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## 5.90.34

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<b>Subsection:</b>	Topical Products	<b>Original Policy Date:</b>	February 16, 2018
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**Last Review Date:** March 12, 2021

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## Topical Products with Quantity Limits

### Description

Bryhali\* Lotion 0.01% (halobetasol propionate)  
Duobrii Lotion 0.01%/0.045% (halobetasol propionate and tazarotene)  
Dovonex Cream 0.005% (calcipotriene)  
Enstilar Foam 0.005/0.064% (calcipotriene and betamethasone dipropionate)  
Lexette\* Topical Foam 0.05% (halobetasol propionate)  
Pennsaid\* Topical Solution 1.5% (diclofenac sodium)  
Pennsaid\* Topical Solution 2% (diclofenac sodium)  
Sorilux Foam 0.005% (calcipotriene)  
Taclonex\* Ointment 0.005/0.064% (calcipotriene and betamethasone dipropionate)  
Taclonex\* Suspension 0.005/0.064% (calcipotriene and betamethasone dipropionate)  
Voltaren Gel 1% (diclofenac sodium)  
Wynzora Cream 0.005/0.064% (calcipotriene and betamethasone dipropionate)

\* Prior authorization for the brand formulation applies only to formulary exceptions due to being a non-covered medication.

### Background

Pharmacy topical products have the potential for misuse. Misuse of these topical products not just over the face but also for any skin problem is quite common. It is very important to inform people

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about the possible complications of these drugs and the extent of the problem because of irrational use of these drugs. The criteria was created with dosing above FDA recommended limits in order to help existing patients that have been taking doses above the FDA recommended limits to safely taper down their doses to the appropriate levels (1-10).

### **Regulatory Status**

FDA approved indication:

1. Diclofenac Sodium Gel 1% (Voltaren) is indicated for the relief of the pain of osteoarthritis of joints amenable to topical treatment, such as the knees and those of the hands. Total dose should not exceed 32 g per day, over all affected joints (1).
2. Diclofenac Sodium Topical Solution 1.5% (Pennsaid) is a nonsteroidal anti-inflammatory drug indicated for the treatment of signs and symptoms of osteoarthritis of the knee(s) (2).
3. Pennsaid Topical Solution 2% is a nonsteroidal anti-inflammatory drug indicated for the treatment of pain of osteoarthritis of the knee(s) (3).
4. Calcipotriene Cream 0.005% (Dovonex) is indicated for the treatment of plaque psoriasis (4).
5. Calcipotriene and Betamethasone Dipropionate Ointment 0.005%/0.064% (Taclonex) is a vitamin D analogue and corticosteroid combination product indicated for the topical treatment of plaque psoriasis in patients 12 years of age and older. Apply Taclonex Ointment to affected area(s) once daily for up to 4 weeks. Discontinue therapy when control is achieved (5).
6. Calcipotriene and Betamethasone Dipropionate Topical Suspension 0.005%/0.064% (Taclonex) is a vitamin D analog and a corticosteroid combination product indicated for the topical treatment of plaque psoriasis of the scalp and body in patients 12 years and older (6).
7. Calcipotriene and Betamethasone Dipropionate Foam 0.005%/0.064% (Enstilar) is a vitamin D analogue and corticosteroid combination product indicated for the topical treatment of plaque psoriasis in patients 18 years of age and older (7).
8. Duobrii Lotion, Bryhali Lotion, and Lexette Topical Foam are indicated for the topical treatment of plaque psoriasis in adults (8-10).
9. Calcipotriene Foam 0.005% (Sorilux) is indicated for the treatment of plaque psoriasis of the scalp and body in adults and pediatric patients 4 years of age and older (11).

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10. Calcipotriene and betamethasone dipropionate 0.005/0.064% cream (Wynzora) is a vitamin D analog and a corticosteroid combination product indicated for the topical treatment of plaque psoriasis of the scalp and body in patients 18 years and older. Therapy with Wynzora is limited to 8 weeks or less (12).

## Related policies

### Policy

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.*

The topical products included in this policy may be considered **medically necessary** in patients with a FDA-approved indication supporting the use of topical product and if the conditions indicated below are met.

The topical products included in this policy may be considered **investigational** in patients for all other indications.

## Prior-Approval Requirements

### Diagnosis

Patient must have the following:

FDA-approved indication supporting the use of topical product

**AND** the following for:

**Halobetasol propionate topical foam (Lexette) 0.05%**

**Halobetasol propionate lotion (Bryhali) 0.01%**

**Halobetasol propionate and tazarotene lotion (Duobrii):**

1. Inadequate treatment response, intolerance, or contraindication to a generic Halobetasol topical product
2. **Duobrii only:** Inadequate treatment response, intolerance, or contraindication to a generic Tazarotene topical product

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## Prior – Approval *Renewal* Requirements

None

### Policy Guidelines

## Pre - PA Allowance

### Quantity

Drug	Quantity
Diclofenac Sodium Gel 1% (Voltaren)	1000 units per 90 days
Diclofenac Sodium Topical Solution 1.5% (Pennsaid)	9 bottles per 90 days
Calcipotriene Cream 0.005% (Dovonex)	120 units per 90 days
Calcipotriene Foam 0.005% (Sorilux)	
Calcipotriene and Betamethasone Dipropionate Ointment 0.005%/0.064%	
Calcipotriene and Betamethasone Dipropionate Suspension 0.005%/0.064%	
Calcipotriene and Betamethasone Dipropionate Foam 0.005%/0.064% (Enstilar)	

## Prior - Approval Limits

### Quantity

Drug	Quantity Limit
For All Topicals Above	Pre-PA allows for the American Academy of Dermatology (AAD) recommended dosage
Calcipotriene and Betamethasone Dipropionate Cream 0.005%/0.064% (Wynzora)	840 units per 56 days
Duobrii Lotion 0.01/0.045% (halobetasol propionate and tazarotene)	300 units per 90 days

### Quantity

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<b>Drug with approved MFE only</b>	<b>Quantity</b>
Bryhali Lotion 0.01% (halobetasol propionate)	400 units per 90 days
Lexette Topical Foam 0.05% (halobetasol propionate)	100 units per 90 days
Pennsaid Topical Solution 2%	9 bottles per 90 days
Taclonex Ointment 0.005%/0.064%	120 units per 90 days
Taclonex Suspension 0.005%/0.064%	120 units per 90 days

### **Prior-Approval *Renewal* Limits**

None

#### **Rationale**

#### **Summary**

This criteria was created with dosing above FDA limits on these medications in order to help existing patients that have been using doses above the FDA limits to safely taper down their doses to the FDA appropriate levels. This will help eliminate inappropriate use of these medications while still providing adequate relief to patients (1-12).

Prior authorization is required to ensure the safe, clinically appropriate and cost-effective use of the topical products included in this policy while maintaining optimal therapeutic outcomes.

#### **References**

1. Voltaren gel 1% [package insert]. Malvern, PA: Endo Pharmaceuticals Inc.; September 2018.
2. Diclofenac Sodium Topical Solution [package insert]. Weston, FL: Apotex Corp.; May 2016.
3. Pennsaid Topical Solution 2% [package insert]. Lake Forest, IL: Horizon Pharma USA Inc., March 2020.
4. Dovonex [package insert]. Dublin, Ireland: LEO Laboratories, LTD.; October 2018.
5. Taclonex Ointment [package insert]. Dublin, Ireland: LEO Pharma, Inc.; June 2017.
6. Taclonex Topical Suspension [package insert]. Madison, NJ: LEO Pharma Inc.; June 2017.
7. Enstilar Foam [package insert]. Madison, NJ: LEO Pharma Inc.; June 2017.
8. Duobrii Lotion [package insert]. Bridgewater, NJ: Bausch Health Americas, Inc.; January 2020.
9. Bryhali Lotion [package insert]. Bridgewater, NJ: Bausch Health Americas, Inc.; June 2020.
10. Lexette Topical Foam [package insert]. Greenville, NC: Mayne Pharma; April 2019.
11. Sorilux Foam [package insert]. Greenville, NC: Mayne Pharma; November 2019.

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12. Wyzora Cream [package insert]. Dover, DE: MC2 Therapeutics; July 2020.

### Policy History

Date	Action
February 2018	Addition to PA
April 2018	Addition of Betamethasone dipropionate ointment 0.05%, diclofenac sodium gel 1% (Voltaren Gel), and fluocinonide cream 0.05% (Lidex-E) to criteria
May 2018	Addition of Calcipotriene and Betamethasone Dipropionate Ointment 0.005%/0.064% (Taclonex)
June 2018	Annual review
October 2018	Addition of Apexicon E (diflorasone diacetate) and Locoid (hydrocortisone butyrate)
November 2018	Annual review and reference update
January 2019	Addition of Halobetasol Lotion 0.01% (Bryhali)
February 2019	Addition of Pennsaid 2% and statement to Pennsaid products and Taclonex: *Prior authorization for the brand formulation applies only to formulary exceptions due to being a non-covered medication
March 2019	Annual review. Addition of Locoid lipocream, lotion, solution, ointment; Enstilar foam; Taclonex suspension; Cordran/Nolix cream, lotion, ointment
August 2019	Addition of Duobrii Lotion
December 2019	Annual review. Removal of Locoid lipocream, lotion, solution, ointment; Cordran/Nolix cream, lotion, ointment; Duobrii Lotion; Bryhali Lotion; Betamethasone dipropionate ointment 0.05%; Lidex-E and Apexicon E to move to Topical Corticosteroid criteria. Also removed PA quantity limits
January 2020	Addition of Duobrii, Bryhali, and Lexette. Changed generic Taclonex suspension to MFE with PA only due to being a non-covered medication
March 2020	Annual review
August 2020	Addition of Sorilux foam and Wyzora cream
September 2020	Annual review. Revision made: generic Taclonex suspension no longer requires MFE and now has a Pre-PA allowance
March 2021	Annual editorial review and reference update

### Keywords

**This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 12, 2021 and is effective on April 1, 2021.**