Roflumilast (ZORYVE) Cream 0.15% in Atopic Dermatitis
Criteria for Use
January 2025

VA Pharmacy Benefits Management Services and National Formulary Committee

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

Exclusion Criteria

If ANY of the following are selected, the patient will NOT meet criteria for roflumilast cream 0.15%.

☐ Moderate to severe liver impairment (Child-Pugh B or C) – relative contraindication

Inclusion Criteria

ALL the following criteria must be selected to meet criteria.

☐ Diagnosis of mild to moderate atopic dermatitis

☐ Prescribed and monitored by a VA / VA Community Care dermatologist or locally designated expert

☐ Tried a topical corticosteroid and a topical calcineurin inhibitor (e.g., tacrolimus ointment 0.1% or 0.03% or pimecrolimus cream 1%) for ≥ 1 month per drug class, unless medically inadvisable, and had intolerance or an inadequate response

Additional Inclusion Criteria – Select If Applicable

☐ For patients who are pregnant or plan to become pregnant: Counseling provided on potential risks vs benefits of treatment and patient informed that it is not known whether use of roflumilast topical cream will harm the unborn baby.^1

☐ For patients who are lactating / providing breastmilk to an infant or plan to do so: Counseling provided on how to minimize potential drug exposure to the breastfed infant via breast milk, as recommended in prescribing information.^2

Other Justification

☐ _____

Footnotes

1 Avoid use during labor and delivery.

2 Advise breastfeeding women not to apply roflumilast directly to the nipple or areola and, if applied to the patient's chest, to avoid exposure via direct contact with the infant's skin.

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