Clinical Policy Title:	clindamycin phosphate/benzoyl peroxide
Policy Number:	RxA.2
Drug(s) Applied:	Onexton®, Acanya®
Original Policy Date:	02/07/2020
Last Review Date:	03/09/2021
Line of Business Policy Applies to:	All lines of business

Background

Clindamycin phosphate/benzoyl peroxide (Onexton®, Acanya®) is a topical combination product of two active ingredients: clindamycin phosphate, a lincosamide antibacterial agent, and benzoyl peroxide, an oxidizing agent with bactericidal and keratolytic effects. It is indicated for the topical treatment of acne vulgaris in patients 12 years of age and older.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
clindamycin phosphate/ benzoyl peroxide (Onexton®)	acne vulgaris	Apply a pea-sized amount to the face once daily	Not available
clindamycin phosphate/ benzoyl peroxide (Acanya®)	acne vulgaris	Apply a pea-sized amount to the face once daily	Not available

Dosage Forms

- Gel Pump (50 g): Onexton®- 1.2% clindamycin phosphate / 3.75% benzoyl peroxide
- Gel Pump (50 g): Acanya®- 1.2% clindamycin phosphate / 2.5% 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.

I. Initial Approval Criteria

A. Acne Vulgaris (must meet all):

1. Diagnosis of acne vulgaris;
2. Age 12 years and older;
3. Failure of preferred generic clindamycin phosphate/benzoyl peroxide topical products (*see Appendix B*), unless contraindicated or clinically significant adverse effects are experienced;
4. Dose does not exceed 1 pump container per month.

Approval Duration:

Commercial: 12 months

Medicaid: 12 months

II. Continued Therapy Approval

A. Acne Vulgaris (must meet all):

1. Currently receiving medication that has been authorized by RxAdvance or member has previously 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 pump container per month.

Approval Duration:
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
Not Applicable

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
1%/5% clindamycin phosphate/ benzoyl peroxide (BenzaClin®)	Apply topically to affected area twice a day (morning and evening)	Not available
1.2%/5% clindamycin phosphate/ benzoyl peroxide (Neuac®)	Apply topically to affected area once daily in the evening	Not available

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):
  - Hypersensitivity (e.g., anaphylaxis) to clindamycin, benzoyl peroxide, any components of the formulation, or lincomycin
  - History of regional enteritis, ulcerative colitis, or antibiotic-associated colitis

- Boxed Warning(s):
  - None Reported

APPENDIX D: General Information

- Minimize sun exposure (including use of tanning beds or sun lamps) following drug application.
- Orally and parenterally administered clindamycin has been associated with severe colitis, which may result in death. Diarrhea, bloody diarrhea, and colitis (including pseudomembranous colitis) have been reported with the use of topical and systemic clindamycin. Onexton® or Acanya® gel should be discontinued if significant diarrhea occurs.

References

1. Onexton® Prescribing Information. Bridgewater, NJ: Bausch Health US, LLC; April 2020. Available at: www.onexton com. Accessed January 19, 2021.
2. Acanya® Prescribing Information. Bridgewater, NJ: Bausch Health US, LLC; February 2020. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/050819s023s024lbl.pdf. Accessed January 20, 2021.
3. Clinical Pharmacology [database online] powered by ClinicalKey. Tampa, FL: Elsevier, 2020. Accessed with subscription at: http://www.clinicalkey.com. Updated January 14, 2020. Accessed January 19, 2021.
4. Clindamycin and Benzoyl Peroxide, Lexi-Drug. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Accessed with subscription at: http://online.lexi.com. Accessed January 19, 2021.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	02/07/2020
1. Updated References 2. Added General information 3. Acanya® removed due to being off-market	05/2020	05/21/2020
Policy was reviewed: 1. Policy title table was updated: Clinical Policy Title was updated to 'clindamycin phosphate/benzoyl peroxide', Drug(s) Applied was updated to 'Onexton®, Acanya®', Line of business policy applies was updated to All lines of business. 2. Background: Indication for Acanya® was added. 3. Dosing information: Indication was added, Dosing information for Acanya® was added. 4. Dosage Forms: Acanya® dosage form was added. 5. Continued therapy approval criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance…". 6. Approval durations were updated to 12 months from Length of Benefit. 7. Appendix A was updated. 8. Appendix B: header verbiage was updated to 'Below are suggested therapeutic alternatives based...'. Discontinued brand Duac was removed. 9. Appendix D: General Information was updated. 10. References were updated.	01/20/2021	03/09/2021