

ZORYVE (roflumilast) cream, foam

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Zoryve (roflumilast) is an inhibitor of phosphodiesterase 4 (PDE4). Inhibition of PDE4 leads to accumulation of intracellular cyclic AMP. The specific mechanism by which Zoryve exerts its therapeutic action is not well defined (1-2).

Regulatory Status

FDA-approved indications: (1-2)

- 1. Zoryve cream is a phosphodiesterase 4 inhibitor:
 - a. Zoryve cream, 0.3%, is indicated for the topical treatment of plaque psoriasis (PsO), including intertriginous areas, in patients 6 years of age and older.
 - b. Zoryve cream, 0.15%, is indicated for the topical treatment of mild to moderate atopic dermatitis (AD) in adult and pediatric patients 6 years of age and older.
- 2. Zoryve foam is a phosphodiesterase 4 inhibitor indicated for the treatment of:
 - a. Seborrheic dermatitis in adult and pediatric patients 9 years of age and older.
 - b. Plaque psoriasis of the scalp and body in adult and pediatric patients 12 years of age and older.

The safety and effectiveness of Zoryve cream in pediatric patients less than 6 years of age have not been established. The safety and effectiveness of Zoryve foam in pediatric patients less than 9 years of age for seborrheic dermatitis have not been established. The safety and effectiveness of Zoryve foam in pediatric patients less than 12 years of age for plaque psoriasis of the scalp and body have not been established (1-2).

Summary

Zoryve (roflumilast) is an inhibitor of phosphodiesterase 4 (PDE4). Zoryve cream is indicated for use in patients with plaque psoriasis or atopic dermatitis, while Zoryve foam is indicated for use in patients with seborrheic dermatitis or plaque psoriasis (1-2).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Zoryve while maintaining optimal therapeutic outcomes.



Federal Employee Program.

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References

1.	Zoryve cream	[package insert]	 Westlake Village, 	CA: Arcutis Biothe	erapeutics, Inc.; Ju	ly 2024.
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2.	Zoryve foar	n [package	insert]. We	estlake Village,	CA: Arcutis I	Biotherapeutics,	Inc.; May	2025.
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