Clinical Policy: Dapsone (Aczone Gel)

Reference Number: CP.PCH.32
Effective Date: 12.01.18
Last Review Date: 11.26
Line of Business: Commercial, HIM/ICHRA

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 and dapsone gel are **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 is one of the following (a or b):
   a. For dapsone (Aczone) 5% gel: ≥ 12 years;
   b. For dapsone (Aczone) 7.5% gel: ≥ 9 years;
3. Failure of ≥ 2 of the following preferred topical anti-acne agents^ (must be from 2 different classes listed below), unless clinically significant adverse effects are experienced or all are contraindicated:*
   a. Topical antibiotics: clindamycin, erythromycin;
   b. Topical anti-infectives: benzoyl peroxide, sodium sulfacetamide/sulfur;
   c. Topical retinoids: adapalene, tretinoin;

   ^Prior authorization may be required for adapalene, tretinoin, and combination products
   **For Illinois HIM requests, the step therapy requirements above do not apply per IL HB 5395*
4. If request is for brand Aczone Gel, member must use generic dapsone gel, unless clinically significant adverse effects are experienced or contraindicated;
5. Dose does not exceed 1 tube or pump per month.

Approval duration:
HIM/ICHRA – 12 months
Commercial – 12 months or duration of request, whichever is less

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial and HIM.PA.33 for health insurance marketplace/ICHRA; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial and HIM.PA.103 for health insurance marketplace/ICHRA; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial and HIM.PA.154 for health insurance marketplace/ICHRA.

II. Continued Therapy

A. Acne Vulgaris (must meet all)**:**
1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
2. Member is responding positively to therapy;
3. If request is for brand Aczone Gel, member must use generic dapsone gel, unless clinically significant adverse effects are experienced or contraindicated;
4. If request is for a dose increase, dose does not exceed 1 tube or pump per month.

Approval duration:
HIM/ICHRA – 12 months
Commercial – 12 months or duration of request, whichever is less

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial and HIM.PA.33 for health insurance marketplace/ICHRA; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial and HIM.PA.103 for health insurance marketplace/ICHRA; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial and HIM.PA.154 for health insurance marketplace/ICHRA.

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/ICHRA, 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 Antibiotics		
clindamycin (Cleocin T®, Clindagel®, Clindacin®)	Apply a thin film BID	Not applicable
erythromycin (Erygel®, Ery®)	Apply a thin film BID	Not applicable
Topical Anti-infectives		
benzoyl peroxide (Benzepro®, PR®, Neutrogena Clear Pore)*	Apply or wash QD to TID	Not applicable
sulfacetamide/sulfur	Apply or wash QD to TID	Not applicable
Topical Retinoids		
adapalene (Differin®)	Apply a thin film QD	Not applicable
tretinoin (Retin-A®)	Apply a thin film QD	Not applicable
Combination products		
Example combination products: • clindamycin/benzoyl peroxide • erythromycin/benzoyl peroxide • adapalene/benzoyl peroxide • clindamycin/tretinoin	Varies	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.
**Available over-the-counter (OTC) in a number of preparations.*

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; December 2021. Available at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=22058b7d-a578-4eaa-a476-ac982337f02a. Accessed August 6, 2026.
2. Aczone Gel 5% Prescribing Information. Madison, NJ: Allergan Inc; May 2018. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/021794s016lbl.pdf. Accessed August 6, 2026.
3. Clinical Pharmacology [database online]. Philadelphia, PA: Elsevier, Inc.; 2026. Available at: https://www.clinicalkey.com/pharmacology/. Accessed August 6, 2026.
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.
5. Reynolds RV, Yeung H, Cheng CE, et al. 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.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
4Q 2022 annual review: no significant changes; references reviewed and updated. Template changes applied to other diagnoses/indications and continued therapy section.	08.24.22	11.22
4Q 2023 annual review: clarified age criteria for dapsone 5% to align with prescriber information; removed commercially unavailable brand name therapeutic alternatives; references reviewed and updated.	08.17.23	11.23
In initial approval criteria, added clarification stating prior authorization may be required for tretinoin.	02.13.24	
4Q 2024 annual review: clarified criteria applies to generic dapsone gel; added member must use generic dapsone gel; in initial	08.01.24	11.24

Reviews, Revisions, and Approvals	Date	P&T Approval Date
approval criteria, clarified failure of two preferred topical anti-acne agents from different listed classes, clarified that adapalene and combination products may require prior authorization updated Appendix B per Clinical Pharmacology; references reviewed and updated		
4Q 2025 annual review: added step therapy bypass for IL HIM per IL HB 5395; extended initial approval duration from 3 months to 12 months for HIM for this maintenance medication for a chronic condition; references reviewed and updated.	08.07.25	11.25
4Q 2026 annual review: added ICHRA line of business; references reviewed and updated.	08.06.26	11.26

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.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise

professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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