# Clinical Policy: Topical Acne Treatment

Reference Number: HIM.PA.71
Effective Date: 12.01.14
Last Review Date: 11.26
Line of Business: HIM/ICHRA

Revision Log

**See Important Reminder at the end of this policy for important regulatory and legal information.**

## Description

The following are topical acne treatment agents requiring prior authorization: clindamycin foam (Clindacin®), clindamycin phosphate/benzoyl peroxide gel 1-5% (BenzaClin®), clindamycin and benzoyl peroxide 1.2-5% gel (Duac® Gel, Neuac®), clindamycin and benzoyl peroxide gel 1.2-2.5% (Acanya®), clindamycin and benzoyl peroxide 1.2-3.75% (Onexton®), erythromycin and benzoyl peroxide gel 5-3% (Benzamycin®), minocycline micronized foam 4% (Amzeeq™), tretinoin microsphere gel (Retin-A Micro® 0.1%).

**Requests for Arazlo, Fabior, Tazorac, and Aczone gel should not be approved using these criteria; refer to applicable formulary policies specific to each product, CP.PCH.32 and CP.PMN.244.*

## FDA Approved Indication(s)

Topical acne agents are indicated for the treatment of acne vulgaris. Acanya, Clindacin, and Onexton are specifically for patients 12 years and older. Amzeeq is specifically indicated for non-nodular moderate to severe acne vulgaris in patients 9 years of age and older.

Limitation(s) of use:

- Duac gel has not been demonstrated to have any additional benefit when compared with benzoyl peroxide alone in the same vehicle when used for the treatment of non-inflammatory acne.
- The Amzeeq formulation of minocycline has not been evaluated in the treatment of infections. To reduce the development of drug-resistant bacteria as well as to maintain the effectiveness of other antibacterial drugs, Amzeeq should be used only as indicated.

## Policy/Criteria

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

It is the policy of health plans affiliated with Centene Corporation® that topical acne treatments are **medically necessary** when the following criteria are met:

**I. Initial Approval Criteria**

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

1. Diagnosis of acne vulgaris;
2. One of the following (a or b):
   a. Age ≥ 12 years;
   b. For Amzeeq requests, age ≥ 9 years;
3. For Acanya and Onexton, both of the following (a and b):*
   **For Illinois HIM requests, the step therapy requirements below do not apply per IL HB 5395*

a. Member must use the individual components (i.e., topical clindamycin phosphate and topical benzoyl peroxide) concurrently unless clinically significant adverse effects are experienced or all are contraindicated (e.g., contraindications to the excipients of all brand and generic products);
b. Failure of at least two preferred generic clindamycin phosphate/benzoyl peroxide topical products^ (*see Appendix B*), unless clinically significant adverse effects are experienced or all are contraindicated (e.g., contraindications to the excipients of all brand and generic products);
*^Prior authorization may be required for generic clindamycin phosphate/benzoyl peroxide products*

4. For all other brand or generic combination products (e.g., Neuac, Benzamycin), both of the following (a and b):*
**For Illinois HIM requests, the step therapy requirements below do not apply per IL HB 5395*
a. Member must use the individual components (e.g., topical clindamycin phosphate and topical benzoyl peroxide) concurrently unless clinically significant adverse effects are experienced or all are contraindicated (e.g., contraindications to the excipients of all brand and generic products);
b. Member must use generic combination product^, if available, unless clinically significant adverse effects are experienced or all are contraindicated;
*^Prior authorization may be required for generic clindamycin phosphate/benzoyl peroxide products*
5. For Clindacin, member must use generic clindamycin topical lotion, gel, solution, and swabs, unless clinically significant adverse effects are experienced or all are contraindicated;*
**For Illinois HIM requests, the step therapy requirements above do not apply per IL HB 5395*
6. For all other topical acne agents, failure of ≥ 2 of the following topical preparations, each from different medication classes, each used for ≥ 2 months, unless clinically significant adverse effects are experienced or all are contraindicated (*see Appendix B)*:*
a. Topical antibiotics: clindamycin, erythromycin;
b. Topical anti-infectives: benzoyl peroxide;
c. Topical retinoids: tretinoin^;
*^Prior authorization may be required for tretinoin*
**For Illinois HIM requests, the step therapy requirements above do not apply per IL HB 5395*
7. Dose does not exceed 1 container (tube, can, pump) per month.

**Approval duration: 12 months**

**B. Other diagnoses/indications** (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
a. For drugs on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: HIM.PA.33 for health insurance marketplace/ICHRA; or
b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the relevant line of business: HIM.PA.103 for health insurance marketplace/ICHRA; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: HIM.PA.154 for health insurance marketplace/ICHRA.

## II. Continued Therapy

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

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
2. Member is responding positively to therapy;
3. Dose does not exceed 1 container (tube, can, pump) per month.

**Approval duration: 12 months**

**B. Other diagnoses/indications** (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: HIM.PA.33 for health insurance marketplace/ICHRA; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the relevant line of business: HIM.PA.103 for health insurance marketplace/ICHRA; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: HIM.PA.154 for health insurance marketplace/ICHRA.

## III. Diagnoses/Indications for which coverage is NOT authorized:

**A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – HIM.PA.154 for health insurance marketplace/ICHRA or evidence of coverage documents.

## IV. Appendices/General Information

*Appendix A: Abbreviation 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 and may require prior authorization.*

| Drug Name | Dosing Regimen | Dose Limit/ Maximum Dose |
|---|---|---|
| **Topical Antibiotics** | | |
| clindamycin (Cleocin T®, Clindagel®) lotion, gel, solution, swabs | Apply a thin film BID | Not applicable |
| erythromycin (Erygel®, Ery®) | Apply a thin film BID | Not applicable |
| **Topical Anti-infectives** | | |
| benzoyl peroxide (Benzepro®, PanOxyl®)* foam, gel, liquid, lotion | Apply or wash QD or TID | Not applicable |
| **Topical Retinoids** | | |
| tretinoin (Retin-A®) | Apply a thin film QD | Not applicable |
| **Combination clindamycin phosphate/benzoyl peroxide products** | | |
| 1%/5% clindamycin phosphate/benzoyl peroxide | Apply topically to affected area BID (morning and evening) | Not applicable |
| 1.2%/5% clindamycin phosphate/benzoyl peroxide (Neuac) | Apply topically to affected area QD in the evening | 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.*
**Available over-the-counter (OTC) in a number of preparations.*

*Appendix C: Contraindications/Boxed Warnings*

- Contraindication(s):
  - Acanya: hypersensitivity to clindamycin, benzoyl peroxide, any components of the formulation, or lincomycin; history of regional enteritis, ulcerative colitis, or antibiotic-associated colitis
  - Amzeeq: hypersensitivity to tetracyclines or any ingredients within Amzeeq
  - BenzaClin: 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
  - Benzamycin: hypersensitivity to any of its components
  - Clindacin: in individuals with a history of regional enteritis or ulcerative colitis, or a history of antibiotic-associated colitis (including pseudomembranous colitis)
  - Onexton: hypersensitivity 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

## V. Dosage and Administration

| Drug Name | Dosing Regimen | Maximum Dose |
|---|---|---|
| clindamycin (Clindacin) | Apply topically once daily to the affected areas | Once daily application |
| clindamycin phosphate and benzoyl peroxide gel (BenzaClin) | Apply topically to affected areas BID | Twice daily application |
| clindamycin phosphate and benzoyl peroxide gel (Neuac) | Apply topically once daily in the evening | Once daily application |
| clindamycin phosphate and benzoyl peroxide gel (Acanya, Onexton) | Apply topically once daily | Once daily application |
| erythromycin and benzoyl peroxide (Benzamycin) | Apply topically twice daily | Twice daily application |
| minocycline micronized (Amzeeq) | Apply topically once daily | Once daily application |
| tretinoin microsphere (Retin-A Micro) | Apply topically once daily before bedtime | Once daily application |

## VI. Product Availability

| Drug Name | Availability |
|---|---|
| clindamycin (Clindacin) | Foam (50 g, 100 g aerosol can): 1% |
| clindamycin phosphate and benzoyl peroxide gel (BenzaClin) | Gel (25 g jar; 35 g and 50 g pump): 1-5% |
| clindamycin phosphate and benzoyl peroxide gel (Neuac) | Gel (45 g tube): 1.2-5% |
| clindamycin phosphate and benzoyl peroxide gel (Acanya) | Gel (50 g pump): 1.2-2.5% |
| clindamycin phosphate and benzoyl peroxide gel (Onexton) | Gel (50 g pump): 1.2-3.75% |
| erythromycin and benzoyl peroxide (Benzamycin) | Gel (46.6 g container): 5-3% |
| minocycline micronized (Amzeeq) | Foam (30 g can): 4% |
| tretinoin microsphere gel (Retin-A Micro) | Gel (20 g, 45 g tube): 0.1%, 0.04%<br>Gel (50 g pump): 0.04%, 0.06%, 0.08%, 0.1% |

## VII. References

1. 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 August 6, 2026.
2. Amzeeq Prescribing Information. Bridgewater, NJ: Foamix Pharmaceuticals Inc.; February 2022. Available at: www.amzeeq.com. Accessed August 6, 2026.

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8. Retin-A Micro Gel Prescribing Information. Bridgewater, NJ: Bausch Health US LLC; September 2025. Available at: www.retinamicro.com. Accessed August 6, 2026.
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10. Reynolds RV, Yeung H, Cheng CE, et al. Guidelines of care for the management of acne vulgaris. *J Am Acad Dermatol*. 2024 May;90(5):1006.e1-1006.e30. doi: 10.1016/j.jaad.2023.12.017.
11. Clinical Pharmacology [database online]. Philadelphia, PA: Elsevier, Inc.; 2026. Available at: https://www.clinicalkey.com/pharmacology/. Accessed August 6, 2026.

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|---|---|---|
| 4Q 2022 annual review: no significant changes; implemented "member must use" language when redirecting to alternative dosage forms of the same active ingredient; references reviewed and updated. Template changes applied to other diagnoses/indications and continued therapy section. | 08.15.22 | 11.22 |
| 4Q 2023 annual review: no significant changes; updated available brand products in Appendix B; references reviewed and updated. | 08.02.23 | 11.23 |
| In initial approval criteria, added clarification stating prior authorization may be required for tretinoin. | 02.13.24 | |
| Ad hoc: removed Differin products from criteria (moved Differin criteria to HIM.PA.109 step therapy criteria); added Acanya and Onexton criteria; revised BenzaClin criteria to apply to all brand or generic combination products (which includes BenzaClin); for combination products, added requirement that the member must use generic combination product if available; for Evoclin, specified generic clindamycin per available formulary agents. | 05.03.24 | |

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|---|---|---|
| 4Q 2024 annual review: no significant changes; references reviewed and updated. | 07.30.24 | 11.24 |
| 4Q 2025 annual review: added step therapy bypass for IL HIM per IL HB 5395; for Clindacin foam, extended initial approval duration from 3 months to 12 months for this maintenance medication for a chronic condition; references reviewed and updated. | 08.08.25 | 11.25 |
| 4Q 2026 annual review: added ICHRA line of business; references reviewed and updated. | 08.06.26 | 11.26 |

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to

recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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