

Criteria-Based Consultation Prescribing Program

CRITERIA FOR DRUG COVERAGE

Roflumilast 0.3% Cream (Zoryve)

Notes:

- Quantity Limits: Yes
- ^Adequate trial is defined as the following:
 - Topical corticosteroids – 8 weeks
 - Topical calcineurin inhibitors – 6 weeks
 - Topical vitamin D analog – 6 weeks
 - Phototherapy – 8 weeks
- *Intolerance excludes adverse drug reactions that are expected, mild in nature, resolve with continued treatment, and do not require medication discontinuation
- **Topical calcineurin inhibitors include tacrolimus (Protopic) 0.03% and 0.1% ointment and pimecrolimus (Elidel) 1% cream. Tacrolimus is the formulary preferred topical calcineurin inhibitor.
 - FDA approved ages:
 - Tacrolimus 0.03% and pimecrolimus 1%: 2 years of age and older. Evidence from clinical trials supports the safe and effective use (off-label) of these products in children younger than 2, including in infants.
 - Tacrolimus 0.1%: 16 years of age and older.

Initiation (new start) criteria, criteria for current Kaiser Permanente members already taking the medication who have not been reviewed previously, and criteria for new members entering Kaiser Permanente already taking the medication who have not been reviewed previously: Non-formulary roflumilast 0.3% cream (Zoryve) will be covered on the prescription drug benefit for 12 months when the following criteria are met:

- Prescriber is a dermatologist
- Patient has a diagnosis of plaque psoriasis
- Patient is 6 years of age or older
- Patient has failed an adequate trial^, or patient has an allergy or intolerance* to all of the following:
 - At least 2 topical steroids
 - At least 1 topical vitamin D analog (e.g., calcitriol ointment, calcipotriene solution)
 - At least 1 topical calcineurin inhibitor** (e.g. tacrolimus 0.1% ointment)
 - Phototherapy (unless documented by prescriber phototherapy not appropriate)

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Continued use criteria for patients previously approved per the above criteria who are currently stable on the medication: Non-formulary **roflumilast 0.3% cream (Zoryve)** will continue to be covered on the prescription drug benefit for 12 months when the following criteria are met:

- Prescriber is a dermatologist
- Patient has responded to roflumilast 0.3% cream as determined by prescriber