# Clinical Policy: Dapsone (Aczone Gel)

Reference Number: CP.PCH.32
Effective Date: 12.01.18
Last Review Date: 11.22
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 ≥ 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 –** 12 months or duration of request, whichever is less
**HIM –** 3 months

**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) 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; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) 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; 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.

**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 a dose increase, dose does not exceed 1 tube or pump per month.

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

**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) 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; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) 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; 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.

**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%<br>Apply topically QD | Not applicable |
| tretinoin (Retin-A®, Retin-A Micro®) | Cream: 0.025%, 0.05%, 0.1%;<br>Gel: 0.01%, 0.025%, 0.05%<br>Microsphere Gel: 0.04%, 0.1%<br>Apply topically QD | Not applicable |
| **Topical Antibiotics** | | |
| benzoyl peroxide-erythromycin (Benzamycin®) | Gel: 5% benzoyl peroxide/3% erythromycin<br>Apply topically QD-BID | Not applicable |
| clindamycin (Cleocin T®, Clindagel®, Clindamax®) | Solution, Gel, Lotion 1%: Apply topically BID<br>Foam 1%: Apply topically QD | Not applicable |
| benzoyl peroxide/ clindamycin phosphate (Duac®, Neuac, Benzaclin) | Duac, Neuac: 1.2% clindamycin/5% benzoyl peroxide: Apply topically QD<br>BenzaClin: 1% clindamycin/5% benzoyl peroxide: Apply topically BID | Not applicable |
| erythromycin (Erygel®) | Solution: 2%; Gel: 2%<br>Apply topically BID | Not applicable |
| sulfacetamide/sulfur | Various strengths<br>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<br><br>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.almirall.us/pdf/aczone_7-5_pi_2019-09.pdf. Accessed August 24, 2022.
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 24, 2022.
3. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2021. Available at: http://www.clinicalpharmacology-ip.com/. Accessed August 24, 2022.
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 |
| Revised approval duration for Commercial line of business from length of benefit to 12 months or duration of request, whichever is less. | 04.26.22 | 08.22 |
| 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 |

**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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