

# Roflumilast (ZORYVE) Cream 0.3% in Plaque Psoriasis

## Criteria for Use

### October 2024

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

*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.

- Psoriasis other than the plaque variant
- Moderate to severe liver impairment (Child-Pugh B or C)

## Inclusion Criteria

ALL of the following must be selected in order to meet criteria:

- Diagnosis of plaque psoriasis (any severity)
- Prescribed and monitored by a VA / VA Community Care dermatologist or locally designated psoriasis expert

## Additional Inclusion Criteria

ONE of the following must be selected in order to meet criteria:

- Tried and had intolerance or inadequate response to  $\geq 2$  classes of topical antipsoriatics unless medically inadvisable ( $\geq 1$  month / class; e.g., corticosteroids, vitamin D analogs, calcineurin inhibitors, etc.; roflumilast required before tapinarof)
- Tried and had intolerance or inadequate response to 1 class of topical antipsoriatics and 1 systemic therapy (phototherapy, conventional immunomodulator, or targeted immunomodulator) unless medically inadvisable, not available, or not feasible <sup>^1, ^2, ^3</sup>

## Additional Inclusion Criteria

Select if appropriate.

- 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 foam will harm the unborn baby.<sup>^4</sup>
- For patients who are breastfeeding or plan to breastfeed: Counseling provided on how to minimize potential drug exposure to the breastfed infant via breast milk, as recommended in prescribing information.<sup>^5</sup>

## Other Justification

## Footnotes

- <sup>1</sup> Phototherapy: NO treatment benefit after 12 treatments or inadequate partial response after 24 treatments. Reasons for phototherapy being medically inadvisable include (and are not limited to) CONFIRMED (preferably by a written biopsy report) history of skin cancer, melanoma or strong likelihood of developing them (e.g., Fitzpatrick skin type I or II = pale skin, easily sunburns).
- <sup>2</sup> Conventional immunomodulator such as methotrexate
- <sup>3</sup> Systemic targeted immunomodulators such as tumor necrosis factor inhibitors, interleukin-17A inhibitors (e.g., ixekizumab), interleukin-23 inhibitors (e.g., risankizumab-rzaa), interleukin-12/23 inhibitor (e.g., ustekinumab), and phosphodiesterase-4 inhibitors (e.g., apremilast).
- <sup>4</sup> Avoid use during labor and delivery.
- <sup>5</sup> 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.

## Supplemental Information

This supplemental information is provided to assist in adjudication of requests for roflumilast cream.

Section	Criterion	Issues for Consideration
<b>Inclusion Criteria</b>	Tried and had intolerance or inadequate response to <b>≥ 2 classes of topical antipsoriatics</b> unless medically inadvisable (≥ 1 month / class; e.g., corticosteroids, vitamin D analogs, calcineurin inhibitors, etc.; roflumilast required before tapinarof)	<p>A prior trial of topical corticosteroids is not necessary and may be medically inadvisable for lesions in sensitive areas such as the face and intertriginous (skin-to-skin) areas.</p> <p>Topical nonsteroidal antiinflammatory treatments like roflumilast may be used alone (e.g., on sensitive areas) or co-used with corticosteroids to reduce or prevent corticosteroid complications. Therefore, use of topical nonsteroidal medications do not always require a prior trial of or an inadequate response to corticosteroids.</p> <hr/> <p><b>Examples of topical therapies</b></p> <p>The following list is not all inclusive. Topical emollients and keratolytics do not count as topical antipsoriatics.</p> <ul style="list-style-type: none"> <li>• Vitamin D analogs: Calcipotriene, calcipotriol</li> <li>• Calcineurin inhibitors: Tacrolimus, pimecrolimus</li> <li>• Retinoids: Tazarotene</li> <li>• Coal tar</li> <li>• Aryl hydrocarbon receptor agonist: Tapinarof</li> </ul> <p>Per the PBM Tapinarof Cream in Psoriasis Criteria (available at: <a href="#">PBM Formulary Management – Criteria For Use – All Documents (sharepoint.com)</a>), a trial of roflumilast is required before tapinarof. Topical roflumilast is labeled to include use on intertriginous (skin fold) areas affected by plaque psoriasis and could be preferred over tapinarof for intertriginous lesions or intertriginous (aka inverse) plaque psoriasis. Tapinarof is not labeled for intertriginous areas and can cause folliculitis and contact dermatitis; however, tapinarof was used on facial and intertriginous areas in phase 3 clinical trials.</p>
	Tried and had intolerance or inadequate response to <b>1 class of topical antipsoriatics and 1 systemic therapy (phototherapy,<sup>1</sup> conventional immunomodulator, or targeted immunomodulator<sup>3</sup>)</b> unless medically inadvisable, not available, or not feasible	Reasons for phototherapy being medically inadvisable include (and are not limited to) CONFIRMED (preferably by a written biopsy report) history of skin cancer, melanoma or strong likelihood of developing them (e.g., Fitzpatrick skin type I or II = pale skin, easily sunburns).

Revised: January 2025 (added strength to title); October 2024 (added / modified footnotes on use in labor and delivery and application to breasts).

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Contact: Francine Goodman, National Clinical Pharmacy Program Manager, VA Pharmacy Benefits Management Services (12PBM)