Clinical Policy: Topical Acne Treatment

Reference Number: HIM.PA.71
Effective Date: 12.01.14
Last Review Date: 11.23
Line of Business: HIM

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: adapalene cream (0.1%) and gel (0.1%) (Differin®), clindamycin foam (Evoclin®), clindamycin phosphate/benzoyl peroxide gel (BenzaClin®), clindamycin and benzoyl peroxide 1.2-5% (Duac® Gel), erythromycin and benzoyl peroxide (Benzamycin®), minocycline micronized foam 4% (Amzeeq™), tretinoin microsphere gel (Retin-A Micro® 0.1%).

Limitations 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.

FDA Approved Indication(s)

Topical acne agents are indicated for the treatment of acne vulgaris.

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 BenzaClin: member must use the individual components (i.e., topical clindamycin phosphate, 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);
4. For Evoclin: member must use clindamycin topical lotion, gel, solution, and swabs unless clinically significant adverse effects are experienced or all are contraindicated;

5. 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:
   a. Topical antibiotics: clindamycin, erythromycin;
   b. Topical anti-infectives: benzoyl peroxide;
   c. Topical retinoids: tretinoin;*
      **Prior authorization may be required for tretinoin*
6. Dose does not exceed 1 container (tube, can, pump) per month.

Approval duration:
Evoclin – 3 months
All other topical acne agents – 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) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: HIM.PA.33 for health insurance marketplace; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: HIM.PA.103 for health insurance marketplace; 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.

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) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: HIM.PA.33 for health insurance marketplace; or

b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: HIM.PA.103 for health insurance marketplace; 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.

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 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
clindamycin (Cleocin T®) lotion, gel, solution, swabs	Apply a thin film BID	BID
erythromycin (Erygel®, Ery®)	Apply a thin film BID	BID
benzoyl peroxide (Benzac®, BPO®, PanOxyl®) foam, gel, liquid, lotion	Apply or wash QD or BID	BID
tretinoin (Retin-A®)	Apply QD at bedtime	QD

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):
  - 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
  - Differin: hypersensitive to adapalene or any of the components in the gel vehicle
  - Duac: hypersensitivity to clindamycin, benzoyl peroxide, any components of the formulation, or lincomycin; history of regional enteritis, ulcerative colitis, or antibiotic-associated colitis (including pseudomembranous colitis)
  - Evoclin: in individuals with a history of regional enteritis or ulcerative colitis, or a history of antibiotic-associated colitis (including pseudomembranous colitis)

- Boxed warning(s): none reported

V. Dosage and Administration

Drug Name	Dosing Regimen	Maximum Dose
adapalene (Differin)	Apply topically once daily in the evening	Once daily application
clindamycin (Evoclin)	Apply topically once daily to the affected areas	Once daily application
clindamycin phosphate/benzoyl peroxide gel (BenzaClin)	Apply topically to affected areas BID	Twice daily application
clindamycin phosphate and benzoyl peroxide (Duac Gel)	Apply topically once daily in the evening	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
adapalene (Differin)	Cream, gel (45 g tube): 0.1% Gel (45 g tube): 0.3%
clindamycin (Evoclin)	Foam (50 g, 100 g aerosol can): 1%
clindamycin phosphate/benzoyl peroxide gel (BenzaClin)	Gel (25 g jar; 35 g and 50 g pump): 1-5%
clindamycin phosphate and benzoyl peroxide (Duac Gel)	Gel (45 g tube): 1.2-5%
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% Gel (50 g pump): 0.04%, 0.06%, 0.08%, 0.1%

VII. References

1. Amzeeq Prescribing Information. Bridgewater, NJ: Foamix Pharmaceuticals Inc.; February 2022. Available at: https://www.amzeeq.com/sites/default/files/2022-05/AMZEEQ-Prescribing-Information.pdf. Accessed August 2, 2023.
2. Benzamycin Topical Gel Prescribing Information. Bridgewater, NJ: Bausch Health US, LLC; November 2020. Available at: https://pi.bauschhealth.com/globalassets/BHC/PI/Benzamycin-PI.pdf. Accessed August 2, 2023.

3. BenzaClin Prescribing Information. Bridgewater, NJ: Valeant Pharmaceuticals; February 2017. Available at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=4c6b2aca-d940-42af-a068-418f015d277a. Accessed August 2, 2023.
4. Differin Cream 0.1% Prescribing Information. Fort Worth, TX: Galderma Laboratories, L.P.; October 2022. Available at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=ab4b2120-57fc-6c61-b239-37c21789c065. Accessed August 2, 2023.
5. Differin Gel 0.3% Prescribing Information. Fort Worth, TX: Galderma Laboratories, L.P.; August 2022. Available at: https://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=a0031324-92a6-4c11-90e2-c2818f7278ec#:~:text=age%20and%20older.-,DIFFERIN%20Gel%2C%200.3%25%20is%20indicated%20for%20the%20topical%20treatment%20of,with%20a%20non%2Dmedicated%20soap. Accessed August 2, 2023.
6. Duac Gel Prescribing Information. Research Triangle Park, NC: Stiefel Laboratories, Inc.; April 2015. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/050741s024lbl.pdf. Accessed August 2, 2023.
7. Evoclin Foam Prescribing Information. Morgantown, WV: Mylan Pharmaceuticals Inc.; April 2018. Available at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=0bf27280-f246-4087-9dd4-3649c57810bb. Accessed August 2, 2023.
8. Retin-A Micro Gel Prescribing Information. Bridgewater, NJ: Bausch Health US LLC; October 2017. Available at: https://pi.bauschhealth.com/globalassets/BHC/PI/Retin-A-Micro-Gel-PI.pdf. Accessed August 2, 2023.
9. Zaenglein AL, Pathy AL, Schlosser BJ, Alikhan A, Baldwin HE, Berson DS, et al. Guidelines of care for the management of acne vulgaris. J Am Acad Dermatol. 2016 Feb 15.
10. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2023. Available at: https://www.clinicalkey.com/pharmacology/. Accessed August 2, 2023..

Reviews, Revisions, and Approvals	Date	P&T Approval Date
4Q 2019 annual review: removed Clindap T cream, Triseon, and Clindagel and added Duac due to changes in PA status; references reviewed and updated.	08.13.19	11.19
Per June SDC and prior clinical guidance, added Amzeeq to criteria with age requirement 9 years or older per prescribing information.	06.02.20	
4Q 2020 annual review: added topical acne agents BenzaClin (adopted from HIM.PA.31, policy to retire) and Evoclin (adopted from HIM.PA.21, policy to retire) to this policy; references reviewed and updated.	08.10.20	11.20
4Q 2021 annual review: no significant changes; updated reference for HIM off-label use to HIM.PA.154 (replaces HIM.PHAR.21); references reviewed and updated.	08.11.21	11.21
4Q 2022 annual review: no significant changes; implemented "member must use" language when redirecting to alternative dosage	08.15.22	11.22

Reviews, Revisions, and Approvals	Date	P&T Approval Date
forms of the same active ingredient; references reviewed and updated. Template changes applied to other diagnoses/indications and continued therapy section.		
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	

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.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.