BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINE

VTAMA® (tapinarof) cream
Generic Equivalent (if available)

This Pharmacy Coverage Guideline (PCG):
- Provides information about the reasons, basis, and information sources we use for coverage decisions
- Is not an opinion that a drug (collectively "Service") is clinically appropriate or inappropriate for a patient
- Is not a substitute for a provider's judgment (Provider and patient are responsible for all decisions about appropriateness of care)
- Is subject to all provisions e.g. (benefit coverage, limits, and exclusions) in the member's benefit plan; and
- Is subject to change as new information becomes available.

Scope
- This PCG applies to Commercial and Marketplace plans
- This PCG does not apply to the Federal Employee Program, Medicare Advantage, Medicaid or members of out-of-state Blue Cross and/or Blue Shield Plans

Instructions & Guidance
- To determine whether a member is eligible for the Service, read the entire PCG.
- This PCG is used for FDA approved indications including, but not limited to, a diagnosis and/or treatment with dosing, frequency, and duration.
- Use of a drug outside the FDA approved guidelines, refer to the appropriate Off-Label Use policy.
- The "Criteria" section outlines the factors and information we use to decide if the Service is medically necessary as defined in the Member's benefit plan.
- The "Description" section describes the Service.
- The "Definition" section defines certain words, terms or items within the policy and may include tables and charts.
- The "Resources" section lists the information and materials we considered in developing this PCG
- **We do not accept patient use of samples as evidence of an initial course of treatment, justification for continuation of therapy, or evidence of adequate trial and failure.**
- Information about medications that require prior authorization is available at www.azblue.com/pharmacy. You must fully complete the request form and provide chart notes, lab workup and any other supporting documentation. The prescribing provider must sign the form. Fax the form to BCBSAZ Pharmacy Management at (602) 864-3126 or email it to Pharmacyprecert@azblue.com.

Criteria:

➢ **Criteria for initial therapy:** Vtama (tapinarof) cream and/or generic equivalent (if available) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

1. Prescriber is a physician specializing in the patient's diagnosis or is in consultation with a Dermatologist

2. Individual is 18 years of age or older

3. Individual has a confirmed diagnosis of moderate to severe plaque psoriasis, as indicated by **ALL** of the following:
    a. Plaque psoriasis involves at least 10% body surface area (BSA) **or** involves less than 10% BSA but includes sensitive areas or areas that significantly impact daily function (e.g., palms, soles of feet, head/neck, or genitalia)

b. A Psoriasis Area and Index (PASI) of at least 10 (see Definitions section)

4. Individual has documented failure (used for ≥ 2 consecutive months), contraindication per FDA label, intolerance, or is not a candidate for **ALL** of the following:
   a. A trial of least **TWO** topical agents (e.g., anthralin, calcipotriene, coal tar, corticosteroid, tazarotene, pimecrolimus, tacrolimus)
   b. A trial of **ONE** immunosuppressive treatment (e.g., cyclosporine, methotrexate)
   c. A trial of Ultraviolet Light therapy (e.g., Photochemotherapy (i.e., psoralen plus ultraviolet A therapy), Phototherapy (i.e., ultraviolet light therapy), or Excimer laser) unless the area(s) of involved skin are too extensive or involve sensitive areas or the individual cannot travel to a care center or there is no care center

5. **If available**: Individual has failure after adequate trial, contraindication per FDA label, intolerance, or is not a candidate for a **generic equivalent** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] (see Definitions section)

6. Individual does **NOT** have any of the following:
   a. Psoriasis other than plaque psoriasis
   b. Any sign of active infection in any active psoriatic lesion
   c. Chronic or acute infection requiring systemic treatment
   d. Immunocompromised condition
   e. Presence of hepatitis B surface antigen (HBsAg), or positive hepatitis C antibody test result, or a positive anti-hepatitis B core antigen (anti-HBc) result

Initial approval duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Vtama (tapinarof) cream and/or generic equivalent (if available) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met **(samples are not considered for continuation of therapy)**:

1. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with a Dermatologist

2. Individual's condition has responded while on therapy with response defined as **THREE** of the following:
   a. No evidence of disease progression
   b. No evidence individual has developed any significant unacceptable adverse drug reactions that may exclude continued use
   c. Achieved and maintains a PGA score of "clear" or "almost clear" with at least a 2-grade or 30% improvement from baseline
   d. Achieved and maintains at least 75% improvement in PASI over baseline
   e. Achieved and maintains a reduction in %BSA affected from baseline

3. Individual has been adherent with the medication

4. **If available**: Individual has failure after adequate trial, contraindication per FDA label, intolerance, or is not a candidate for a **generic equivalent** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] (see Definitions section)

5. Individual has not developed any significant adverse drug effects that may exclude continued use such as:
    a. Severe folliculitis includes application site folliculitis and folliculitis
    b. Severe nasopharyngitis includes nasopharyngitis, nasal congestion, pharyngitis, respiratory tract infection (RTI) viral, rhinorrhea, sinus congestion, upper RTI, and viral upper RTI
    c. Severe contact dermatitis includes dermatitis, contact dermatitis, hand dermatitis, and rash
    d. Severe headache includes headache, migraine, and tension headache
    e. Severe pruritus includes application site pruritus, pruritus, generalized pruritus, and genital pruritus
    f. Severe influenza includes influenza and influenza-like illness

6. Individual does **NOT** have any of the following:
    a. Psoriasis other than plaque psoriasis
    b. Any sign of active infection in any active psoriatic lesion
    c. Chronic or acute infection requiring systemic treatment
    d. Immunocompromised
    e. Presence of hepatitis B surface antigen (HBsAg), or positive hepatitis C antibody test result, or a positive anti-hepatitis B core antigen (anti-HBc) result

Renewal duration: 12 months

- Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

    1. **Off-Label Use of Non-Cancer Medications**

    2. **Off-Label Use of Cancer Medications**

Description:

Vtama (tapinarof) 1% cream is an aryl hydrocarbon receptor (AhR) agonist indicated for the topical treatment of plaque psoriasis in adults. The specific mechanisms by which it exerts its therapeutic action in plaque psoriasis patients are unknown. Tapinarof modulates the expression of interleukin-17 and the skin-barrier proteins filaggrin and loricrin.

Numerous topical and systemic therapies are available for the treatment of psoriasis. Treatment is chosen based on disease severity, presence of important comorbidities, patient preference, cost, convenience, efficacy, and evaluation of individual patient response. Clinical trials are needed to evaluate the efficacy and safety of tapinarof cream as compared with existing treatments for plaque psoriasis.

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Definitions:

U.S. Food and Drug Administration (FDA) MedWatch Forms for FDA Safety Reporting
MedWatch Forms for FDA Safety Reporting | FDA

Physician Global Assessment (PGA) score:
PGA is a tool for assessing the current state/severity of an individual's psoriasis at a given timepoint. It is a static 5-point assessment of overall disease severity, as determined by the provider, using the clinical characteristics of erythema, scaling, and plaque thickness/elevation as guidelines. Higher PGA scores represent more severe disease.

0	Clear	No signs of psoriasis, but post-inflammatory discoloration may be present
1	Almost clear	Only minimal plaque elevation, scaling, and erythema
2	Mild	Slight plaque elevation, scaling, and erythema
3	Moderate	Moderate plaque elevation, scaling, and erythema
4	Severe	Very marked plaque elevation, scaling, and erythema

Psoriasis Area and Severity Index (PASI):

	Head	Upper Extremities	Trunk	Lower extremities
1. Redness[1]				
2. Thickness[1]				
3. Scale[1]				
4. Sum of rows 1,2 and 3				
5. Area score[2]				
6. Score of row 4 x row 5 x the area multiplier	row 4 x row 5 x 0.1	row 4 x row 5 x 0.2	Row 4 x row 5 x 0.3	Row 4 x row 5 x 0.4
7. Sum row 6 for each column for PASI score				

Steps in generating PASI score:
(a) Divide body into four areas: head, arms, trunk to groin, and legs to top of buttocks.
(b) Generate an average score for the erythema, thickness, and scale for each of the 4 areas (0 = clear; 1–4 = increasing severity)[1].
(c) Sum scores of erythema, thickness, and scale for each area.
(d) Generate a percentage for skin covered with psoriasis for each area and convert that to a 0–6 scale (0 = 0%; 1 = <10%; 2 = 10–<30%; 3 = 30–<50%; 4 = 50–<70%; 5 = 70–<90%; 6 = 90–100%).
(e) Multiply score of item (c) above times item (d) above for each area and multiply that by 0.1, 0.2, 0.3, and 0.4 for head, arms, trunk, and legs, respectively.
(f) Add these scores to get the PASI score.

[1] Erythema, induration and scale are measured on a 0–4 scale (none, slight, mild, moderate, severe)
[2] Area scoring criteria (score: % involvement)
0: 0 (clear)
1: <10%
2: 10–<30%
3: 30–<50%
4: 50–<70%
5: 70–<90%
6: 90–<100%

Feldman, SR and Krueger, GG. Psoriasis assessment tools in clinical trials. Ann Rheum Dis 2005; 64 (Suppl III): ii65-ii68.

ORIGINAL EFFECTIVE DATE: 08/18/2022 | ARCHIVE DATE: | LAST REVIEW DATE: 08/15/2024 | LAST CRITERIA REVISION DATE: 08/15/2024

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Resources:

Vtama (tapinarof) cream 1% product information, revised by Dermavant Sciences, Inc. 05-2022. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed June 11, 2024.

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Feldman SR, Bhutani T. Chronic plaque psoriasis in adults: Overview of management. In: UpToDate, Dellavalle RP, Duffin KC, Ofori AO (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Literature current through June 2024. Topic last updated July 08, 2024. Accessed July 19, 2024.

Feldman SR. Psoriasis: Epidemiology, clinical manifestations, and diagnosis. In: UpToDate, Dellavalle RP, Duffin KC, Ofori AO (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Literature current through June 2024. Topic last updated September 12, 2022. Accessed July 18, 2024.

Feldman SR. Lewitt GM. Chronic plaque psoriasis in adults: Treatment of disease amenable to topical therapy. In: UpToDate, Dellavalle RP, Duffin KC, Ofori AO (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Literature current through June 2024. Topic last updated July 08, 2024. Accessed July 18, 2024.

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Gold LS, Bhatia N, Tallman AM, et al: A phase 2b, randomized clinical trial of tapinarof cream for the treatment of plaque psoriasis: Secondary efficacy and patient-reported outcomes. J Am Acad Dermatol 2021 March; 84 (3):624-631. Accessed June 08, 2022. Re-evaluated July 18, 2024.

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 February; 84(2):432-70. Accessed July 19, 2024.

ClinicalTrials.gov Identifier NCT03956355. Tapinarof for the Treatment of Plaque Psoriasis in Adults (3001). Last Updated June 24, 2021. Available from: http://clinicaltrials.gov. Accessed June 06, 2022. Re-evaluate July 18, 2024.

ClinicalTrials.gov Identifier NCT03983980. Tapinarof for the Treatment of Plaque Psoriasis in Adults (3002). Last Updated August 31, 2021. Available from: http://clinicaltrials.gov. Accessed June 06, 2022. Re-evaluated July 18, 2024.