<table>
<thead>
<tr>
<th>TOPICAL CORTICOSTEROIDS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Alcovate Cream, Ointment 0.05%</strong> <em>(alclometasone dipropionate)</em></td>
</tr>
<tr>
<td><strong>Apexicon E Cream 0.05%</strong> <em>(diflorasone diacetate)</em></td>
</tr>
<tr>
<td><strong>Ala Scalp Lotion 2%</strong> <em>(hydrocortisone)</em></td>
</tr>
<tr>
<td><strong>Capex Shampoo 0.01%</strong> <em>(fluocinolone acetonide)</em></td>
</tr>
<tr>
<td><strong>Cloderm Cream 0.10%</strong> <em>(clocortolone pivalate)</em></td>
</tr>
<tr>
<td><strong>Clodan Shampoo 0.05%</strong> <em>(clobetasol propionate)</em></td>
</tr>
<tr>
<td><strong>Cordran Cream 0.025%</strong></td>
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<tr>
<td><strong>Cordran Cream, Lotion, Ointment 0.05%</strong></td>
</tr>
<tr>
<td><strong>Cordran Tape 4mcg</strong> <em>(fluorandrenolide)</em></td>
</tr>
<tr>
<td><strong>Cormax Solution 0.05%</strong> <em>(clobetasol propionate)</em></td>
</tr>
<tr>
<td><strong>Cutivate Cream, Lotion 0.05%</strong></td>
</tr>
<tr>
<td><strong>Cutivate Ointment 0.005%</strong> <em>(fluticasone propionate)</em></td>
</tr>
<tr>
<td><strong>Cyclocort Cream, lotion, Ointment 0.1%</strong> <em>(amcinonide)</em></td>
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<tr>
<td><strong>Dermatop Cream, Ointment 0.1%</strong> <em>(prednicarbate)</em></td>
</tr>
<tr>
<td><strong>Desonate Gel 0.05%</strong></td>
</tr>
<tr>
<td><strong>Desonide Cream Lotion, Ointment 0.05%</strong> <em>(desonide)</em></td>
</tr>
<tr>
<td><strong>Desowen Lotion 0.05%</strong> <em>(desonide)</em></td>
</tr>
<tr>
<td><strong>Diprosone Cream, Lotion, Ointment 0.05%</strong> <em>(betamethasone dipropionate)</em></td>
</tr>
<tr>
<td><strong>Diprolene AF Cream, Gel, Lotion, Ointment 0.05%</strong> <em>(betamethasone dipropionate)</em></td>
</tr>
<tr>
<td><strong>Elocon Cream, Ointment, Solution 0.1%</strong> <em>(mometasone furoate)</em></td>
</tr>
<tr>
<td>Halog Cream, Ointment, Solution 0.1% (halcinonide)</td>
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<tr>
<td>--------------------------------------------------</td>
</tr>
<tr>
<td>Hydrocortisone Cream, Lotion, Ointment 1%, 2.5%</td>
</tr>
<tr>
<td>Impoyz Cream 0.025% (clobetasol propionate)</td>
</tr>
<tr>
<td>Lidex E Cream 0.05% (fluocinonide)</td>
</tr>
<tr>
<td>Lidex Gel, Ointment, Solution, Cream 0.05%</td>
</tr>
</tbody>
</table>

*Prior authorization for certain non-covered formulations applies only to formulary exceptions

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**RATIONAL FOR INCLUSION IN PA PROGRAM**

**Background**

The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. 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 in order to limit existing patients that have been taking doses above the FDA recommended limits and get them down to appropriate levels. This criteria is also intended to help prevent use of topical corticosteroids in topical foot baths (1-63).

**Regulatory Status**

FDA approved indication: (1-63)

1. Alclometasone dipropionate, amcinonide, betamethasone dipropionate, betamethasone valerate, clobetasol propionate, clocortolone pivalate, desonide, desoximetasone, diflorasone diacetate, fluocinolone acetonide, fluocinonide, flurandrenolide, fluticasone propionate, halcinonide, halobetasol propionate, hydrocortisone, hydrocortisone acetate, hydrocortisone butyrate, hydrocortisone probutate, hydrocortisone valerate, mometasone furoate, prednicarbate, triamcinolone acetonide are indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses

2. Clobetasol Propionate Emollient Base Cream, Clobex Shampoo, Clobex Lotion, Clobex Spray, Derma-Smooth/FS (Scalp) Oil, Impoyz Cream, Olux Foam, Sernivo Spray, Topicort Spray, Ultravate Lotion are indicated for the treatment of psoriasis.

3. Cutivate Lotion, Derma-Smooth/FS (Body) Oil, Desonate Gel, Locoid Lipocream, Locoid Lotion, Verdeso Foam are indicated for the treatment of atopic dermatitis.
4. Capex Shampoo, Locoid Solution are indicated for the relief of the inflammatory and pruritic manifestations of seborrheic dermatitis.

The approval quantity limit for all TCS is based on the average American Academy of Dermatology (AAD) estimation for twice daily dosing over 9% body surface area (BSA) for acute treatment and for maintenance therapy, taking into consideration the available package sizes across the TCS class. The three month limit will be 460gm or 460mL per month, which is 3 times the one month limit (59-63).

Since manufacturer package sizes may vary, it is the discretion of the dispensing pharmacy to fill quantities up to these quantity limits. In such cases the filling limit and day supply may be less than what is indicated. For example, Pandel is available as an 80 gram tube, the initial limit is set at 460gm as a 90 day supply, therefore if dispensed as 240gm this may be considered less than a 90 day supply (59-63).

Summary
The criteria was created in order to limit existing patients that have been taking doses above the American Academy of Dermatology (AAD) recommended limits and get them down to appropriate levels. This will help eliminate inappropriate use of these medications while still providing adequate relief to patients (1-62).

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
                July 2013.
30. Hydrocortisone Cream 2.5%, Ointment 2.5% [package insert]. Bronx, NY; Perrigo; August 2015.
39. Olux Foam [package insert]. San Antonio, TX: DPT Laboratories, Ltd.; April 2018
40. Olux-E Foam [package insert]. San Antonio, TX: DPT Laboratories, Ltd.; May 2018
57. AHFS DI (Adult and Pediatric) [database online]. Hudson, OH: Lexi-Comp, Inc.;
    http://online.lexi.com/lco/action/index/dataset/complete_ashp [available with subscription].


