# DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

**POLICY:** Topical Corticosteroids – Fluocinonide Drug Quantity Management Policy – Per Days

- fluocinonide 0.05% cream (generic only)
- fluocinonide 0.05% gel (generic only)
- fluocinonide 0.05% ointment (generic only)
- fluocinonide 0.05% solution (generic only)
- fluocinonide emulsified base 0.05% cream (generic only)
- Vanos® (fluocinonide 0.1% cream – Bausch, generic)

**REVIEW DATE:** 09/11/2024

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***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. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. 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.*

## CIGNA NATIONAL FORMULARY COVERAGE:

### OVERVIEW

Fluocinonide cream, cream-emulsified base, ointment, gel, and solution are indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses, including moderate to severe plaque psoriasis.[1-3] Vanos (generics) is specifically indicated in patients ≥ 12 years of age.

Moderate to severe psoriasis is typically defined as involvement of more than 5% to 10% of the body surface area (BSA) 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 BSA. Patients with > 5% to 10% BSA 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

Fluocinonide 0.05% cream, cream-emulsified base, ointment, gel, and solution are applied to the affected area as a thin film two to four times daily, depending on the severity of the condition.[1,2]

Dosing of fluocinonide 0.1% cream (Vanos, generic) varies by indication.[3] For plaque psoriasis, it is applied as a thin layer to the affected skin areas once or twice daily. Twice daily application has been shown to be more effective in achieving treatment success during 2 weeks of treatment of plaque psoriasis. For atopic dermatitis, fluocinonide 0.1% cream should be applied once daily to the affected areas. In this patient population, once daily application has been found to be as effective as twice daily administration in achieving treatment success following 2 weeks of therapy. For other corticosteroid-responsive dermatoses, apply a thin layer of cream once or twice daily to the affected areas.

## Availability

Fluocinonide 0.05% cream is available as 15 gram, 30 gram, 60 gram, and 120 gram tubes.[1] Fluocinonide 0.05% gel, ointment, and emulsified base cream are available as 15 gram, 30 gram, and 60 gram tubes. Fluocinonide 0.05% solution is available as a 20 mL and a 60 mL bottle.[2] Fluocinonide 0.1% cream (Vanos, generic) is available as 30 gram, 60 gram, and 120 gram tubes.[3]

### Application Information

When determining the amount of a topical corticosteroid to apply, a standard measure, the fingertip unit (FTU), is often used. 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 gram 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 BSA. Therefore, it is assumed that 1 gram 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 topical fluocinonide 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.

## POLICY STATEMENT

This Drug Quantity Management program has been developed to prevent stockpiling, misuse, and/or overuse of fluocinonide. 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.

## Drug Quantity Limits

| Product | Package Size | Retail Maximum Quantity per 30 Days | Home Delivery Maximum Quantity per 90 Days |
|---|---|---|---|
| fluocinonide 0.05% cream (generic only) | 15 gram tube<br>30 gram tube<br>60 gram tube<br>120 gram tube | 120 grams | 360 grams |
| fluocinonide 0.05% gel (generic only) | 15 gram tube<br>30 gram tube<br>60 gram tube | 120 grams | 360 grams |
| fluocinonide 0.05% ointment (generic only) | 15 gram tube<br>30 gram tube<br>60 gram tube | 120 grams | 360 grams |
| fluocinonide 0.05% solution (generic only) | 20 mL bottle<br>60 mL bottle | 120 mL | 360 mL |
| fluocinonide emulsified base 0.05% cream (generic only) | 15 gram tube<br>30 gram tube<br>60 gram tube | 120 grams | 360 grams |
| Vanos® (fluocinonide 0.1% cream, generic) | 30 gram tube<br>60 gram tube<br>120 gram tube | 120 grams | 360 grams |

**Topical Corticosteroids – Fluocinonide Drug Quantity Management Policy – Per Days product(s) is(are) covered as medically necessary when the following criteria is(are) met. Any other exception is considered not medically necessary.**

### CRITERIA

Approval of additional quantities of topical fluocinonide products is recommended if the patient is using the product for an FDA-approved indication AND meets ONE of the following:

Fluocinonide 0.05% cream, fluocinonide 0.05% gel, fluocinonide 0.05% ointment, fluocinonide emulsified base 0.05% cream, fluocinonide 0.1% cream (Vanos, generic)

1. If the patient needs to treat greater than 8% of body surface area, approve the requested quantity, not to exceed 180 grams per 30 days at retail and 540 grams per 90 days at home delivery.

2. If the patient needs to administer the medication more frequently than two times a day, approve the requested quantity, not to exceed 180 grams per 30 days at retail and 540 grams per 90 days at home delivery.

Fluocinonide 0.05% solution

1. If the patient needs to treat greater than 8% of body surface area, approve the requested quantity, not to exceed 180 mL per 30 days at retail and 540 mL per 90 days at home delivery.

**2.** If the patient needs to administer the medication more frequently than two times a day, approve the requested quantity, not to exceed 180 mL per 30 days at retail and 540 mL per 90 days at home delivery.

## EXCLUSIONS

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

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

## REFERENCES


1. Fluocinonide cream, cream-emulsified base, gel, ointment [prescribing information]. Hawthorne, NY: Taro: February 2018.
2. Fluocinonide solution [prescribing information]. Hawthorne, NY: Taro; April 2021.
3. Vanos® 0.1% cream [prescribing information]. Bridgewater, NJ: Bausch; May 2017.
4. Sidbury R, Alikhan A, Bercovitch L, et al. Guidelines of care for the management of atopic dermatitis in adults with topical therapies. *J Am Acad Dermatol*. 2023;89(1):e1-e20.


## HISTORY

| Type of Revision | Summary of Changes | Review Date |
|---|---|---|
| Annual Revision | No criteria changes. | 09/11/2023 |
| Annual Revision | No criteria changes. | 09/11/2024 |