RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Clinical Policy Title: **Halobetasol Propionate/Tazarotene (Duobrii™)**
Policy Number: **RxA.107**
Drug(s) Applied: **Halobetasol Propionate/Tazarotene (Duobrii™)**
Last Review Date: **04/2020**
Line of Business: **Commercial, Medicaid**

Background

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.

Duobrii™ lotion is indicated for the topical treatment of plaque psoriasis in adults.

Indication	Dosing Regimen	Maximum Dose
Plaque psoriasis	Apply a thin layer of lotion once daily to the affected areas until control is achieved.	50 g/week

Lotion 0.01%/0.045%: 100 g tubes

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

I. Initial Approval Criteria

A. Plaque Psoriasis (must meet all)**:**

1. Diagnosis of PsO with body surface area involvement ≤ 20%;
2. Age 18 years of age or older;
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);
7. In females of reproductive potential, obtain a negative pregnancy test within 2 weeks prior to initiating treatment

Approval duration: 12 months

II. Continued Therapy

A. Plaque Psoriasis (must meet all)**:**

1. Currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;
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 tubes per month).

Approval duration: 12 months

III. Appendices

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.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
halobetasol propionate 0.05% cream/ointment (Ultravate)	Apply a thin layer to the affected skin QD to BID Treatment should be limited to two weeks.	50 g/week
clobetasol propionate 0.05% cream/foam/gel/ lotion/ointment/shampoo/ spray (Clobex®, Olux-E®, Olux®)	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.	50 g/week
tazarotene (Tazorac) cream and gel	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/cm^2) to cover only the lesion with a thin film.	2 mg/cm^2/day

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

References
1. Duobrii Prescribing Information. Bridgewater, NJ: Bausch Health Americas, Inc., April 2019. Available at https://www.duobrii.com. Accessed April 30, 2020
2. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed April 30,2020.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy was established	01/2020	02/07/2020
Removal of 45 g and 60 g package size Added to initial criteria: In females of reproductive potential, obtain a negative pregnancy test within 2 weeks prior to initiating treatment Updated References	4/30/2020	5/21/2020