DRUG QUANTITY MANAGEMENT POLICY - PER DAYS

POLICY: Topical Corticosteroids – Flurandrenolide Drug Quantity Management Policy – Per Days

- Cordran® (flurandrenolide cream 0.025% and 0.05% [generic], ointment 0.05% [generic], lotion 0.05% [generic] Almirall)
- Nolix[™] (flurandrenolide cream 0.05%, lotion 0.05% Artesa Labs, generic)

REVIEW DATE: 03/23/2022

OVERVIEW

Flurandrenolide cream, lotion and ointment are indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses, including moderate to severe plaque psoriasis.¹⁻⁴

Moderate to severe psoriasis is typically defined as involvement of more than 5% to 10% of the body surface area or involvement of the face, palm or sole, or disease that is otherwise disabling. For reference, the entire palmar surface, including fingers, of one hand is approximately 1% percent of the body surface area. Patients with > 5% to 10% body surface area affected are generally candidates for phototherapy or systemic therapy, since application of topical agents to a large area is not usually practical or acceptable for most patients.

Dosing/Availability

Flurandrenolide cream, lotion and ointment are applied to the affected area two to three times daily.¹⁻³

Cordran 0.025% cream is supplied in 120 gram tubes.² Flurandrenolide 0.05 % cream is supplied in 60 gram and 120 gram tubes; Cordran 0.05% cream is supplied in 120 gram tubes and Nolix 0.05% gram is supplied in 60 gram tubes.^{2,3} Flurandrenolide 0.05% lotion (Cordran, Nolix, generic) is supplied in 120 gram bottles.^{1,4} Flurandrenolide 0.05% ointment (Cordran, generic) is supplied in 60 gram tubes.²

Application Information

When determining the amount of a topical corticosteroid to apply, a standard measure, the fingertip unit (FTU), is often used.⁵ One FTU is the amount of product that is squeezed out of a standard tube along an adult's fingertip. One FTU is equivalent to approximately 0.5 g and provides enough product to treat an area of skin that is twice the size of one adult hand, or approximately 2% of an adult's total body surface area (BSA). Therefore, it is assumed that 1 g of a topical corticosteroid would provide enough product for one application to approximately 4% of the patient's BSA. For children, an FTU is still the amount of product that will fit on an adult's index fingertip. The amount of BSA that the application will cover depends on the size of the child.

Based on the FTU method, the quantity limits below provide enough flurandrenolide cream, ointment, or lotion to cover approximately 8% of the patient's BSA when applying two times daily for 1 month.

POLICY STATEMENT

This Drug Quantity Management program has been developed to prevent stockpiling, misuse, and/or overuse of flurandrenolide. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for 1 year in duration.

Automation: None.

Drug Quantity Limits

Product	Package Size	Maximum Quantity per 30 Days
Cordran [®]	120 gram tube	120 grams*
(flurandrenolide cream 0.025%)		
flurandrenolide cream 0.05%	60 gram tube	120 grams*
(Cordran [®] , Nolix [™] , generics)	120 gram tube	-
Flurandrenolide ointment 0.05%	60 gram tube	120 grams*
(Cordran®, generics)		
Flurandrenolide lotion 0.05%	120 mL bottle	120 mL*
(Cordran [®] , Nolix [™] , generics)		

This is enough drug to cover 8% of the body surface area when applying two times daily for 30 days.

CRITERIA

Approval of additional quantities of topical flurandrenolide products is recommended if the patient is using the product for an FDA-approved indication and meets one of the following criteria:

Cordran 0.025% cream

- 1. If a patient needs to treat greater than 8% of body surface area, approve up to 240 grams per month.
- 2. If a patient needs to administer the medication more frequently than two times a day, approve up to 240 grams per month.

<u>flurandrenolide 0.05% cream (Cordran, Nolix, generic)</u>, and <u>flurandrenolide 0.05% ointment (Cordran, generic)</u>

- 1. If a patient needs to treat greater than 8% of body surface area, approve up to 180 grams per month.
- 2. If a patient needs to administer the medication more frequently than two times a day, approve up to 180 grams per month.

Flurandrenolide lotion (Cordran, Nolix, generic)

- 1. If a patient needs to treat greater than 8% of body surface area or is administering more frequently than two times a day, approve up to 240 mL per month.
- 2. If a patient needs to administer the medication more frequently than two times a day, approve up to 240 mL per month.

EXCLUSIONS

Approval of additional quantities of topical flurandrenolide products is NOT recommended in the following situations:

- 1. No overrides are recommended for use in compounded formulations.
- 2. No overrides are recommended for any non-FDA-approved indications.

REFERENCES

- 1. Cordran Lotion, 0.05% [prescribing information]. Malvern PA: Almirall; July 2016.
- 2. Cordran Cream, 0.025%, 0.05%; Cordran Ointment, 0.05% [prescribing information]. Malvern PA: Almirall; May 2017.

$\label{eq:continuous} \mbox{Topical Corticosteroids} - \mbox{Flurandrenolide DQM Policy} - \mbox{Per Days} \\ \mbox{Page 3}$

- 3. Nolix Cream, 0.05% [prescribing information]. Austin, TX: Artesa Labs; August 2017.
- 4. Nolix Lotion, 0.05% [prescribing information]. Austin, TX: Artesa Labs; October 2017.
- 5. Eichenfeld LF, Tom WL, Berger TG, et al. Guidelines of care for the management of atopic dermatitis. *J Am Acad Dermatol*. 2014;71:116-132.