount in a thin layer to the acne affected areas topically BID after washing 7.5%: Apply a pea-sized amount in a thin layer to the entire face and other affected areas topically QD after washing	Not applicable

VI. Product Availability

- Gel tube (30 g, 60 g, 90 g): 5%, 7.5%
- Gel pump (30 g, 60 g, 90 g): 7.5%

VII. References

1. Aczone Gel 7.5% Prescribing Information. Exton, PA: Almirall, LLC; September 2019. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/207154s004lbl.pdf. Accessed August 10, 2021.
2. Aczone Gel 5% Prescribing Information. Irvine, CA: Allergan Inc; May 2018. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/021794s016lbl.pdf. Accessed August 10, 2021.
3. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2021. Available at: <http://www.clinicalpharmacology-ip.com/>. Accessed August 10, 2021.
4. Zaenglein AL, Pathy AL, Schlosser BJ et al. Guidelines of care for the management of acne vulgaris. J Am Acad Dermatol. 2016 May;74(5):945-73.e33. doi:10.1016/j.jaad.2015.12.037.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created (adopted from CP.CPA.338, policy to retire); added HIM line of business; references reviewed and updated.	08.21.20	11.20
4Q 2021 annual review: no significant changes; updated reference for HIM off-label use to HIM.PA.154 (replaces HIM.PHAR.21); references reviewed and updated.	08.10.21	11.21

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

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