# DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

**POLICY:** Dermatology – Zoryve Drug Quantity Management Policy – Per Days
- Zoryve® (roflumilat 0.15% cream – Arcutis)
- Zoryve® (roflumilast 0.3% cream – Arcutis)
- Zoryve® (roflumilast 0.3% foam – Arcutis)

**REVIEW DATE:** 08/06/2025

***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 WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. 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

Zoryve is a topical phosphodiesterase 4 inhibitor.[1,2]

**Zoryve 0.3% cream** is indicated for the topical treatment of **plaque psoriasis**, including intertriginous areas, in patients ≥ 6 years of age.[1]

**Zoryve 0.15% cream** is indicated for the topical treatment of mild to moderate **atopic dermatitis** in patients ≥ 6 years of age.[1]

**Zoryve 0.3%** foam is indicated for the treatment of:[2]
- **Seborrheic dermatitis** in patients ≥ 9 years of age.
- **Plaque psoriasis** of the scalp and body in patients ≥ 12 years of age.

## Dosing

Both Zoryve (0.15% and 0.3%) cream and Zoryve foam are applied to affected areas once daily.[1,2] The pivotal studies for Zoryve 0.15% cream enrolled patients with atopic dermatitis, with a body surface area (BSA) involvement ≥ 3%.[1] The mean BSA involvement was 14%. The pivotal studies for Zoryve 0.3% cream enrolled patients with plaque psoriasis, with a BSA involvement of 2% to 20%. The pivotal studies for Zoryve foam enrolled patients with seborrheic dermatitis affecting a median 2.5% of the patient's BSA.[2] In the pivotal studies for Zoryve foam for plaque psoriasis of the scalp and body enrolled patients with total overall psoriasis involvement of scalp and non-scalp areas was ≤ 25% of the patient's BSA, not including palms and/or soles.[4,5]

## Availability

Zoryve is available as a 0.15% cream supplied in 60 gram tubes, a 0.3% cream, supplied in 60 gram tubes and a 0.3% foam, supplied in 60 gram pressurized aluminum cans.[1,2]

## Application Information

For topical product application, a standard measure, the finger-tip 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 2 g of a topical agent would provide enough product for one application to approximately 8% of the patient's BSA.

Based on the FTU method, the quantity limit of 60 grams per 30 days at retail and 180 grams per 90 days at home delivery is estimated to provide enough Zoryve to cover approximately 8% of the patient's BSA when applying once daily for 1 month (30 days) or 3 months (90 days), respectively.

**POLICY STATEMENT**

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of Zoryve. 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 | Strength and Form | Retail Maximum Quantity per 30 Days | Home Delivery Maximum Quantity per 90 days |
|---|---|---|---|
| Zoryve® (roflumilast 0.15% cream) | 60 gram tube | 60 grams | 180 grams |
| Zoryve® (roflumilast 0.3% cream) | 60 gram tube | 60 grams | 180 grams |
| Zoryve® | 60 gram can | 60 grams | 180 grams |

| | | | |
|---|---|---|---|
| (roflumilast 0.3% foam) | | | |

**EXCEPTIONS TO THE QUANTITY LIMITS LISTED ABOVE ARE COVERED AS MEDICALLY NECESSARY WHEN THE FOLLOWING CRITERIA ARE MET. ANY OTHER EXCEPTION IS CONSIDERED NOT MEDICALLY NECESSARY.**

## CRITERIA

Zoryve 0.15% and 0.3% cream

**1.** If a patient needs to treat greater than 8% of their body surface area, approve the requested quantity, not to exceed 180 grams (3 tubes) per 30 days at retail and 540 grams (9 tubes) per 90 days at home delivery.

Zoryve 0.3% foam

**1.** If a patient needs to treat greater than 8% of their body surface area, approve the requested quantity, not to exceed 240 grams (4 cans) per 30 days at retail and 600 grams (10 cans) per 90 days at home delivery.

## REFERENCES


1. Zoryve® cream [prescribing information]. Westlake Village, CA; Arcutis: July 2024.
2. Zoryve® foam [prescribing information]. Westlake Village, CA; Arcutis: May 2025.
3. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 3. Guidelines of care for the management and treatment of psoriasis with topical therapies. *J Am Acad Dermatol*. 2009;60(4):643-659.
4. Gooderham MJ, Alonso-Llamazares J, Bagel J, et al. Roflumilast foam, 0.3%, for psoriasis of the scalp and body: the ARRECTOR phase 3 randomized clinical trial. JAMA Dermatol. 2025 May 7. [Online ahead of print].
5. Kircik LH, Alonso-Llamazares J, Bhatia N, et al. Once-daily roflumilast foam 0.3% for scalp and body psoriasis: a randomized, double-blind, vehicle-controlled phase IIb study. *Br J Dermatol*. 2023;189(4):392-399.


## HISTORY

| Type of Revision | Summary of Changes | Review Date |
|---|---|---|
| Early Annual Revision | **Zoryve 0.3% foam:** New quantity limit was added to the policy of 1 can (60 grams) per 30 days at retail and 3 cans (180 grams) per 90 days at home delivery. No overrides apply. | 01/10/2024 |
| Early Annual Revision | **Zoryve 0.15% cream:** New quantity limit was added to the policy of 60 grams per 30 days at retail and 180 grams per 90 days at home delivery. Clinical overrides provide an approval of up to 180 grams per 30 days at retail and up to 540 grams per 90 days at home delivery if the patient needs to treat greater than 8% of their body surface area. | 08/28/2024 |
| Annual Revision | **Zoryve 0.3% foam:** New clinical override was added to approve the requested quantity, not to exceed 240 grams (4 cans) per 30 days at retail and 600 grams (10 cans) per 90 days at home delivery, if a patient needs to treat greater than 8% of their body surface area. | 08/06/2025 |