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 has a confirmed diagnosis of **ONE** of the following:
    a. Individual is 18 years or older with moderate to severe **plaque psoriasis**, as indicated by **ALL** of the following:
        i. 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)
        ii. A Psoriasis Area and Index (PASI) of at least 10 (see Definitions section)

b. Individual is 2 years of age or older with **atopic dermatitis**, as indicated by **ALL** of the following:
   i. Atopic dermatitis covers at least 5% up to 35% of the body surface area (BSA)
   ii. Has an Investigator Global Assessment (IGA) score of 3 or more
   iii. Has an Eczema Area and Severity Index (EASI) score of 6 or more
   iv. Has a Numerical Rating Scale - Pruritus score of at least 4 or more for individuals 12 years of age or older (see Definitions section)

3. 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. **For plaque psoriasis**:
      i. A trial of least **TWO** topical agents (e.g., anthralin, calcipotriene, coal tar, corticosteroid, tazarotene, pimecrolimus, tacrolimus)
      ii. A trial of **ONE** immunosuppressive treatment (e.g., cyclosporine, methotrexate)
      iii. 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
   b. **For Atopic Dermatitis**:
      i. Moderate to severe disease **ALL** of the following:
         1. A trial of **TWO** topical medium to high potency corticosteroids (such as triamcinolone acetonide 0.1%, mometasone furoate 0.1%, betamethasone dipropionate 0.05%, desoximetasone 0.05%, and others) choice of topical corticosteroid potency is based on the individual's age, body area involved, and degree of skin inflammation
         2. Individual has documented failure (used for > 3 consecutive months), contraindication per FDA label, intolerance, or not a candidate for Dupixent (dupilumab) [adults & children 6 months or older]
         3. Individual has documented failure (used for > 3 consecutive months), contraindication per FDA label, intolerance, or is not a candidate for Rinvoq (upadacitinib) [adults & children 12 years or older]

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 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

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- **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 (for plaque psoriasis) or EASI (for atopic dermatitis) over baseline
     e. Achieved and maintains a reduction in %BSA affected from baseline
     f. Improvement in Numerical Rating Scale - Pruritus score for individual 12 years of age or older

  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:

PHARMACY COVERAGE GUIDELINE

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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. Vtama (tapinarof) cream is also indicated for the topical treatment of atopic dermatitis in adults and pediatric patients 2 years of age and older.

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.

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: Psoriasis
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.

Investigator Global Assessment Scale (IGA):
Validated-Investigator-Global-Assessment-Scale_vIGA-AD_2017.pdf (eczemacouncil.org) [Accessed October 09, 2021]

The IGA score is selected using the morphologic descriptors that best describe the overall appearance of the lesions at a given time point. It is not necessary that all characteristics under Morphological Description be present.

Score	Morphological Description
0 – Clear	No inflammatory signs of atopic dermatitis (no erythema (reddening), no induration (hardening of soft tissue)/papulation, no lichenification (thick leathery skin), no oozing/crusting). Post-inflammatory hyperpigmentation and/or hypopigmentation may be present.
1 – Almost clear	Barely perceptible erythema, barely perceptible induration/papulation, and/or minimal lichenification. No oozing or crusting.
2 – Mild	Slight but definite erythema (pink), slight but definite induration/papulation, and/or slight but definite lichenification. No oozing or crusting.
3 – Moderate	Clearly perceptible erythema (dull red), clearly perceptible induration/papulation, and/or clearly perceptible lichenification. Oozing and crusting may be present.
4 – Severe	Marked erythema (deep or bright red), marked induration/papulation, and/or marked lichenification. Disease is widespread in extent. Oozing or crusting may be present.

Notes:
1. In indeterminate cases, use extent to differentiate between scores.
For example: • Patient with marked erythema (deep or bright red), marked papulation and/or marked lichenification that is limited in extent (instead of widespread), would be considered "3 – Moderate".

2. Excoriations should not be considered when assessing disease severity

EASI score | DermNet NZ

What is an EASI score?
An EASI score is a tool used to measure the extent (area) and severity of atopic eczema (Eczema Area and Severity Index). It takes a few minutes and experience to calculate it accurately.
EASI score does not include a grade for dryness or scaling. Include only inflamed areas.

Body regions
There are four body regions:

- Head and neck
  - Face occupies 33% (17% each side), neck 33% (17% front and back) and scalp 33% of the head and neck region
- Trunk (including genital area)
  - Front occupies 55% and back 45% of the trunk
- Upper limbs
  - Each arm occupies 50% of the upper limbs region (front or back of one arm is 25%)
- Lower limbs (including buttocks)
  - Each leg occupies 45% (front or back of one leg is 22.5%) and buttocks 10% of the lower limbs region

Area score
Area score is recorded for each of the four regions of the body. The area score is the percentage of skin affected by eczema for each body region.

Area score	Percentage of skin affected by eczema in each region
0	No active eczema in this region
1	1-9
2	10-29
3	30-49
4	50-69
5	70-89
6	90-100: the entire region is affected by eczema

Severity score
Severity score is recorded for each of the four regions of the body. The severity score is the sum of the intensity scores for four signs. The four signs are:

1. Redness (erythema, inflammation)
2. Thickness (induration, papulation, swelling—acute eczema)
3. Scratching (excoriation)

4. Lichenification (lined skin, furrowing, prurigo nodules—chronic eczema).

The *average* intensity of each sign in each body region is assessed as: none (0), mild (1), moderate (2) and severe (3).

Half scores are allowed. It may be difficult to assess redness in dark skin. If in doubt, increase the average redness score by one level. The 16 images below have been chosen as typical examples of different intensities of each sign.

Score	Intensity of redness, thickness/swelling, scratching. lichenification
0	None, absent
1	Mild (just perceptible)
2	Moderate (obvious)
3	Severe

Calculations
For each region, record the intensity for each of four signs and calculate the severity score.

- Severity score = redness intensity + thickness intensity + scratching intensity + lichenification intensity

For each region, multiple the severity score by the area score and by a multiplier. The multiplier is different for each body site.

- Head and neck: severity score x area score x 0.1 (in children 0–7 years, x 0.2)
- Trunk: severity score x area score x 0.3
- Upper limbs: severity score x area score x 0.2
- Lower limbs: severity score x area score x 0.4 (in children 0–7 years, x 0.3)

Add up the total scores for each region to determine the final EASI score. The minimum EASI score is 0 and the maximum EASI score is 72. A higher EASI score represents more severe disease.

IGAxBSA Severity Evaluation

- A practice-friendly alternative to the Eczema Area and Severity Index to assess atopic dermatitis severity in children
- Studies have shown high and consistent agreement between IGA×BSA and EASI
- Suggested severity strata for IGA×BSA are:
  - Mild: 0-30
  - Moderate: 30.1-130
  - Severe: 130.1-400

<u>Numerical Rating Scale - Pruritus Resources (pruritussymposium.de)</u>

The NRS is comprised of one item and represents the numbers 0 (“no itch”) to 10 (“worst imaginable itch”). Subjects are asked to rate the intensity of their itch using this scale. It features high reliability and concurrent validity and is a popular choice for all patients due to its simple format.
Time needed for completion: 1 minute

- Validated in several languages
- It can be interpreted as follows:

NRS 0 - no pruritus
NRS <3 - mild pruritus
NRS ≥ 3< 7 - moderate pruritus
NRS ≥ 7< 9 - severe pruritus
NRS ≥ 9 - very sever pruritus

Resources:

Vtama (tapinarof) cream 1% product information, revised by Dermavant Sciences, Inc. 12-2024. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed March 26, 2025.

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