Clinical Policy: Topical Acne Treatment
Reference Number: HIM.PA.71
Effective Date: 12.01.14
Last Review Date: 02.18
Line of Business: Health Insurance Marketplace

Coding Implications
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/gel/lotion (Differin®), adapalene and benzoyl peroxide (Epiduo®), azelaic acid (Azelex®), clindamycin phosphate and benzoyl peroxide (Benzaclin®, Duac®, Neuac®), erythromycin and benzoyl peroxide (Benzamycin®), adapalene and clindamycin phosphate (Clindap-T® Cream, Triseon®), tretinoin microsphere gel (Retin-A Micro® 0.1%), clindamycin phosphate and tretinoin (Veltin®, Ziana®), clindamycin phosphate (Cleocin-T®).

**FDA approved indication**
Topical acne agents are indicated for the treatment of acne vulgaris.

**Policy/Criteria**
*Provider must submit documentation (which may include office chart notes and lab results) 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. Age ≥ 12 years;
3. Failure of ≥ 2 of the following topical preparations each from different medication classes, each trialed for ≥ 2 months, unless all are contraindicated or clinically significant adverse effects are experienced;
   a. Topical antibiotics: clindamycin, erythromycin;
   b. Topical anti-infectives: benzoyl peroxide;
   c. Topical retinoids: tretinoin;
4. Dose does not exceed 1 container per month.

**Approval duration: 12 months**

**B. Other diagnoses/indications**

1. Refer to HIM.PHAR.21 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

**II. Continued Therapy**

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

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. Dose does not exceed 1 container per month.

**Approval duration: 12 months**

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

1. Currently receiving medication via health plan benefit and documentation supports positive response to therapy.
   **Approval duration: Duration of request or 12 months (whichever is less)**; or
2. Refer to HIM.PA.21 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

## 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.PHAR.21 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®) | Apply a thin film twice daily | Apply twice daily |
| erythromycin (Erygel®, Ery®) | Apply a thin film twice daily | Apply twice daily |
| benzoyl peroxide (Benzac®, BPO®, Brevoxyl®, PanOxyl®) | Apply or wash once or twice daily | Apply twice daily |
| tretinoin (Retin-A®, Retin-A Micro®) | Apply once daily | Apply once daily |

*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.*

## V. References

1. 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.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2017. Available at: http://clinicalpharmacology-ip.com/default.aspx.

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|---|---|---|
| Reformatted guideline to new format. Adjusted criteria for flow. Added Workflow reference document. Added tretinoin microsphere to this guideline. | 12.15 | 12.15 |
| Removed general description of different acne agent as this applies to agents that are covered without PA. Replaced the description section to indicate the policy is applicable to formulary topical acne agent requiring PA. Added requirement for diagnosis. Updated continuation criteria. Removed workflow document. Updated references to reflect current literature search. | 08.16 | 11.16 |
| Converted to new template. | 04.17 | 08.17 |
| 1Q18 annual review:<br>-Added Cleocin-T and Neuac to criteria.<br>-Added age limit of ≥ 12 years per HIM formulary. Changed requirement from 2 to ≥ 2. | 12.05.17 | 02.18 |

**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.

**Note: For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.