BlueCross BlueShield
Federal Employee Program

TOPICAL PRODUCTS WITH QUANTITY LIMITS

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.

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 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).

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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).

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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).

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.

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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.