Clinical Policy: Halobetasol Propionate/Tazarotene (Duobrii)
Reference Number: CP.PMN.208
Effective Date: 05.21.19
Last Review Date: 08.19
Line of Business: Commercial, Medicaid

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

Description
Duobrii lotion is a combination product containing halobetasol propionate 0.01% and tazarotene 0.045%. Halobetasol propionate is a corticosteroid and tazarotene is a retinoid.

FDA Approved Indication(s)
Duobrii lotion is indicated for the topical treatment of plaque psoriasis in adults.

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 Duobrii is medically necessary when the following criteria are met:

I. Initial Approval Criteria
   A. Plaque Psoriasis (must meet all):
      1. Diagnosis of PsO with body surface area involvement ≤ 20%;
      2. Age ≥ 18 years;
      3. Prescribed by or in consultation with a dermatologist;
      4. Failure of generic halobetasol propionate and generic clobetasol propionate, unless both are contraindicated or clinically significant adverse effects are experienced;
      5. Failure of generic tazarotene, unless contraindicated or clinically significant adverse effects are experienced;
      6. Dose does not exceed 100 g per month (one 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): CP.CPA.09 for commercial and CP.PMN.53 for Medicaid.

II. Continued Therapy
   A. Plaque Psoriasis (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 100 g per month (one 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): CP.CPA.09 for commercial and CP.PMN.53 for Medicaid

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 and CP.PMN.53 for Medicaid

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>halobetasol propionate 0.05% cream/ointment (Ultravate)</td>
<td>Apply a thin layer to the affected skin QD to BID Treatment should be limited to two weeks.</td>
<td>50 g/week</td>
</tr>
<tr>
<td>clobetasol propionate 0.05% cream/foam/gel/lotion/ointment/shampoo/spray (Clobex®, Olux-E®, Olux®)</td>
<td>Apply a thin layer to the affected skin BID Treatment for mild to moderate plaque psoriasis should be limited to 2 weeks; moderate to severe treatment up to 4 weeks.</td>
<td>50 g/week</td>
</tr>
<tr>
<td>tazarotene (Tazorac) cream and gel</td>
<td>Apply gel or cream, 0.05% with strength increased to 0.1% if tolerated and medically indicated, qPM to psoriatic lesions, using enough (2 mg/cm²) to cover only the lesion with a thin film.</td>
<td>2 mg/cm²/day</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): pregnancy
- 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>Plaque psoriasis</td>
<td>Apply a thin layer of lotion once daily to the affected areas until control is achieved.</td>
<td>50 g/week</td>
</tr>
</tbody>
</table>

VI. Product Availability

Lotion 0.01%/0.045%: 45 g, 60 g, and 100 g tubes

VII. References


<table>
<thead>
<tr>
<th>Reviews, Revisions, and Approvals</th>
<th>Date</th>
<th>P&amp;T Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Policy created.</td>
<td>05.21.19</td>
<td>08.19</td>
</tr>
<tr>
<td>Removed HIM line of business; modified dosing limits in Section I and II from 200 g (two tubes) to 100 g (one tube) per month per SDC.</td>
<td>12.02.19</td>
<td></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.

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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.

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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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