Clinical Policy: Halcinonide (Halog)
Reference Number: HIM.PA.20
Effective Date: 08.28.18
Last Review Date: 11.20
Line of Business: HIM

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

Description
Halcinonide (Halog®) is a high potency topical corticosteroid with anti-inflammatory, antipruritic and vasoconstrictive actions.

FDA Approved Indication(s)
Halog is indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

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 Halog is medically necessary when the following criteria are met:

I. Initial Approval Criteria
   A. Dermatologic Inflammation and Pruritus (must meet all):
      1. Diagnosis of dermatologic inflammation or pruritus;
      2. Failure of two formulary high potency topical corticosteroids in the previous 6 months, unless contraindicated or clinically significant adverse effects are experienced (see Appendix B for examples);
      3. Dose does not exceed one 60 gm tube 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. Dermatologic Inflammation and Pruritus (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. If request is for a dose increase, new dose does not exceed one 60 gm tube per month.
      Approval duration: 12 months
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): 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 policies – HIM.PHAR.21 for health insurance marketplace 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>augmented betamethasone 0.05% gel, cream, ointment, lotion (Diprolene®)</td>
<td>Apply topically to the affected area(s) BID</td>
<td>Should not be used for longer than 2 consecutive weeks</td>
</tr>
<tr>
<td>clobetasol propionate 0.05% cream, ointment, gel, solution (Temovate®)</td>
<td>Apply topically to the affected area(s) BID</td>
<td>Should not be used for longer than 2 consecutive weeks</td>
</tr>
<tr>
<td>diflorasone diacetate 0.05% ointment, cream (Apexicon®, Psorcon®)</td>
<td>Apply topically to the affected area(s) BID</td>
<td>Should not be used for longer than 2 consecutive weeks</td>
</tr>
<tr>
<td>halobetasol propionate 0.05% cream, ointment (Ultravate®)</td>
<td>Apply topically to the affected area(s) BID</td>
<td>Should not be used for longer than 2 consecutive weeks</td>
</tr>
<tr>
<td>fluocinonide acetonide 0.05% cream, ointment,</td>
<td>Apply topically to the affected area(s) BID</td>
<td>Should not be used for longer than 2 consecutive weeks</td>
</tr>
<tr>
<td>Drug Name</td>
<td>Dosing Regimen</td>
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<tr>
<td>-----------------------------------------------</td>
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<td>-------------------------------------------------------------</td>
</tr>
<tr>
<td>gel, solution (Lidex®)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>desoximetasone 0.25% cream, ointment (Topicort®)</td>
<td>Apply topically to the affected area(s) BID</td>
<td>Should not be used for longer than 2 consecutive weeks</td>
</tr>
<tr>
<td>desoximetasone 0.05% cream, gel (Topicort®)</td>
<td>Apply topically to the affected area(s) BID</td>
<td>Should not be used for longer than 2 consecutive weeks</td>
</tr>
<tr>
<td>mometasone 0.1% ointment (Elocon®)</td>
<td>Apply topically to the affected area(s) BID</td>
<td>Should not be used for longer than 2 consecutive weeks</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): history of hypersensitivity to any of the components of the preparation
- Boxed warning(s): 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>Dermatologic inflammation and pruritus</td>
<td>Apply to the affected area BID to TID</td>
<td>3 applications/day</td>
</tr>
</tbody>
</table>

VI. Product Availability
- Cream (0.1%): 30 g, 60 g
- Ointment (0.1%): 60 g

VII. References

Reviews, Revisions, and Approvals

<table>
<thead>
<tr>
<th></th>
<th>Date</th>
<th>P&amp;T Approval Date</th>
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<tr>
<td>Policy created</td>
<td>08.21.18</td>
<td>10.18</td>
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Reviews, Revisions, and Approvals

<table>
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<tr>
<th>Description</th>
<th>Date</th>
<th>P&amp;T Approval Date</th>
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<td>4Q 2019 annual review: no significant changes; references reviewed and updated.</td>
<td>08.13.19</td>
<td>11.19</td>
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<tr>
<td>4Q 2020 annual review: no significant changes; references reviewed and updated.</td>
<td>08.08.20</td>
<td>11.20</td>
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**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.

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