DRUG QUANTITY MANAGEMENT POLICY - PER DAYS

POLICY: Dermatology – Zoryve Drug Quantity Management Policy – Per Days

• Zoryve[™] (roflumilast 0.3% cream – Arcutis Biotherapeutics)

REVIEW DATE: 08/17/2022

OVERVIEW

Zoryve, a phosphodiesterase 4 inhibitor, is indicated for the topical treatment of **plaque psoriasis**, including intertriginous areas, in patients > 12 years of age.¹

Dosing

Apply Zoryve to affected areas once daily (QD) and rub in completely. The pivotal studies enrolled patients with plaque psoriasis, with a body surface area involvement of 2% to 20%.

Availability

Zoryve is available as a 0.3% cream (3 mg of roflumilast per gram), supplied in 60 g tubes.¹

Application Information

For topical product application, a standard measure, the finger-tip unit (FTU), is often used.² 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 limits of 60 g per 30 days are estimated to provide enough Zoryve to cover approximately 8% of the patient's BSA when applying QD for 1 month (30 days).

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.

Automation: None.

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)

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CRITERIA

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.

REFERENCES

- Zoryve[™] cream [prescribing information.] Westlake, CA; Arcutis Biotherapeutics: July 2022.
 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.