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Section:	Prescription Drugs	**Effective Date:**	January 1, 2024
Subsection:	Topical Products	**Original Policy Date:**	February 16, 2018
Subject:	Topical Products with Quantity Limits	**Page:**	1 of 7

Last Review Date: December 8, 2023

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)

* Non-covered medications must go through prior authorization and the formulary exception process.

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 about the possible complications of these drugs and the extent of the problem because of irrational

use of these drugs. The policy 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 indications:

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. Diclofenac sodium topical solution 2% (Pennsaid) 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).

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** if the conditions indicated below are met.

The topical products included in this policy may be considered **investigational** 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%

1. Inadequate treatment response, intolerance, or contraindication to a generic halobetasol topical product

AND the following for:

Halobetasol propionate and tazarotene lotion (Duobrii):

1. Inadequate treatment response, intolerance, or contraindication to a generic halobetasol topical product **AND** a generic tazarotene topical product

Prior – Approval *Renewal* Requirements

Duobrii only:

Diagnosis

Patient must have the following:

FDA-approved indication supporting the use of topical product

1. Improvement in condition

Policy Guidelines

Pre - PA Allowance

Quantity

Drug	Quantity Limit
Diclofenac sodium gel 1%	1000 units per 90 days
Diclofenac sodium topical solution 1.5%	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	Duration

For all topicals above	Pre-PA allows for the American Academy of Dermatology (AAD) recommended dosage	90 days
Wynzora cream 0.005%/0.064% (calcipotriene and betamethasone dipropionate)	840 units per 56 days	56 days
Duobrii lotion 0.01/0.045% (halobetasol propionate and tazarotene)	300 units per 90 days	12 months

Quantity

Drug **with Approved Formulary Exception Only**	Quantity Limit	Duration
Bryhali lotion 0.01% **brand** (halobetasol propionate)	400 units per 90 days	90 days
Lexette topical foam 0.05% **brand** (halobetasol propionate)	100 units per 90 days	90 days
Pennsaid topical solution 2% (diclofenac sodium) **brand** and **generic**	9 bottles per 90 days	90 days
Taclonex ointment 0.005%/0.064% **brand** (calcipotriene and betamethasone dipropionate)	120 units per 90 days	90 days
Taclonex suspension 0.005%/0.064% **brand** (calcipotriene and betamethasone dipropionate)	120 units per 90 days	90 days
Voltaren gel 1% **brand** (diclofenac sodium)	1000 units per 90 days	90 days

Prior–Approval *Renewal* Limits

Quantity

Drug	Quantity Limit	Duration
Duobrii lotion 0.01/0.045% (halobetasol propionate and tazarotene)	300 units per 90 days	12 months

Rationale

Summary
This policy 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.
12. Wynzora 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 Wynzora 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
September 2021	Per FEP: changed Duobrii's PA duration from 90 days to 12 months with renewal allowed
December 2021	Annual review. Voltaren (brand name only) requires formulary exception + PA
June 2022	Added diclofenac sodium 2% to the formulary exception + PA chart due to being a plan exclusion
September 2022	Annual review
December 2022	Annual review
September 2023	Annual review
December 2023	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 8, 2023 and is effective on January 1, 2024.