Section: Prescription Drugs
Subsection: Topical Products
Subject: Topical Products with Quantity Limits
Effective Date: January 1, 2020
Original Policy Date: February 16, 2018
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Last Review Date: December 6, 2019

Topical Products with Quantity Limits

Description

Dovonex Cream 0.005% (calcipotriene)
Enstilar Foam 0.005/0.064% (calcipotriene and betamethasone dipropionate)
Pennsaid* Topical Solution 1.5% (diclofenac sodium)
Pennsaid* Topical Solution 2% (diclofenac sodium)
Taclonex* Ointment, Suspension 0.005/0.064% (calcipotriene and betamethasone dipropionate)
Voltaren Gel 1% (diclofenac sodium)

* 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 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 (1-23).

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 (1).
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: (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).

Related policies

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

Prior – Approval Renewal Requirements
None

Policy Guidelines

Pre - PA Allowance

Quantity

<table>
<thead>
<tr>
<th>Drug</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diclofenac Sodium Gel 1% (Voltaren)</td>
<td>1000 units per 90 days</td>
</tr>
<tr>
<td>Diclofenac Sodium Topical Solution 1.5% (Pennsaid)</td>
<td>9 bottles per 90 days</td>
</tr>
<tr>
<td>Calcipotriene Cream 0.005% (Dovonex)</td>
<td>120 units per 90 days</td>
</tr>
<tr>
<td>Calcipotriene and Betamethasone Dipropionate Ointment, Suspension 0.005%/0.064%</td>
<td>120 units per 90 days</td>
</tr>
<tr>
<td>Calcipotriene and Betamethasone Dipropionate Foam 0.005%/0.064% (Enstilar)</td>
<td></td>
</tr>
</tbody>
</table>

Prior - Approval Limits
Pre-PA allows for the FDA recommended maximum dosage

Quantity

<table>
<thead>
<tr>
<th>Drug with approved MFE only</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pennsaid Topical Solution 2%</td>
<td>9 bottles per 90 days</td>
</tr>
<tr>
<td>Taclonex Ointment, Suspension 0.005%/0.064%</td>
<td>120 units per 90 days</td>
</tr>
</tbody>
</table>

Prior–Approval Renewal Limits
None
Rationale

Summary
Diclofenac sodium topical solution and Pennsaid topical solution are nonsteroidal anti-inflammatory drugs indicated for the treatment of signs and symptoms of osteoarthritis of the knee(s), and diclofenac sodium topical gel 1% is used for the treatment of osteoarthritis of joints amenable to treatment. Calcipotriene Cream 0.005% and Calcipotriene and Betamethasone Dipropionate Ointment 0.005%/0.064% are indicated for the treatment of plaque psoriasis. 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 allow physicians the time to work with their patients in creating a custom taper that is safe and provides adequate relief (1-7).

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

Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>February 2018</td>
<td>Addition to PA</td>
</tr>
<tr>
<td>April 2018</td>
<td>Addition of Betamethasone dipropionate ointment 0.05%, diclofenac sodium gel 1% (Voltaren Gel), and fluocinonide cream 0.05% (Lidex-E) to criteria</td>
</tr>
<tr>
<td>May 2018</td>
<td>Addition of Calcipotriene and Betamethasone Dipropionate Ointment 0.005%/0.064% (Taclonex)</td>
</tr>
<tr>
<td>June 2018</td>
<td>Annual review</td>
</tr>
<tr>
<td>October 2018</td>
<td>Addition of Apexicon E (diflorasone diacetate) and Locoid (hydrocortisone butyrate)</td>
</tr>
</tbody>
</table>
### Section: Prescription Drugs

**Effective Date:** January 1, 2020

### Subsection: Topical Products

**Original Policy Date:** February 16, 2018

### Subject: Topical Products with Quantity Limits

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<table>
<thead>
<tr>
<th>Date</th>
<th>Event Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>November 2018</td>
<td>Annual review and reference update</td>
</tr>
<tr>
<td>January 2019</td>
<td>Addition of Halobetasol Lotion 0.01% (Bryhali)</td>
</tr>
<tr>
<td>February 2019</td>
<td>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</td>
</tr>
<tr>
<td>March 2019</td>
<td>Annual review. Addition of Locoid lipocream, lotion, solution, ointment; Enstilar foam; Taclonex suspension; Cordran/Nolix cream, lotion, ointment</td>
</tr>
<tr>
<td>August 2019</td>
<td>Addition of Duobrii Lotion</td>
</tr>
<tr>
<td>December 2019</td>
<td>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</td>
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**Keywords**

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This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 6, 2019 and is effective on January 1, 2020.