



Effective Date..... 2/1/2023
 Next Review Date..... 2/1/2024

Drug Quantity Management – Per Days Topical Corticosteroids – Diflorasone

Table of Contents

National Formulary Medical Necessity1
 Conditions Not Covered.....2
 Background.....2
 References2
 Revision History.....3

Product Identifier(s)

Effective 1/1/23 to 2/6/23: 108150
Effective 2/7/23: 65507

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

National Formulary Medical Necessity

Drugs Affected

- diflorasone 0.05% cream (generic only)
- diflorasone 0.05% ointment (generic only)

This Drug Quantity Management program has been developed to prevent stockpiling, misuse, and/or overuse of topical diflorasone. 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, unless noted below.

Drug Quantity Limits

Product	Package Size	Retail Maximum Quantity per 30 days	Home Delivery Maximum Quantity Per 90 days
diflorasone 0.05% cream (generic only)	30 g tube	120 grams	360 grams
	60 g tube		
diflorasone 0.05% ointment	15 g tube	120 grams	360 grams

(generic only)			
----------------	--	--	--

Criteria

Cigna covers quantities of diflorasone 0.05% cream and diflorasone 0.05% ointment as medically necessary if the individual is using the product for an FDA-approved indication and meets one of the following criteria:

1. If the individual needs to treat greater than 8% of body surface area, approve the quantity requested, not to exceed 180 grams per 30 days at retail or 540 grams per 90 days at home delivery.
2. If the individual needs to administer topical diflorasone more frequently than two times per day, approve the requested quantity, not to exceed 180 grams per 30 days at retail or 540 grams per 90 days at home delivery.

Conditions Not Covered

Any other exception is considered not medically necessary, including the following:

1. No overrides are recommended for use in any compounded formulations.

Background

Overview

Diflorasone, a high-potency topical corticosteroid, is indicated for the relief of the inflammatory and pruritic manifestations of **corticosteroid-responsive dermatoses**.^{1,2} Psoriasis and atopic dermatitis are examples of two corticosteroid-responsive dermatoses.

Dosing/Availability

Diflorasone 0.05% cream can be applied to the affected area twice daily,¹ whereas diflorasone 0.05% ointment can be applied up to three times daily.² Diflorasone cream is available in 30 g and 60 g tubes. Diflorasone ointment is available in 15 g, 30 g, 45 g, and 60 g tubes.^{1,2}

Application Information

When determining the amount of a topical corticosteroid to apply, a standard measure, the fingertip unit (FTU), is often used.³ 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 diflorasone cream or ointment to cover approximately 8% of the patient's BSA when applying two times daily for 30 days (at retail) or 90 days (at home delivery).

References

1. Diflorasone 0.05% cream [prescribing information]. Hawthorne, NY: Taro, December 2019.
2. Diflorasone 0.05% ointment [prescribing information]. Hawthorne, NY: Taro, January 2020.
3. 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.

Revision History

Type of Revision	Summary of Changes	Approval Date
Annual Revision	No criteria changes; updated drugs affected section and criteria verbiage. Policy was updated to include the existing quantity limits when the product is obtained via home delivery.	12/02/2022

“Cigna Companies” refers to operating subsidiaries of Cigna Corporation. All products and services are provided exclusively by or through such operating subsidiaries, including Cigna Health and Life Insurance Company, Connecticut General Life Insurance Company, Evernorth Behavioral Health, Inc., Cigna Health Management, Inc. and HMO or service company subsidiaries of Cigna Health Corporation. The Cigna name, logo, and other Cigna marks are owned by Cigna Intellectual Property, Inc. © 2023 Cigna.