Clinical Policy: Dapsone (Aczone Gel)
Reference Number: CP.CPA.338
Effective Date: 12.01.18
Last Review Date: 11.18
Line of Business: Commercial

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

Description
Dapsone (Aczone® Gel) is a sulfone.

FDA Approved Indication(s)
Aczone Gel is indicated for the topical treatment of acne vulgaris. The 7.5% strength is specifically indicated in patients 12 years of age and older

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 Aczone Gel is 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 TWO preferred topical anti-acne agents (e.g., topical adapalene, tretinoin, benzoyl peroxide/erythromycin, clindamycin, benzoyl peroxide/clindamycin phosphate, erythromycin, sulfacetamide/sulfur) unless contraindicated or clinically significant adverse effects are experienced.
   
   Approval duration: Length of Benefit

   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): CP.CPA.09 for commercial.

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.
   
   Approval duration: Length of Benefit

   B. Other diagnoses/indications (must meet 1 or 2):
1. Currently receiving medication via Centene 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): CP.CPA.09 for commercial.

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 policies – CP.CPA.09 for commercial or evidence of coverage documents.

IV. Appendices/General Information
   *Appendix A: Abbreviation/Acronym 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 for all relevant lines of business 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><strong>Topical Retinoids</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>adapalene (Differin®)</td>
<td>Lotion, Cream: 0.1%; Gel: 0.1%, 0.3% Apply topically QD</td>
<td>Not applicable</td>
</tr>
<tr>
<td>tretinoin (Retin-A®, Retin-A Micro®)</td>
<td>Cream: 0.025%, 0.05%, 0.1%; Gel: 0.01%, 0.025%, 0.05% Microsphere Gel: 0.04%, 0.1% Apply topically QD</td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>Topical Antibiotics</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>benzoyl peroxide-erythromycin (Benzamycin®)</td>
<td>Gel: 5% benzoyl peroxide/3% erythromycin Apply topically QD-BID</td>
<td>Not applicable</td>
</tr>
<tr>
<td>clindamycin (Cleocin T®, Clindagel®, Clindamax®)</td>
<td>Solution, Gel, Lotion 1%: Apply topically BID Foam 1%: Apply topically QD</td>
<td>Not applicable</td>
</tr>
<tr>
<td>benzoyl peroxide/clindamycin phosphate (Duac®, Neuac, Benzaclin)</td>
<td>Duac, Neuac: 1.2% clindamycin/5% benzoyl peroxide: Apply topically QD BenzaClin: 1% clindamycin/5% benzoyl peroxide: Apply topically BID</td>
<td>Not applicable</td>
</tr>
<tr>
<td>erythromycin (Erygel®)</td>
<td>Solution: 2%; Gel: 2% Apply topically BID</td>
<td>Not applicable</td>
</tr>
<tr>
<td>sulfacetamide/sulfur</td>
<td>Various strengths Apply topically QD to TID</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>
CLINICAL POLICY

Dapsone

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
None reported

V. Dosage and Administration

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acne vulgaris</td>
<td>5%: Apply a thin layer to the acne affected areas topically BID after washing</td>
<td>Not applicable</td>
</tr>
<tr>
<td></td>
<td>7.5%: Apply a thin layer to the entire face and other affected areas topically QD after washing</td>
<td></td>
</tr>
</tbody>
</table>

VI. Product Availability

- 5% gel: 30 g, 60 g, 90 g tube
- 7.5% gel: 30 g, 60 g, 90 g pump

VII. References


Reviews, Revisions, and Approvals

<table>
<thead>
<tr>
<th>Date</th>
<th>P&amp;T Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>08.03.18</td>
<td>11.18</td>
</tr>
</tbody>
</table>

Policy created: split from previously approved policy CP.CPA.213; no significant changes from previously approved corporate policy; added age; references reviewed and updated.

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.

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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.

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