**TOPICAL PRODUCTS WITH QUANTITY LIMITS**

- Apexicon E Topical Cream 0.05% (diflorasone diacetate)
- Bryhali* Lotion 0.01% (halobetasol propionate)
- Cordran Cream 0.025% (flurandrenolide)
- Cordran Cream, Lotion, Ointment 0.05% (flurandrenolide)
- Diprosone Ointment 0.05% (betamethasone dipropionate)
- Dovonex Cream 0.005% (calcipotriene)
- Duobrii** Lotion 0.01/0.045% (halobetasol propionate and tazarotene)
- Enstilar Foam 0.005/0.064% (calcipotriene and betamethasone dipropionate)
- Lexette* Topical Foam 0.05% (halobetasol propionate)
- Lidex-E Cream 0.05% (fluocinonide)
- Locoid Cream, Lipocream, Lotion, Ointment, Solution 0.1% (hydrocortisone butyrate)
- Nolix Cream, Lotion 0.05% (flurandrenolide)
- Pennsaid* Topical Solution 1.5% (diclofenac sodium)
- Pennsaid* Topical Solution 2% (diclofenac sodium)
- Taclonex* Ointment, Suspension 0.005/0.064% (calcipotriene and betamethasone dipropionate)
- Vanos Cream 0.1% (fluocinonide)
- Voltaren Gel 1% (diclofenac sodium)

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

** These medications are currently pending tier determination and may not be available at this time.

** RATIONALE FOR INCLUSION IN PA PROGRAM**

**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. Betamethasone Dipropionate Ointment 0.05% (Diprosone) is a topical corticosteroid indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses (1).
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Apexicon E Topical Cream 0.05% (diflornasone diacetate)
Bryhali* Lotion 0.01% (halobetasol propionate)
Cordran Cream 0.025% (flurandrenolide)
Cordran Cream, Lotion, Ointment 0.05% (flurandrenolide)
Diprosone Ointment 0.05% (betamethasone dipropionate)
Dovonex Cream 0.005% (calcipotriene)
Duobrii** Lotion 0.01/0.045% (halobetasol propionate and tazarotene)
Enstilar Foam 0.005/0.064% (calcipotriene and betamethasone dipropionate)
Lexette* Topical Foam 0.05% (halobetasol propionate)
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Vanos Cream 0.1% (fluocinonide)
Voltaren Gel 1% (diclofenac sodium)

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Limitations of use:
Betamethasone dipropionate products should not be used with occlusive dressings (1).
Apply a thin film of betamethasone dipropionate ointment to the affected skin areas once daily.
In some cases, twice daily dosage may be necessary (1).

2. 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 (2).

Limitations of use:
Diclofenac gel 1% has not been evaluated for use on the spine, hip, or shoulder. A history of asthma, urticarial, or allergic type reactions after taking aspirin or other NSAIDs is considered a contraindication to use of this medication (2).

Total dose should not exceed 32 g per day, over all affected joints (2).

3. 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) (3).
TOPOCAL PRODUCTS WITH QUANTITY LIMITS

Apexicon E Topical Cream 0.05% (diflorasone diacetate)
Bryhali* Lotion 0.01% (halobetasol propionate)
Cordran Cream 0.025% (flurandrenolide)
Cordran Cream, Lotion, Ointment 0.05% (flurandrenolide)
Diprosone Ointment 0.05% (betamethasone dipropionate)
Dovonex Cream 0.005% (calcipotriene)
Duobrii** Lotion 0.01/0.045% (halobetasol propionate and tazarotene)
Enstilar Foam 0.005/0.064% (calcipotriene and betamethasone dipropionate)
Lexette* Topical Foam 0.05% (halobetasol propionate)
Lidex-E Cream 0.05% (fluocinonide)
Locoid Cream, Lipocream, Lotion, Ointment, Solution 0.1% (hydrocortisone butyrate)
Nolix Cream, Lotion 0.05% (flurandrenolide)
Pennsaid* Topical Solution 1.5% (diclofenac sodium)
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Voltaren Gel 1% (diclofenac sodium)

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Limitations of use:
Most common adverse effects from this medication are application site reactions. A history of asthma, urticarial, or allergic type reactions after taking aspirin or other NSAIDs is considered a contraindication to use of this medication (3).

Use the lowest effective dosage for the shortest duration consistent with individual patient treatment goals. The recommended dose is 40 drops on each painful knee, 4 times a day (3).

4. Pennsaid Topical Solution 2% is a nonsteroidal anti-inflammatory drug indicated for the treatment of pain of osteoarthritis of the knee(s) (4).

5. Calcipotriene Cream 0.005% (Dovonex) is indicated for the treatment of plaque psoriasis. (4)

Limitations of Use:
The safety and effectiveness of topical calcipotriene in dermatoses other than psoriasis have not been established. Dovonex should not be used by patients with demonstrated
TOPICAL PRODUCTS WITH QUANTITY LIMITS

Apexicon E Topical Cream 0.05% (diflorasone diacetate)
Bryhali* Lotion 0.01% (halobetasol propionate)
Cordran Cream 0.025% (flurandrenolide)
Cordran Cream, Lotion, Ointment 0.05% (flurandrenolide)
Diprosone Ointment 0.05% (betamethasone dipropionate)
Dovonex Cream 0.005% (calcipotriene)
Duobrii** Lotion 0.01/0.045% (halobetasol propionate and tazarotene)
Enstilar Foam 0.005/0.064% (calcipotriene and betamethasone dipropionate)
Lexette* Topical Foam 0.05% (halobetasol propionate)
Lidex-E Cream 0.05% (fluocinonide)
Locoid Cream, Lipocream, Lotion, Ointment, Solution 0.1% (hydrocortisone butyrate)
Nolix Cream, Lotion 0.05% (flurandrenolide)
Pennsaid* Topical Solution 1.5% (diclofenac sodium)
Pennsaid* Topical Solution 2% (diclofenac sodium)
Taclonex* Ointment, Suspension 0.005/0.064% (calcipotriene and betamethasone dipropionate)
Vanos Cream 0.1% (fluocinonide)
Voltaren Gel 1% (diclofenac sodium)

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hypercalcemia or evidence of vitamin D toxicity. Dovonex Cream should not be used on the face (4).

Apply a thin layer of Dovonex Cream to the affected skin twice daily and rub in gently and completely. The safety and efficacy of Dovonex Cream have been demonstrated in patients treated for eight weeks (4).

6. 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 (6).

Limitations of use:

Adult patients should not use more than 100 grams per week. Patients age 12 to 17 years should not use more than 60 grams per week. Not for use on the face, groin, or axillae (6).
TOPICAL PRODUCTS WITH QUANTITY LIMITS

Apexicon E Topical Cream 0.05% (diflorasone diacetate)
Bryhali* Lotion 0.01% (halobetasol propionate)
Cordran Cream 0.025% (flurandrenolide)
Cordran Cream, Lotion, Ointment 0.05% (flurandrenolide)
Diprosone Ointment 0.05% (betamethasone dipropionate)
Dovonex Cream 0.005% (calcipotriene)
Duobrii** Lotion 0.01/0.045% (halobetasol propionate and tazarotene)
Enstilar Foam 0.005/0.064% (calcipotriene and betamethasone dipropionate)
Lexette* Topical Foam 0.05% (halobetasol propionate)
Lidex-E Cream 0.05% (fluocinonide)
Locoid Cream, Lipocream, Lotion, Ointment, Solution 0.1% (hydrocortisone butyrate)
Nolix Cream, Lotion 0.05% (flurandrenolide)
Pennsaid* Topical Solution 1.5% (diclofenac sodium)
Pennsaid* Topical Solution 2% (diclofenac sodium)
Taclonex* Ointment, Suspension 0.005/0.064% (calcipotriene and betamethasone dipropionate)
Vanos Cream 0.1% (fluocinonide)
Voltaren Gel 1% (diclofenac sodium)

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7. 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:
   a. Plaque psoriasis of the scalp and body in patients 18 years and older.
   b. Plaque psoriasis of the scalp in patients age 12 to 17 years.

8. 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 (8).

9. Fluocinonide Cream 0.05% (Lidex) is indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid responsive dermatoses (9).

Limitations of use:
Topical corticosteroids are contraindicated in those patients with a history of hypersensitivity to any of the components of the preparation (9).
Topical Products with Quantity Limits

**Clinical Rationale**

10. Fluocinonide Cream 0.1% (Vanos) is indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid responsive dermatoses in patients 12 years of age or older (10).

**Limitations of use:**

Treatment beyond 2 consecutive weeks is not recommended and the total dosage should not exceed 60 g per week because the safety of Vanos Cream for longer than 2 weeks has not been established and because of the potential for the drug to suppress the hypothalamic-pituitary-adrenal (HPA) axis. Therapy should be discontinued when control of the disease is achieved. If no improvement is seen within 2 weeks, reassessment of the diagnosis may be necessary. Do not use more than half of the 120 g tube per week. Vanos Cream should not be used in the treatment of rosacea or perioral dermatitis, and should not be used on the face, groin, or axillae (10).

11. Diflorasone diacetate cream 0.05% (Apexicon E) is indicated for relief of the inflammatory and pruritic manifestations of corticosteroid responsive dermatoses (11).
**TOPICAL PRODUCTS WITH QUANTITY LIMITS**

Apexicon E Topical Cream 0.05% (diluracine diacetate)  
Bryhali* Lotion 0.01% (halobetasol propionate)  
Cordran Cream 0.025% (flurandrenolide)  
Cordran Cream, Lotion, Ointment 0.05% (flurandrenolide)  
Diprosone Ointment 0.05% (betamethasone dipropionate)  
Dovonex Cream 0.005% (calcipotriene)  
Duobrii** Lotion 0.01/0.045% (halobetasol propionate and tazarotene)  
Enstilar Foam 0.005/0.064% (calcipotriene and betamethasone dipropionate)  
Lexette* Topical Foam 0.05% (halobetasol propionate)  
Lidex-E Cream 0.05% (fluocinonide)  
Locoid Cream, Lipocream, Lotion, Ointment, Solution 0.1% (hydrocortisone butyrate)  
Nolix Cream, Lotion 0.05% (flurandrenolide)  
Pennsaid* Topical Solution 1.5% (diclofenac sodium)  
Pennsaid* Topical Solution 2% (diclofenac sodium)  
Taclonex* Ointment, Suspension 0.005/0.064% (calcipotriene and betamethasone dipropionate)  
Vanos Cream 0.1% (fluocinonide)  
Voltaren Gel 1% (diclofenac sodium)

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12. Halobetasol propionate foam (Lexette) and lotion (Bryhali) is indicated for the topical treatment of plaque psoriasis in adults (12-13).

13. Hydrocortisone butyrate (Locoid cream, Locoid Lipocream, and Locoid Ointment) is indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses. Hydrocortisone butyrate (Locoid Lipocream) is also indicated for the treatment of mild to moderate atopic dermatitis in patients 3 months to 18 years of age. Hydrocortisone butyrate (Locoid lotion) is indicated for the topical treatment of mild to moderate atopic dermatitis in patients 3 months of age and older. Hydrocortisone butyrate (Locoid solution) is indicated for the relief of the inflammatory and pruritic manifestations of seborrheic dermatitis (14-18).

14. Flurandrenolide cream, lotion, ointment (Cordran, Nolix) are indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses (19-22).

15. Halobetasol propionate and tazarotene lotion (Duobrii) is indicated for the topical treatment of plaque psoriasis in adults (23).
**TOPICAL PRODUCTS WITH QUANTITY LIMITS**

- Apexicon E Topical Cream 0.05% (diflorasone diacetate)
- Bryhali* Lotion 0.01% (halobetasol propionate)
- Cordran Cream 0.025% (flurandrenolide)
- Cordran Cream, Lotion, Ointment 0.05% (flurandrenolide)
- Diprosone Ointment 0.05% (betamethasone dipropionate)
- Dovonex Cream 0.005% (calcipotriene)
- Duobrii** Lotion 0.01/0.045% (halobetasol propionate and tazarotene)
- Enstilar Foam 0.005/0.064% (calcipotriene and betamethasone dipropionate)
- Lexette* Topical Foam 0.05% (halobetasol propionate)
- Lidex-E Cream 0.05% (fluocinonide)
- Locoid Cream, Lipocream, Lotion, Ointment, Solution 0.1% (hydrocortisone butyrate)
- Nolix Cream, Lotion 0.05% (flurandrenolide)
- Pennsaid* Topical Solution 1.5% (diclofenac sodium)
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Duobrii lotion contains tazarotene, which is a teratogenic substance. In females of reproductive potential, a negative pregnancy test should be obtained within 2 weeks prior to initiating treatment and patients should be advised to use an effective method of contraception during treatment (23).

**Summary**

Betamethasone dipropionate ointment 0.05% is a topical corticosteroid indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses. 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. Topical corticosteroids are indicated for the relief of the inflammatory and pruritic manifestations. 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.
TOPICAL PRODUCTS WITH QUANTITY LIMITS

Apexicon E Topical Cream 0.05% (diflorasone diacetate)
Bryhali* Lotion 0.01% (halobetasol propionate)
Cordran Cream 0.025% (flurandrenolide)
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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

**TOPICAL PRODUCTS WITH QUANTITY LIMITS**

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Voltaren Gel 1% (diclofenac sodium)

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<thead>
<tr>
<th>Product Name</th>
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<tbody>
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