

Clinical Policy Title:	dapsone
Policy Number:	RxA.331
Drug(s) Applied:	Aczone® Gel
Original Policy Date:	03/06/2020
Last Review Date:	09/14/2020
Line of Business Policy Applies to:	All lines of business

Background

Dapsone (Aczone® Gel) is a sulfone.

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.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
Dapsone (Aczone® Gel)	Acne vulgaris	<p>Gel 5%: Apply a thin layer to the acne affected areas topically Twice Daily after washing.</p> <p>Gel 7.5%: Apply a thin layer to the entire face and other affected areas topically Once Daily after washing .</p>	Not applicable

Dosage Forms

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

Clinical Policy

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

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

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 contraindicated or clinically significant adverse effects are experienced;
4. Dose does not exceed 1 tube or pump per month.

Approval duration

Commercial: 12 months

Medicaid: 12 months

II. Continued Therapy

A. Acne Vulgaris (must meet all):

1. Member is currently receiving the medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
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

Medicaid: 12 months

III. Appendices

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 Once Daily	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 Once Daily	Not applicable
Topical Antibiotics		
benzoyl peroxide-erythromycin (Benzamycin®)	Gel: 5% benzoyl peroxide/3% erythromycin Apply topically Once to Twice Daily	Not applicable

clindamycin (Cleocin T®, Clindagel®, Clindamax®)	Solution, Gel, Lotion 1%: Apply topically Twice Daily Foam 1%: Apply topically Once Daily	Not applicable
benzoyl peroxide/ clindamycin phosphate (Duac®, Neuac, Benzaclin)	Duac®, Neuac: 1.2% clindamycin/5% benzoyl peroxide: Apply topically Once Daily BenzaClin: 1% clindamycin/5% benzoyl peroxide: Apply topically Twice Daily	Not applicable
erythromycin (Erygel®)	Solution: 2%; Gel: 2% Apply topically Twice Daily	Not applicable
sulfacetamide/sulfur	Various strengths Apply topically Once to Three Times Daily	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

- Contraindication(s):
 - None.
- Boxed Warning(s):
 - None.

APPENDIX D: General Information

The anti-inflammatory properties of dapsone result from inhibition of granulocyte cytotoxicity, via inhibition of peroxidases and scavenging of reactive oxygen species. The antimicrobial properties of dapsone result from competitive inhibition of dihydropteroate synthase, a bacterial enzyme necessary for synthesis of folic acid. The mechanism of action of dapsone gel in treating acne vulgaris is not known.

References

1. Aczone Gel 7.5% Prescribing Information. Exton, PA: Almirall, LLC; September 2019. Available at: <https://www.aczone.com>. Accessed June 28, 2020.
2. Aczone Gel 5% Prescribing Information. Irvine, CA: Allergan Inc; May 2018. Available at: https://www.allergan.com/assets/pdf/aczone_pi. Accessed June 28, 2020.
3. Micromedex® Healthcare Series [Internet Database]. Greenwood Village, CO: Truven Health Analytics. Updated periodically. Accessed June 28, 2020.
4. https://www.almirall.us/pdf/aczone_7-5_pi_2019-09.pdf. Accessed June 28, 2020.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established	01/2020	03/06/2020

<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1) Background updated. 2) Dosing information updated. 3) Clinical policy (initial approval criteria) was updated. 4) Appendices updated. 5) References were updated. 	<p>06/2020</p>	<p>09/14/2020</p>