Topical Psoriasis Agents

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Topical Psoriasis Agents policy is to ensure appropriate selection of patients for therapy based on product labeling, clinical guidelines, and clinical studies. The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Zoryve (roflumilast) cream, 0.3% is a phosphodiesterase-4 (PDE4) inhibitor indicated for the topical treatment of plaque psoriasis, including intertriginous areas, in patients 12 years of age and older.

Vtama (tapinarof) cream, 1% is an aryl hydrocarbon receptor agonist indicated for the topical treatment of plaque psoriasis in adults.

POLICY

Criteria for Initial Approval

A. Zoryve (roflumilast) may be considered **medically necessary** when the following criteria are met:

- The requested drug is being prescribed for topical treatment of plaque psoriasis
  AND
- The patient is 12 years of age or older
  AND
  - The patient has experienced an inadequate treatment response or intolerance to at least TWO of the following (unless all options are contraindicated):

- high to super-high potency generic topical corticosteroid (i.e., betamethasone dipropionate, clobetasol, fluocinonide, or halobetasol) used concurrently with generic topical calcipotriene cream or solution, OR
- generic topical calcipotriene/betamethasone suspension
- high- to ultrahigh-potency topical corticosteroid used concurrently with generic tazarotene 0.1% cream

AND

- If additional quantities are being requested, then the requested drug is being prescribed to treat a body surface area that requires more than 60 grams per month.

Approval will be for 6 months with a quantity limit not to exceed 60 gm per 30 days. Coverage for 120 gm per 30 days will be provided when treating a body surface area that requires more than 60 grams per month.

B. Vtama (tapinarof) may be considered **medically necessary** when the following criteria are met:

- The requested drug is being prescribed for topical treatment of plaque psoriasis
  AND
- The patient is 18 years of age or older
  AND
  - The patient has experienced an inadequate treatment response or intolerance to at least TWO of the following (unless all options are contraindicated):
    - high to super-high potency generic topical corticosteroid (i.e., betamethasone dipropionate, clobetasol, fluocinonide, or halobetasol) used concurrently with generic topical calcipotriene cream or solution, OR
    - generic topical calcipotriene/betamethasone suspension
    - high- to ultrahigh-potency topical corticosteroid used concurrently with generic tazarotene 0.1% cream

  AND
- If additional quantities are being requested, then the requested drug is being prescribed to treat a body surface area that requires more than 60 grams per month.

Approval will be for **6 months** with a quantity limit not to exceed 60 gm per 30 days. Coverage for 120 gm per 30 days will be provided when treating a body surface area that requires more than 60 grams per month.

Continuation of Therapy

The continuation of treatment with the requested medication may be considered medically necessary when the patient has achieved or maintained a positive clinical response to therapy as evidenced by improvement in signs and symptoms from baseline (e.g., itching, redness, flaking, scaling, burning, cracking, pain).

Approval will be for **12 months** with a quantity limit not to exceed 60 gm per 30 days. Coverage for 120 gm per 30 days will be provided when treating a body surface area that requires more than 60 grams per month.

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits

Zoryve - 60 grams per 30 days

Vtama – 60 grams per 30 days

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- Code(s), if applicable

REFERENCES

- Zoryve [package insert]. Westlake Village, CA: Arcutis Biotherapeutics, Inc.; July 2022.
- Vtama [package insert]. Long Beach, CA: Dermavant Sciences Inc; May 2022.
- Lexicomp Online, AHFS DI (Adult and Pediatric) Online, Hudson, Ohio: UpToDate, Inc.; 2022; Accessed August 12, 2022.
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- Elmets CA, Korman NJ, Prater EF, et al. Joint AAD-NPF Guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. J Am Acad Dermatol. 2021; 84(2):432-470.
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POLICY HISTORY

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