

Clinical Policy Title:	tretinoin and benzoyl peroxide
Policy Number:	RxA.702
Drug(s) Applied:	Twynéo®
Original Policy Date:	08/20/2021
Last Review Date:	09/14/2021
Line of Business Policy Applies to:	All lines of business

Background

Tretinoin and benzoyl peroxide (Twynéo®) is a combination of tretinoin, a retinoid, and benzoyl peroxide indicated for the topical treatment of acne vulgaris in adults and pediatric patients 9 years of age and older.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
tretinoin and benzoyl peroxide (Twynéo®)	Acne vulgaris	Apply a thin layer of Twynéo® to the affected areas once daily.	1 application per day topically.

Dosage Forms

- Cream: 0.1% tretinoin/3% benzoyl peroxide.

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. Prescribed by or in consultation with dermatologist;
3. Age ≥ 9 years;
4. Failure of adapalene-benzoyl peroxide in the past 3 months at up to maximally indicated dose, unless contraindicated or clinically significant adverse effects are experienced.
5. Dose does not exceed 1 application topically per day.

Approval Duration

Commercial: 3 months

Medicaid: 3 months

II. Continued Therapy Approval

A. Acne vulgaris (must meet all):

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.

1. Member is currently receiving 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 application topically per day.

Approval Duration

Commercial: 3 months

Medicaid: 3 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key

Not applicable.

APPENDIX B: Therapeutic Alternatives

adapalene-benzoyl peroxide

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
 - History of serious hypersensitivity reaction to benzoyl peroxide or any component of Twyneo®.
- Boxed Warning(s):
 - None reported.

APPENDIX D: General Information

- Hypersensitivity: Severe hypersensitivity reactions, including anaphylaxis and angioedema, have been reported with use of benzoyl peroxide products.
- Skin Irritation: Pain, dryness, exfoliation, erythema, and irritation may occur with use of Twyneo®. Avoid application of Twyneo® to cuts, abrasions, eczematous or sunburned skin.

References

1. Twyneo® prescribing information. Whippany, NJ: Sol-Gel Technologies Inc; July 2021. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214902s000lbl.pdf. Accessed August 20, 2021.
2. Clinical Pharmacology [database online] powered by ClinicalKey. Tampa, FL: Elsevier, 2021. Accessed with subscription at: <http://www.clinicalkey.com>. Accessed August 20, 2021.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	8/20/2021	09/14/2021