DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

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

REVIEW DATE: 01/10/2024

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

Zoryve is a topical phosphodiesterase 4 inhibitor.[1,2] Zoryve cream is indicated for the topical treatment of **plaque psoriasis**, including intertriginous areas, in patients ≥ 6 years of age.[1] Zoryve foam is indicated for the treatment of **seborrheic dermatitis** in patients ≥ 9 years of age.[2]

Dosing

Both Zoryve cream and Zoryve foam are applied to affected areas once daily.[1,2] The pivotal studies for Zoryve cream enrolled patients with plaque psoriasis, with a body surface area involvement of 2% to 20%.[1] The pivotal studies for Zoryve foam

enrolled patients with seborrheic dermatitis affecting a median 2.5% of the patient's body surface area.[2]

Availability

Zoryve is available as a 0.3% cream (3 mg of roflumilast per gram), supplied in 60 g tubes and a 0.3% foam, supplied in 60 g 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 g per 30 days at retail and 180 g per 90 days at home delivery is estimated to provide enough Zoryve to cover approximately 8% of the patient's BSA when applying QD 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 0.3% cream)	60 gram tube	1 tube (60 grams)	3 tubes (180 grams)
Zoryve® (roflumilast 0.3% foam)	60 gram cans	1 can (60 grams)	3 cans (180 grams)

Dermatology – Zoryve 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

Zoryve 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

No overrides recommended.

REFERENCES

1. Zoryve® cream [prescribing information]. Westlake Village, CA; Arcutis: October 2023.
2. Zoryve® foam [prescribing information]. Westlake Village, CA; Arcutis: December 2023.
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.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	08/23/2023
Early Annual Revision	**Zoryve 0.3% foam:** New quantity limit 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