

Clinical Policy Title:	adapalene/benzoyl peroxide
Policy Number:	RxA.371
Drug(s) Applied:	Epiduo® Forte
Original Policy Date:	03/06/2020
Last Review Date:	06/10/2021
Line of Business Policy Applies to:	All lines of business

Background

Adapalene 0.3%/benzoyl peroxide 2.5% (Epiduo® Forte) is a topical combination product of two active ingredients: adapalene, a retinoid, and benzoyl peroxide, an oxidizing agent with bactericidal and keratolytic effects. It is indicated for the topical treatment of acne vulgaris.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
adapalene 0.3%/benzoyl peroxide 2.5% (Epiduo® Forte)	Acne vulgaris	Apply a pea-sized amount to each affected area of the face and/or trunk topically once daily after washing	Not applicable

Dosage Forms

- Gel pump (15 g, 30 g, 45 g, 60 g, 70 g): adapalene 0.3%/benzoyl peroxide 2.5%

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 12 years of age or older;
3. Failure of two preferred topical anti-acne agents including trial of at least one topical retinoid agent (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 container(45 g or 60 g) per month.

Approval duration

Commercial: 12 months

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.

Medicaid: 12 months

II. Continued Therapy Approval

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 container (45 g or 60 g) 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

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: 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

Drug Name	Dosing Regimen	Dose Limit/Maximum Dose
Topical Retinoids		
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

- Epiduo® forte gel combines two active ingredients, adapalene and benzoyl peroxide which work together but in different ways:
- Adapalene belongs to a group of products known as retinoids and acts specifically on the skin processes that cause acne.
- The other active ingredients, benzoyl peroxide, works as an antimicrobial agent and by softening and peeling the outer layer of the skin.

References

1. Epiduo® Forte Prescribing Information. Fort Worth, TX: Galderma Laboratories; July 2015. Available at: <https://www.Epiduoforte.com>. Accessed April 19, 2021.
2. Micromedex® Healthcare Series [Internet Database]. Greenwood Village, CO: Truven Health Analytics. Updated periodically. Accessed April 19, 2021.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: 1) Clinical policy (initial approval criteria & continued therapy approval) was updated. 2) Appendices updated. 3) References were updated.	07/2020	09/14/2020
Policy was reviewed: 1) Dosing Information QD changed to once daily 2) Updated dosing criteria to include 60 g gel pump 3) Updated trial and fail criteria under I.A.3	04/16/2021	06/10/2021

<p>4) Appendix B: Therapeutic Alternatives verbiage changed to "Below are suggested.."</p> <p>5) References were reviewed and revised</p>		
---	--	--