Clinical Policy: Topical Acne Treatment
Reference Number: HIM.PA.71
Effective Date: 12.01.14
Last Review Date: 11.19
Line of Business: HIM*

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

*For Health Insurance Marketplace members, if request is through the pharmacy benefit, this policy applies only when the referenced drug is on the health plan approved formulary. Request for non-formulary drugs must be reviewed using the policy: HIM.PA.103.

Description
The following are topical acne treatment agents requiring prior authorization: adapalene cream (0.1%) and gel (0.1%) (Differin®), erythromycin and benzoyl peroxide (Benzamycin®), clindamycin and benzoyl peroxide 1.2-5% (Duac® Gel), tretinoin microsphere gel (Retin-A Micro® 0.1%).

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. Age ≥ 12 years;
      3. Failure of ≥ 2 of the following topical preparations, each from different medication classes, each used 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 the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PHAR.21 for health insurance marketplace.

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 the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PHAR.21 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.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.

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dosing Regimen</th>
<th>Dose Limit/Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>clindamycin (Cleocin T®)</td>
<td>Apply a thin film BID</td>
<td>BID</td>
</tr>
<tr>
<td>erythromycin (Erygel®, Ery®)</td>
<td>Apply a thin film BID</td>
<td>BID</td>
</tr>
<tr>
<td>benzoyl peroxide (Benzac®, BPO®, Brevoxyl®, PanOxyl®)</td>
<td>Apply or wash QD or BID</td>
<td>BID</td>
</tr>
<tr>
<td>tretinoin (Retin-A®)</td>
<td>Apply QD</td>
<td>QD</td>
</tr>
</tbody>
</table>

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):
     o Benzamycin: benzoic acid hypersensitivity, macrolide hypersensitivity
CLINICAL POLICY
Topical Acne Treatment

- 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)
- Retin-A: retinoid hypersensitivity

Boxed warning(s): none reported

V. Dosage and Administration

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>adapalene (Differin)</td>
<td>Apply topically once daily</td>
<td>Once daily application</td>
</tr>
<tr>
<td>clindamycin phosphate and benzoyl peroxide (Duac Gel)</td>
<td>Apply topically once daily, in the evening</td>
<td>Once daily application</td>
</tr>
<tr>
<td>erythromycin and benzoyl peroxide (Benzamycin)</td>
<td>Apply topically twice daily</td>
<td>Twice daily application</td>
</tr>
<tr>
<td>tretinoin microsphere (Retin-A Micro 0.1%)</td>
<td>Apply topically once daily</td>
<td>Once daily application</td>
</tr>
</tbody>
</table>

VI. Product Availability

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Availability</th>
</tr>
</thead>
<tbody>
<tr>
<td>adapalene (Differin)</td>
<td>Cream, gel: 0.1% Gel: 0.3%</td>
</tr>
<tr>
<td>clindamycin phosphate and benzoyl peroxide (Duac Gel)</td>
<td>Gel: 1.2-5%</td>
</tr>
<tr>
<td>erythromycin and benzoyl peroxide (Benzamycin)</td>
<td>Gel: 5-3%</td>
</tr>
<tr>
<td>tretinoin microsphere gel (Retin-A Micro)</td>
<td>Gel: 0.1%</td>
</tr>
</tbody>
</table>

VII. References

4. Differin Gel 0.3% Prescribing Information. Fort Worth, TX: Galderma Laboratories, L.P.; February 2012. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/021753s004lbl.pdf. Accessed August 13, 2019.
CLINICAL POLICY
Topical Acne Treatment


Reviews, Revisions, and Approvals

<table>
<thead>
<tr>
<th>Description</th>
<th>Date</th>
<th>P&amp;T Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reformatted guideline to new format. Adjusted criteria for flow. Added Workflow reference document. Added tretinoin microsphere to this guideline.</td>
<td>12.15</td>
<td>12.15</td>
</tr>
<tr>
<td>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.</td>
<td>08.16</td>
<td>11.16</td>
</tr>
<tr>
<td>Converted to new template.</td>
<td>04.17</td>
<td>08.17</td>
</tr>
<tr>
<td>1Q18 annual review: Added Cleocin-T and Neuac to criteria. Added age limit of ≥ 12 years per HIM formulary. Changed requirement from 2 to ≥ 2.</td>
<td>12.05.17</td>
<td>02.18</td>
</tr>
<tr>
<td>1Q 2019 annual review: no significant changes; updated age limit for Epiduo per labeling; references reviewed and updated.</td>
<td>11.05.18</td>
<td>02.19</td>
</tr>
<tr>
<td>Removed Azelex, Epiduo, clindamycin phosphate and benzoyl peroxide (Benzaclin, Duac), Veltin, and Ziana as they are addressed in separate corporate approved policies (refer to HIM.PA.31 for Benzaclin/Duac and HIM.PA.109 Step Therapy for all others); clarified adapalene formulations requiring PA.</td>
<td>03.01.19</td>
<td></td>
</tr>
<tr>
<td>4Q 2019 annual review: removed Clindap T cream, Triseon, and Clindagel and added Duac due to changes in PA status; references reviewed and updated.</td>
<td>08.13.19</td>
<td>11.19</td>
</tr>
</tbody>
</table>

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 Health Insurance Marketplace members, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the non-formulary policy; HIM.PA.103.

©2014 Centene Corporation. All rights reserved. All materials are exclusively owned by Centene Corporation and are protected by United States copyright law and international copyright law. No part of this publication may be reproduced, copied, modified, distributed, displayed, stored in a retrieval system, transmitted in any form or by any means, or otherwise published without the prior
written permission of Centene Corporation. You may not alter or remove any trademark, copyright or other notice contained herein. Centene® and Centene Corporation® are registered trademarks exclusively owned by Centene Corporation.