

Commercial PA Criteria

Effective: October 2012

Prior Authorization: Topical Agents for Psoriasis, Seborrheic Dermatitis, Atopic Dermatitis

Products Affected: Dovonex Cream (calcipotriene 0.005%); Calcipotriene Foam; Dovonex (calcipotriene 0.005%) solution; Duobrii Lotion (balobetasol and tazarotene 0.01%/0.045%); Enstilar Foam (calcipotriene/betamethasone dipropionate); Sorilux Foam (calcipotriene 0.005%), Vtama (tapinarof) topical cream, Wynzora (calcipotriene 0.005% and betamethasone dipropionate 0.064%) cream, Zoryve (roflumilast) 0.3% cream, Zoryve (roflumilast) 0.3% foam, Zoryve (roflumilast) 0.15% cream

Medication Description:

Psoriasis is a chronic skin condition that causes raised, red or silvery, scaly patches (plaques) to appear on the skin. It is an auto-immune disease in which patients shed their skin too quickly, causing dead skin cells to pile up on the surface. Normal skin cell turnover usually takes about a month, but for psoriasis patients the turnover can happen in only a few days. Affecting over 7 million adults in the United States, psoriasis is a common skin condition that develops in both men and women at equal rates – often first appearing between the ages of 15 and 35. While scientists differ on its exact cause, genetics and the immune system both play major roles in the development of plaque psoriasis. Plaque psoriasis is the most common and can appear as red bumpy patches that are covered with a silver-white buildup of dead skin cells. It usually appears on the scalp, knees, and lower back and can be itchy and painful and may crack and bleed. According to the National Psoriasis Foundation, the goal is to get the patient's psoriasis down to 1 percent body surface area (BSA) or less three months after starting a new treatment. Topical treatments are often the first line treatment recommended.

Seborrheic Dermatitis – Seborrheic dermatitis is a common skin condition that mainly affects your scalp. It causes scaly patches, inflamed skin and stubborn dandruff. It usually affects oily areas of the body, such as the face, sides of the nose, eyebrows, ears, eyelids and chest. Topical treatments are often the first line treatment recommended.

Covered Uses:

- **Duobrii Lotion, Dovonex Cream, Enstilar Foam, Vtama cream, Wynzora, and Zoryve** are indicated for the topical treatment of plaque psoriasis.
- **Dovonex Solution** is indicated for the topical treatment of chronic, moderately severe psoriasis of the scalp.
- **Calcipotriene foam, Sorilux Foam** is indicated for the topical treatment of plaque psoriasis of the scalp and body.
- **Zoryve Foam** is indicated for the topical treatment of seborrheic dermatitis
- **Zoryve 0.15% cream** is indicated for the topical treatment of mild to moderate atopic dermatitis.

Exclusion Criteria:

1. **Duobrii Lotion:** Patients who are pregnant
2. **Zoryve Cream/Foam:** Moderate to severe liver impairment (Child-Pugh B or C); **AND not** receiving concomitant treatment with Otezla® (apremilast tablets)

Required Medical Information:

1. Diagnosis

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2. Previous therapy regimen

Age Restrictions:

Dovonex Cream, Dovonex Solution, Duobrii Lotion, Vtama, Wyzora: 18 years of age or older

Calcipotriene foam, Sorilux Foam: 4 years of age and older

Enstilar Foam and Zoryve 0.3% cream: 12 years and older

Zoryve Foam: 9 years of age and older

Zoryve 0.15% cream: 6 years of age and older

Prescriber Restrictions: Prescribed by, or in consultation with a dermatologist.

Coverage duration:

Dovonex, Sorilux, and Wyzora: no more than 8 weeks

Duobrii and Enstilar: 12 weeks only

Vtama and Zoryve: 12 months

Other Criteria:

Dovonex Cream, Calcipotriene Foam or Sorilux Foam is medically necessary when all of the following criteria are met:

1. Patient has clinically documented plaque psoriasis; **AND**
2. Patient has a documented intolerance to, or treatment failure of an adequate trial of calcipotriene solution, ointment or cream

Dovonex Solution is medically necessary when all of the following criteria are met:

1. Patient has clinically documented plaque psoriasis of the scalp; **AND**
2. Patient has a documented intolerance to, or treatment failure of an adequate trial of calcipotriene solution, ointment or cream.

Duobrii Lotion is medically necessary when all of the following criteria are met:

1. Patient has clinically documented plaque psoriasis; **AND**
2. Patient has a documented intolerance to, or treatment failure of an adequate trial of generic halobetasol cream or ointment in combination with generic tazarotene cream.

Enstilar Foam and Wyzora Cream is medically necessary when the following criteria are met:

1. Patient is diagnosed with plaque psoriasis; **AND**
2. Patient has had an adequate trial (of 2 weeks' duration) of any one of the following:
 - a. Taclonex Suspension/Ointment (calcipotriene/betamethasone); **OR**
 - b. Calcipotriene cream; **OR**
 - c. Calcipotriene ointment; **OR**
 - d. Calcipotriene solution; **OR**
 - e. Sorilux Foam

Vtama Topical Cream and Zoryve 0.3% Topical Cream is medically necessary when the following criteria are met:

- A. Patient has psoriasis involvement estimated to affect $\leq 20\%$ of the body surface area; **AND**
- B. Patient meets **ONE** of the following criteria (i or ii):
 - i. Patient meets all of the following criteria (a, b, and c):
 - a. Patient has tried at least one medium-, medium-high, high-, and/or super-high potency prescription topical

corticosteroid; **AND**

b. This topical corticosteroid was applied daily for at least 4 consecutive weeks; **AND**

c. Inadequate efficacy was demonstrated with this topical corticosteroid, according to the prescriber; **OR**

ii. Patient is treating psoriasis affecting one of the following areas: face, eyes/eyelids, skin folds, and/or genitalia;

AND

C. Patient meets ALL of the following criteria (i, ii, and iii):

i. Patient has tried at least one topical vitamin D analog; **AND**

Note: Examples of topical vitamin D analogs include calcipotriene 0.005% foam (Sorilux, authorized generic), calcipotriene 0.005% cream (Dovonex, generic), calcipotriene 0.005% ointment (generic only), calcitriol 3 mcg/g ointment (Vectical, generic), calcipotriene 0.005% and betamethasone dipropionate 0.064% foam (Enstilar), calcipotriene 0.005% and betamethasone dipropionate 0.064% cream (Wynzora), calcipotriene 0.005% and betamethasone dipropionate 0.064% ointment (Taclonex, generic), calcipotriene 0.005% and betamethasone dipropionate 0.064% suspension (Taclonex, generic. Concomitant use of a topical vitamin d analog and a topical corticosteroid would meet the requirement

ii. This topical vitamin D analog was applied daily for at least 4 consecutive weeks; **AND**

iii. Inadequate efficacy was demonstrated with this topical vitamin D analog, according to the prescriber

Zoryve Foam is medically necessary when the following criteria are met:

A. Patient is diagnosed with Seborrheic Dermatitis **AND**

B. Patient has a documented intolerance to, or treatment failure of an adequate trial of ciclopirox gel/shampoo or selenium sulfide shampoo/foam/lotion.

Zoryve 0.15 % Cream is medically necessary when n the following criteria are met:

A. Patient has a diagnosis of mild to moderate atopic dermatitis **AND**

B. Patient has a dermatologic condition on or around the face, eyes/eyelids, axilla, or genitalia.

References:

1. Sorilux® foam full prescribing information. Stiefel Laboratories, Research Triangle Park, NC.
2. Dovonex package insert, LEO Laboratories, LTD, Dublin, Ireland
3. Enstilar package insert, LEO Pharma, 1 SylvanWay, Parsippany, NJ 07054
4. Duobrii [package insert]. Bridgewater, NJ; Bausch Health Americas, Inc.; April 2019.
5. Wynzora (calcipotriene and betamethasone dipropionate) cream [prescribing information]. Dover, DE: MC2 Therapeutics Inc; July 2020
6. WYNZORA Cream full prescribing information. MC2 Therapeutics Ltd.
7. Vtama® cream [prescribing information]. Long Beach, CA: Dermavant; May 2022.
8. Zoryve® cream [prescribing information]. Westlake, CA: Arcutis Biotherapeutics. 2022.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	Update	Added Duobrii Lotion	All	08/02/19

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2	Update	Updated template from CCI to EH; CCI P&T Review History: 10/12, 10/13, 10/14, 11/15, 5/16, 8/17, 7/18 CCI Revision Record: 4/13, 8/16	All	8/02/2019
3	Update	Added Wynzora cream	Products affected, covered uses, duration and other criteria	1/5/2021
4	Update	Added Vtama cream	Products Affected, Covered Uses and Other Criteria	8/11/2022
5	Update	Revised Policy: Replaced “Dovonex Foam” with “Calcipotriene Foam” in Products Affected; Added Dovonex Solution to Products Affected; Updated Age Restrictions from all 18 years and older to: <u>“Dovonex Cream, Dovonex Solution, Duobrii Lotion, Vtama, Wynzora: 18 years of age or older</u> <u>Calcipotriene foam, Sorilux Foam: 4 years of age and older</u> <u>Enstilar Foam: 12 years and older”</u> ; Other Criteria- Enstilar Foam and Wynzora Cream- updated “Dovonex Cream” to “Calcipotriene cream”	Products Affected; Age Restrictions; Other Criteria	9/20/2022
6	Update Policy	Added Calcipotriene Foam to Other Criteria with Dovonex Cream and Sorilux Foam	Other Criteria	9/22/2022
7	Update Policy	Added Zoryve Cream	Products Affected, Age Restrictions, Exclusion Criteria, Coverage Duration and Other Criteria	11/10/2022
8	Update Policy	Addition of Zoryve Foam Policy name change from Psoriasis to Psoriasis and Seborrheic dermatitis	Products Affected, Age Restrictions, Exclusion Criteria, coverage duration and other criteria	1/14/2024
9	Update Policy	Policy name change from Psoriasis and Seborrheic dermatitis to Topical Agents for Psoriasis, Seborrheic Dermatitis, Atopic Dermatitis. Addition of Zoryve 0.15% cream for atopic dermatitis Separate indication for Zoryve 0.15%cream and Zoryve 0.3% cream	Prior Authorization, Products Affected, Age Restrictions, Exclusion Criteria, coverage duration and other criteria	4/21/2025