Clinical Policy Title:	dapsone
Policy Number:	RxA.331
Drug(s) Applied:	Aczone® Gel
Original Policy Date:	03/06/2020
Last Review Date:	04/18/2022
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	Gel 5%: Apply a thin layer to the acne affected areas topically twice daily after washing. Gel 7.5%: Apply a thin layer to the entire face and other affected areas topically once daily after washing.	Not applicable

Dosage Forms

- Gel tube (60 g, 90 g): 5%
- Gel pump (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. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

A. Acne Vulgaris (must meet all)**:**

1. Diagnosis of acne vulgaris;
2. Age ≥ 9 years for 7.5%;
3. Age ≥ 12 years for 5%;
4. 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;

5. 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
None.

APPENDIX B: Therapeutic Alternatives
Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Topical Retinoids		
adapalene (Differin®)	Lotion, Cream, Solution, Swab: 0.1%; Gel/Jelly: 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%, 0.06%, 0.08%, 0.1% Apply topically Once Daily	Not applicable
Topical Antibiotics		
benzoyl peroxide-erythromycin (Benzamycin®)	Gel: 5% benzoyl peroxide/3% erythromycin Apply topically Twice Daily	Not applicable
clindamycin (Cleocin T®, Clindagel®)	Solution, Gel, Lotion 1%: Apply topically Twice Daily	Not applicable
benzoyl peroxide/ clindamycin phosphate (Neuac, Benzaclin)	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

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
sulfacetamide/sulfur	Various strengths Apply topically Once to Three Times Daily	Not applicable

*The American Academy of Dermatology acne guidelines recommend erythromycin (topical) be used in conjugation with other therapies (not as monotherapy) due to risk of bacterial resistance.
Therapeutic alternatives are listed as generic (Brand name®) when the drug is available by both generic and brand; Brand name® when the drug is available by brand only and generic name when the drug is available by generic only.

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - None reported.

- Boxed Warning(s):
  - None reported.

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 February 08, 2022
2. Aczone Gel 5% Prescribing Information. Madison, NJ: Allergan Inc; May 2018. Available at: https://www.allergan.com/assets/pdf/aczone_pi. Accessed February 08, 2022.
3. Dapsone Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. Available at: http://www.micromedexsolutions.com Accessed February 08, 2022.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established	01/2020	03/06/2020
Policy was reviewed: 1) Background updated. 2) Dosing information updated. 3) Clinical policy (initial approval criteria) was updated. 4) Appendices updated. 5) References were updated.	06/2020	09/14/2020

Policy was reviewed: 1) Dosage Forms was updated to remove “30g” tube and pump. 2) Statement about provider sample, ‘‘The provision of provider samples does not guarantee coverage…” was added to Clinical Policy. 3) Therapeutic Alternatives verbiage was rephrased to "Below are suggested therapeutic alternatives based on clinical guidance..". 4) Appendix B was updated to include “solution, swab… …jelly…” and “0.06%... …0.08%...”. 5) Appendix B was updated to remove “Foam 1%: apply topically once daily…”. 6) Appendix B footnote was updated to include “*The American Academy of Dermatology acne guidelines recommend…” 7) Statement about drug listing format in Appendix B is rephrased to "Therapeutic alternatives are listed as generic (Brand name®) when the drug is available by both generic and brand; Brand name® when the drug is available by brand only and generic name when the drug is available by generic only". 8) References were reviewed and updated.	05/28/2021	09/14/2021
Policy was reviewed: 1. Initial Approval Criteria, I.A.2 and I.A.3: Updated to include age criteria. 2. Appendix A: Updated to remove abbreviations <old abbreviation FDA. 3. References were reviewed and updated.	02/08/2022	04/18/2022