

# 5.90.39

<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	April 1, 2021
<b>Subsection:</b>	Topical Products	<b>Original Policy Date:</b>	January 1, 2020
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**Last Review Date:** March 12, 2021

## Topical Corticosteroids

### Description

Alcovate Cream, Ointment 0.05% (alclometasone dipropionate)	Locoid Cream, Lipocream, Lotion, Ointment, Solution 0.1% (hydrocortisone butyrate)
Apexicon E Cream 0.05% (diflorasone diacetate)	Luxiq Foam 0.12% (betamethasone valerate)
Ala Scalp Lotion 2% (hydrocortisone)	Micort-HC Cream 2.5% (hydrocortisone acetate)
Capex Shampoo 0.01% (fluocinolone acetonide)	Nolix Cream, Lotion 0.05% (flurandrenolide)
Cloderm Cream 0.10% (clocortolone pivalate)	Olux Foam 0.05% Olux E Emulsion Foam 0.05% (clobetasol propionate)
Clobex Lotion, Shampoo, Spray 0.05% Clodan Shampoo 0.05% (clobetasol propionate)	Pandel Cream 0.1% (hydrocortisone probutate)
Cordran Cream 0.025% Cordran Cream, Lotion, Ointment 0.05% Cordran Tape 4mcg (flurandrenolide)	Psorcon Cream, Ointment 0.05% (diflorasone)
Cormax Solution 0.05% (clobetasol propionate)	Sernivo Spray 0.05% (betamethasone dipropionate)
Cutivate Cream, Lotion 0.05% Cutivate Ointment 0.005% (fluticasone propionate)	Synalar Cream, Ointment, Solution 0.01% Synalar Cream, Ointment 0.025% (fluocinolone acetonide)

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Cyclocort Cream, lotion, Ointment 0.1% (amcinonide)	Temovate-E Cream 0.05% Temovate Cream, Gel, Ointment, Solution 0.05% (clobetasol propionate)
Derma-smooth /FS body oil 0.01% Derma-smooth /FS scalp oil 0.01% (fluocinolone acetonide)	Texacort Solution 2.5% (hydrocortisone)
Dermatop Cream, Ointment 0.1% (prednicarbate)	Topicort Cream, Gel, Ointment, Spray 0.05% 0.25% (desoximetasone)
Desonate Gel 0.05% Desonide Cream Lotion, Ointment 0.05% Desowen Lotion 0.05% (desonide)	Triamcinolone Cream, Lotion, Ointment, Spray 0.025%, 0.05%, 0.1%, 0.5% Triderm Cream 0.1%, 0.5% Kenalog aerosol spray 0.147 mg/ml (triamcinolone acetonide)
Diprosone Cream, Lotion, Ointment 0.05% Diprolene AF Cream, Gel, Lotion, Ointment 0.05% (betamethasone dipropionate)	Tridesilon Cream 0.05% Verdeso Foam 0.05% (desonide)
Elocon Cream, Ointment, Solution 0.1% (mometasone furoate)	Trianex* Ointment 0.05% (triamcinolone acetonide)
Halog Cream, Ointment, Solution 0.1% (halcinonide)	Ultravate Cream, Lotion, Ointment 0.05% (halobetasol propionate)
Hydrocortisone Cream, Lotion, Ointment 1%, 2.5%	Wescort Cream, Ointment 0.2% (hydrocortisone valerate)
Impoyz Cream 0.025% (clobetasol proprionate)	Valisone Cream, Lotion, Ointment 0.01% (betamethasone valerate)
Lidex E Cream 0.05% Lidex Gel, Ointment, Solution, Cream 0.05% (fluocinonide)	Vanos* Cream, Gel, Ointment, Solution 0.1% (fluocinonide)
	Verdeso Foam 0.05% (desonide)

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

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## 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

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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).

## 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

## Prior – Approval *Renewal* Requirements

None

### Policy Guidelines

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## Pre - PA Allowance

### Quantity

<b>ALCLOMETASONE DIPROPIONATE</b>	<b>Strength</b>	<b>UOM</b>	<b>Potency</b>	<b>3 MONTH LIMIT</b>
ALCLOMETASONE CREAM	0.05%	GM	Low to medium	460
ALCLOMETASONE OINTMENT	0.05%	GM	Low to medium	460
<b>AMCINONIDE</b>	<b>Strength</b>	<b>UOM</b>	<b>Potency</b>	<b>3 MONTH LIMIT</b>
AMCINONIDE CREAM	0.1%	GM	high	460
AMCINONIDE LOTION	0.1%	ML	high	460
AMCINONIDE OINTMENT	0.1%	GM	high	460
<b>BETAMETHASONE DIPROPIONATE</b>	<b>Strength</b>	<b>UOM</b>	<b>Potency</b>	<b>3 MONTH LIMIT</b>
SERNIVO SPRAY	0.05%	ML	medium	460
BETAMETHASONE DIPROPIONATE CREAM	0.05%	GM	medium	460
BETAMETHASONE DIPROPIONATE LOTION	0.05%	ML	medium	460
BETAMETHASONE DIPROPIONATE OINTMENT	0.05%	GM	very high	460
DIPROLENE AF AUGMENTED CREAM	0.05%	GM	high	460
BETAMETHASONE DIPROPIONATE AUGMENTED CREAM	0.05%	GM		
BETAMETHASONE DIPROPIONATE AUGMENTED GEL	0.05%	GM	very high	460
BETAMETHASONE DIPROPIONATE AUGMENTED LOTION	0.05%	ML	very high	460
DIPROLENE AUGMENTED OINTMENT	0.05%	GM	very high	460
BETAMETHASONE DIPROPIONATE AUGMENTED OINTMENT	0.05%	GM		
<b>BETAMETHASONE VALERATE</b>	<b>Strength</b>	<b>UOM</b>	<b>Potency</b>	<b>3 MONTH LIMIT</b>

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BETAMETHASONE VALERATE CREAM	0.1%	GM	medium	460
LUXIQ AEROSOL FOAM	0.12%	GM	medium	460
BETAMETHASONE VALERATE AEROSOL FOAM	0.12%	GM		
BETAMETHASONE VALERATE LOTION	0.1%	ML	medium	460
BETAMETHASONE VALERATE OINTMENT	0.1%	GM	medium	460
<b>CLOBETASOL PROPIONATE</b>	<b>Strength</b>	<b>UOM</b>	<b>Potency</b>	<b>3 MONTH LIMIT</b>
CLOBEX SPRAY	0.05%	ML	very high	460
CLOBETASOL SPRAY	0.05%	ML		
CORMAX SOLUTION	0.05%	ML	high	460
TEMOVATE SOLUTION	0.05%	ML		
IMPOYZ CREAM	0.025%	GM	high	460
TEMOVATE CREAM	0.05%	GM	very high	460
CLOBETASOL CREAM	0.05%	GM		
OLUX AEROSOL FOAM	0.05%	GM	very high	460
CLOBETASOL AEROSOL FOAM	0.05%	GM		
CLOBETASOL GEL	0.05%	GM	very high	460
CLOBEX LOTION	0.05%	ML	very high	460
CLOBETASOL LOTION	0.05%	ML		
TEMOVATE OINTMENT	0.05%	GM	very high	460
CLOBETASOL OINTMENT	0.05%	GM		
CLOBEX SHAMPOO	0.05%	ML	very high	460
CLODAN SHAMPOO	0.05%	ML		
CLOBETASOL E EMOLLIENT CREAM	0.05%	GM	very high	460
OLUX-E AEROSOL EMULSION FOAM	0.05%	GM	very high	460

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CLOBETASOL AEROSOL EMULSION FOAM	0.05%	GM		
<b>CLOCORTOLONE PIVALATE</b>	<b>Strength</b>	<b>UOM</b>	<b>Potency</b>	<b>3 MONTH LIMIT</b>
CLODERM CREAM	0.10%	GM	medium	460
CLOCORTOLONE CREAM	0.10%	GM		
<b>DESONIDE</b>	<b>Strength</b>	<b>UOM</b>	<b>Potency</b>	<b>3 MONTH LIMIT</b>
DESOWEN CREAM	0.05%	GM	Low to medium	460
DESONIDE CREAM	0.05%	GM		
TRIDESILON CREAM	0.05%	GM	Low	
DESONIDE CREAM	0.05%	GM		
VERDESO AEROSOL FOAM	0.05%	GM	Low	460
DESONATE GEL	0.05%	GM	Low	460
DESOWEN LOTION	0.05%	ML	Low to medium	460
DESONIDE LOTION	0.05%	ML		
DESONIDE OINTMENT	0.05%	GM	Low	460
<b>DESOXIMETASONE</b>	<b>Strength</b>	<b>UOM</b>	<b>Potency</b>	<b>3 MONTH LIMIT</b>
TOPICORT SPRAY	0.25%	ML	high to very high	460
DESOXIMETASONE SPRAY	0.25%	ML		
TOPICORT CREAM	0.05%	GM	medium	460
DESOXIMETASONE CREAM	0.05%	GM		
TOPICORT CREAM	0.25%	GM	high	460
DESOXIMETASONE CREAM	0.25%	GM		
TOPICORT GEL	0.05%	GM	high	460
DESOXIMETASONE GEL	0.05%	GM		
TOPICORT OINTMENT	0.05%	GM	high	460

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DESOXIMETASONE OINTMENT	0.05%	GM		
TOPICORT OINTMENT	0.25%	GM	high	460
DESOXIMETASONE OINTMENT	0.25%	GM		
<b>DIFLORASONE DIACETATE</b>	<b>Strength</b>	<b>UOM</b>	<b>Potency</b>	<b>3 MONTH LIMIT</b>
PSORCON CREAM	0.05%	GM	high	460
DIFLORASONE CREAM	0.05%	GM		
DIFLORASONE OINTMENT	0.05%	GM	very high	460
APEXICON E CREAM	0.05%	GM	high	460
<b>FLUOCINOLONE ACETONIDE</b>	<b>Strength</b>	<b>UOM</b>	<b>Potency</b>	<b>3 MONTH LIMIT</b>
DERMA-SMOOTH /FS BODY OIL	0.01%	ML	Low to medium	460
FLUOCINOLONE BODY OIL	0.01%	ML		
DERMA-SMOOTH /FS SCALP OIL	0.01%	ML	Low to medium	460
FLUOCINOLONE SCALP OIL	0.01%	ML		
SYNALAR SOLUTION	0.01%	ML	Low	460
FLUOCINOLONE SOLUTION	0.01%	ML		
FLUOCINOLONE CREAM	0.01%	GM	Low	460
SYNALAR CREAM	0.025%	GM	medium	460
FLUOCINOLONE CREAM	0.025%	GM		
SYNALAR OINTMENT	0.025%	GM	medium	460
FLUOCINOLONE OINTMENT	0.025%	GM		
CAPEX SHAMPOO	0.01%	ML	Low to medium	460
<b>FLUOCINONIDE</b>	<b>Strength</b>	<b>UOM</b>	<b>Potency</b>	<b>3 MONTH LIMIT</b>
FLUOCINONIDE SOLUTION	0.05%	ML	high	460
FLUOCINONIDE CREAM	0.05%	GM	high	460



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FLUOCINONIDE GEL	0.05%	GM	high	460
FLUOCINONIDE OINTMENT	0.05%	GM	high	460
FLUOCINONIDE-E EMULSIFIED CREAM	0.05%	GM	high	460
FLUOCINONIDE CREAM	0.1%	GM	very high	460
FLUOCINONIDE GEL	0.1%	GM	very high	460
FLUOCINONIDE OINTMENT	0.1%	GM	very high	460
FLUOCINONIDE SOLUTION	0.1%	GM	very high	460
<b>FLURANDRENOLIDE</b>	<b>Strength</b>	<b>UOM</b>	<b>Potency</b>	<b>3 MONTH LIMIT</b>
CORDRAN CREAM	0.025%	GM	high	460
CORDRAN CREAM	0.05%	GM	high	460
NOLIX CREAM	0.05%	GM		
CORDRAN LOTION	0.05%	ML	high	460
NOLIX LOTION	0.05%	ML		
CORDRAN OINTMENT	0.05%	GM	high	460
FLURANDRENOLIDE OINTMENT	0.05%	GM		
CORDRAN TAPE	4 MCG	EA	high	2 Rolls
<b>FLUTICASONE PROPIONATE</b>	<b>Strength</b>	<b>UOM</b>	<b>Potency</b>	<b>3 MONTH LIMIT</b>
FLUTICASONE CREAM	0.05%	GM	medium	460
CUTIVATE LOTION	0.05%	ML	medium	460
FLUTICASONE LOTION	0.05%	ML		
FLUTICASONE OINTMENT	0.005%	GM	medium	460
<b>HALCINONIDE</b>	<b>Strength</b>	<b>UOM</b>	<b>Potency</b>	<b>3 MONTH LIMIT</b>
HALOG CREAM	0.1%	GM	high	460
HALOG OINTMENT	0.1%	GM	high	460

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HALOG SOLUTION	0.1%	ML	high	460
<b>HALOBETASOL PROPIONATE</b>	<b>Strength</b>	<b>UOM</b>	<b>Potency</b>	<b>3 MONTH LIMIT</b>
ULTRAVATE CREAM	0.05%	GM	very high	460
HALOBETASOL CREAM	0.05%	GM		
HALOBETASOL AEROSOL FOAM	0.05%	GM		
ULTRAVATE LOTION	0.05%	ML	very high	460
ULTRAVATE OINTMENT	0.05%	GM	very high	460
HALOBETASOL OINTMENT	0.05%	GM		
<b>HYDROCORTISONE</b>	<b>Strength</b>	<b>UOM</b>	<b>Potency</b>	<b>3 MONTH LIMIT</b>
TEXACORT SOLUTION	2.5%	ML	Low	460
HYDROCORTISONE CREAM	1%	GM	Low	460
HYDROCORTISONE CREAM	2.5%	GM	Low	460
ALA SCALP LOTION	2%	ML	Low	460
HYDROCORTISONE LOTION	2.5%	ML	Low	460
HYDROCORTISONE OINTMENT	1%	GM	Low	460
HYDROCORTISONE OINTMENT	2.5%	GM	Low	460
<b>HYDROCORTISONE ACETATE</b>	<b>Strength</b>	<b>UOM</b>	<b>Potency</b>	<b>3 MONTH LIMIT</b>
MICORT-HC CREAM	2.5%	GM	Low	460
<b>HYDROCORTISONE VALERATE</b>	<b>Strength</b>	<b>UOM</b>	<b>Potency</b>	<b>3 MONTH LIMIT</b>
HYDROCORTISONE VALERATE CREAM	0.2%	GM	medium	460
WESTCORT OINTMENT	0.2%	GM	medium	460
HYDROCORTISONE VALERATE OINTMENT	0.2%	GM		
<b>HYDROCORTISONE PROBUTATE</b>	<b>Strength</b>	<b>UOM</b>	<b>Potency</b>	<b>3 MONTH LIMIT</b>
PANDEL CREAM	0.1%	GM	medium	460

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<b>HYDROCORTISONE BUTYRATE</b>	<b>Strength</b>	<b>UOM</b>	<b>Potency</b>	<b>3 MONTH LIMIT</b>
LOCOID SOLUTION	0.1%	ML	medium	460
HYDROCORTISONE BUTYRATE SOLUTION	0.10%	ML		
LOCOID CREAM	0.1%	GM	medium	460
HYDROCORTISONE BUTYRATE CREAM	0.1%	GM		
LOCOID LOTION	0.1%	ML	medium	460
HYDROCORTISONE LOTION	0.1%	ML		
LOCOID OINTMENT	0.1%	GM	medium	460
HYDROCORTISONE BUTYRATE OINTMENT	0.1%	GM		
LOCOID HYDROPHILIC LIPOCREAM	0.1%	GM	medium	460
HYDROCORTISONE BUTYRATE HYDROPHILIC LIPOCREAM	0.10%	GM		
<b>MOMETASONE FUROATE</b>	<b>Strength</b>	<b>UOM</b>	<b>Potency</b>	<b>3 MONTH LIMIT</b>
MOMETASONE SOLUTON	0.1%	ML	medium	460
ELOCON CREAM	0.1%	GM	medium	460
MOMETASONE CREAM	0.1%	GM		
ELOCON OINTMENT	0.1%	GM	medium	460
MOMETASONE OINTMENT	0.1%	GM		
<b>PREDNICARBATE</b>	<b>Strength</b>	<b>UOM</b>	<b>Potency</b>	<b>3 MONTH LIMIT</b>
PREDNICARBATE CREAM	0.1%	GM	medium	460
DERMATOP OINTMENT	0.1%	GM	medium	460
PREDNICARBATE OINTMENT	0.1%	GM		
<b>TRIAMCINOLONE ACETONIDE</b>	<b>Strength</b>	<b>UOM</b>	<b>Potency</b>	<b>3 MONTH LIMIT</b>
KENALOG AEROSOL SPRAY	SPRAY	GM	high	460
TRIAMCINOLONE AEROSOL SPRAY	SPRAY	GM		

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TRIAMCINOLONE CREAM	0.025%	GM	medium	460
TRIAMCINOLONE CREAM	0.1%	GM	medium	460
TRIAMCINOLONE CREAM	0.5%	GM	high	460
TRIAMCINOLONE LOTION	0.025%	ML	medium	460
TRIAMCINOLONE LOTION	0.1%	ML	medium	460
TRIAMCINOLONE OINTMENT	0.025%	GM	medium	460
TRIANEX OINTMENT	0.05%	GM	medium	None
TRIAMCINOLONE OINTMENT	0.1%	GM	medium	460
TRIAMCINOLONE OINTMENT	0.5%	GM	high	460

\*Pre-PA allows for the American Academy of Dermatology (AAD) recommended dosage

\*Patients are limited to 460 units per 90 days of any combination of the above (excluding Cordran tape) for Pre-PA

## Prior - Approval Limits

### Quantity

Drug	Quantity Limit
For All Topicals Above	Pre-PA allows for the American Academy of Dermatology (AAD) recommended dosage

Medication <u>with approved formulary exception only</u>	Strength	UOM	Potency	3 MONTH LIMIT
TRIANEX OINTMENT	0.05%	GM	medium	460
VANOS (FLUOCINONIDE CREAM)	0.1%	GM	very high	460

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## Prior-Approval *Renewal* Limits

None

### Rationale

#### 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

1. Ala Scalp Lotion [package insert]. Johnson City, TN: Crown Laboratories, Inc.; May 2017.
2. Alclometasone Ointment [package insert]. Hawthorne, NY: Taro Pharmaceuticals Inc.; January 2017.
3. Amcinonide Cream [package insert]. Melville, NY: Fougera Pharmaceuticals Inc.; August 2012.
4. ApexiCon E Cream [package insert]. Melville, NY: PharmaDerm; October 2018.
5. Betamethasone Dipropionate Cream [package insert]. South Plainfield, NJ: G&W Laboratories, Inc.; June 2015.
6. Betamethasone Dipropionate Ointment [package insert]. Buena, New Jersey: Teligent Pharma, Inc.; September 2017.
7. Betamethasone Dipropionate Augmented Lotion [package insert]. Melville, NY: Fougera Pharmaceuticals Inc.; May 2018.
8. Betamethasone Valerate Lotion [package insert]. Newtown, PA: STI Pharma LLC; July 2017.
9. Capex Shampoo [package insert]. Fort Worth, Texas: Galderma Laboratories, L.P.; December 2015
10. Clobetasol Propionate Emollient Base Cream [package insert]. Melville, New York: Fougera Pharmaceuticals Inc., September 2016.
11. Clobex Spray [package insert]. Fort Worth, TX: Galderma Laboratories, L.P.; January 2019.
12. Cloderm Cream [package insert]. San Antonio, TX: DPT Laboratories; June 2017.
13. Cordran Cream, Ointment [package insert]. San Antonio, TX: DPT Laboratories; May 2017.
14. Cutivate Lotion [package insert]. Melville, NY: PharmaDerm; July 2015.
15. Derma-Smoothe/FS Body Oil [package insert]. Sanford, FL: Hill Dermaceuticals, Inc.; October 2013.
16. Derma-Smoothe/FS Scalp Oil [package insert]. Sanford, FL: Hill Dermaceuticals, Inc.; January 2014.
17. Dermatop Ointment [package insert]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; November 2012.
18. Desonate Gel [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; July 2014.
19. Desonide Ointment [package insert]. Hawthorne, NY: Taro Pharmaceuticals U.S.A., Inc.; October 2015.

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## Policy History

Date	Action
December 2019	Addition to PA – QL established to limit foot bath use/waste
January 2020	Removed Duobrii, Bryhali, and Lexette from policy to add to Topical Products with Quantity Limits policy. Pre-PA quantity changed to 460/90 from 360/90
March 2020	Annual review
June 2020	Addition of Halog Solution
September 2020	Annual review
December 2020	Trianex and Vanos require formulary exception + PA
March 2021	Annual review

## Keywords

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