Original Effective Date: 08/01/2022
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Last P&T Approval/Version: 04/30/2025
Next Review Due By: 04/2026
Policy Number: C23729-A

Vtama (tapinarof) Cream

PRODUCTS AFFECTED

Vtama (tapinarof)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Plaque psoriasis, Atopic Dermatitis

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. PLAQUE PSORIASIS:
   1. Documented diagnosis of plaque psoriasis
      AND
   2. Documentation treatment area is ≤ 20%

AND

3. Documentation of inadequate response, serious side effects, contraindication or clinical rationale of inappropriateness to topical corticosteroids OR plaque psoriasis involves sensitive areas of the body or areas that would significantly impact daily function (ex. face, neck, hands, feet, genitals)
   AND
4. Documentation of inadequate response, serious side effects, contraindication or clinical rationale of inappropriateness to ONE of the following: tacrolimus, pimecrolimus, calcipotriene, or tazarotene
   AND
5. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal

B. ATOPIC DERMATITIS:
1. Documented diagnosis of moderate to severe chronic atopic dermatitis (eczema)
   AND
2. Documentation of inadequate response, serious side effects, or contraindication to TWO of the following: topical corticosteroids or preferred/formulary topical calcineurin inhibitor (tacrolimus, pimecrolimus))
   AND
3. Documentation of prescriber baseline assessment of disease activity (e.g., affected BSA, severity of eczematous lesions, pruritus, etc.)
   AND
4. IF THIS IS A NON-FORMULARY/NON-PREFERRED PRODUCT: Documentation of trial/failure of or serious side effects to a majority (not more than 3) of the preferred formulary/PDL alternatives for the given diagnosis. Submit documentation including medication(s) tried, dates of trial(s) and reason for treatment failure(s).

CONTINUATION OF THERAPY:

A. PLAQUE PSORIASIS, ATOPIC DERMATITIS:
1. Adherence to therapy at least 85% of the time as verified by the prescriber or member medication fill history OR adherence less than 85% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation
   AND
2. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity
   AND
3. Documentation of positive clinical response as demonstrated by low disease activity and/or improvements in the condition's signs and symptoms (e.g., reduction of affected BSA, improvements in severity of eczematous lesions, decrease in pruritus severity, etc.)

DURATION OF APPROVAL:

Initial authorization: 6 months, Continuation of Therapy: 12 months
MOLINA REVIEWER NOTE: For Texas Marketplace, please see Appendix.

PRESCRIBER REQUIREMENTS:

Prescribed by or in consultation with a board-certified dermatologist, allergist, or immunologist [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:

Plaque Psoriasis: 18 years of age and older
Atopic Dermatitis: 2 years of age and older

QUANTITY:

Member's BSA affected <10%: maximum 60 grams/30 days

Member's BSA affected >10%: maximum 180 grams/30 days

PLACE OF ADMINISTRATION:
The recommendation is that topical medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Topical

DRUG CLASS:
Antipsoriatics

FDA-APPROVED USES:
Indicated for the topical treatment of plaque psoriasis in adults and the topical treatment of atopic dermatitis in adults and pediatric patients 2 years of age and older.

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*

State Specific Information
State Marketplace
Texas (Source: Texas Statutes, Insurance Code)
"Sec. 1369.654. PROHIBITION ON MULTIPLE PRIOR AUTHORIZATIONS.
(a) A health benefit plan issuer that provides prescription drug benefits *may not require an enrollee to receive more than one prior authorization annually* of the prescription drug benefit for *a prescription drug prescribed to treat an autoimmune disease, hemophilia, or Von Willebrand disease*.
(b) This section does not apply to:
(1) opioids, benzodiazepines, barbiturates, or carisoprodol;
(2) prescription drugs that have a typical treatment period of less than 12 months;
(3) drugs that:
(A) have a boxed warning assigned by the United States Food and Drug Administration for use; and
(B) must have specific provider assessment; or
(4) the use of a drug approved for use by the United States Food and Drug Administration in a manner other than the approved use."

APPENDIX 1:
Dosing
No universal standard exists for quantity of application, although suggested methods include use of the adult fingertip unit (the amount from the distal interphalangeal joint to the fingertip, or approximately
0.5 grams (gm), being applied over an area equal to 2 adult palms), following the rule of 9's that measures the percent affected area, and use of charts that propose amounts based on patient age and body site. In adults, the rule of nines is used as a rough indicator of % BSA. Palmar hand surface is approximately 1% BSA.

Anatomic Surface	% of Body Surface
Head and neck	9%
Anterior trunk	18%
Posterior trunk	18%
Arms, including hands	9% each
Legs, including feet	18% each
Genitalia	1%

Quantity for 1% BSA, suggested AAD estimation Grams per application

- 0.5gm per application over 2 palms (1% BSA per palm) = 0.25gm per application over 1% BSA grams per month for 1%BSA
- At 0.25gm per application over 1%BSA x 40 applications per month = 0.25gm x 40 = 10gm per 1%BSA per month
- For example, Quantity sufficient based on above calculations for 9%BSA and 18%BSA Grams per month for 9%BSA
- 9%BSA x 10gm = 90 grams/ month Grams per month for 18%BSA
- 18%BSA x 10gm = 180 grams / month
- For example, Quantity sufficient based on above calculations for select drugs with max dosing

APPENDIX 2:

Physician Global Assessment (PGA)

Score/Grade		Description
0	Clear	No signs of psoriasis; post inflammatory hyperpigmentation may be present
1	Almost clear	No thickening; normal to pink coloration; no to minimal focal scaling
2	Mild	Just detectable to mild thickening; pink to light red coloration; predominantly fine scaling
3	Moderate	Clearly distinguishable to moderate thickening; dull to bright red, clearly distinguishable erythema; moderate scaling
4	Severe	Severe thickening with hard edges; bright to deep dark red coloration; severe/coarse scaling covering almost all or all lesions

APPENDIX 3:

Guidelines of care for the management of psoriasis and psoriatic arthritis (AAD 2009)
Guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures (Joint AAD-NPF 2021)
Although not FDA approved for psoriasis, the topical calcineurin inhibitors tacrolimus and pimecrolimus are often used in the treatment of psoriasis. Both agents have demonstrated efficacy when used under occlusion, on facial and intertriginous psoriasis, and are used as steroid-sparing agents for prolonged (>4 weeks) use. The off-label combination of tacrolimus and 6% salicylic acid for 12 weeks may be used for the treatment of plaque psoriasis.

APPENDIX 4:

Topical Steroids by Potency

Very High Potency

Betamethasone dipropionate (augmented)
Clobetasol
Diflorasone diacetate ointment
Halobetasol

High Potency

Amcinonide
Betamethasone dipropionate
Desoximetasone gel, ointment, or cream 0.25% or more
Diflorasone diacetate cream
Fluocinolone cream 0.2% or more
Fluocinonide

Halcinonide
Triamcinolone 0.5% or more
Medium Potency
Beclomethasone
Betamethasone benzoate
Betamethasone valerate
Hydrocortisone acetate
Clobetasone
Clocortolone
Desoximetasone cream less than 0.25%
Diflucortolone
Fluocinolone ointment or topical solution or cream less than 0.2%
Flurandrenolide 0.025% or more
Fluticasone
Hydrocortisone butyrate
Hydrocortisone valerate
Mometasone Prednicarbate
Triamcinolone less than 0.5%
Low Potency Alclometasone
Desonide
Dexamethasone
Flumethasone
Flurandrenolide less than 0.025%
Hydrocortisone

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
More than 7.5 million adults in the United States have psoriasis. The overall U.S. prevalence of psoriasis in adults ≥20 years of age is 3.0%. Plaque psoriasis (PsO) is the most common subtype, affecting 80%– 90% of those with psoriasis. Plaque psoriasis is a chronic, immune-mediated, hyperproliferative skin condition that is characterized by well-demarcated, thick, oval-circular plaques with an appearance that can vary by skin type. For some patients, the skin may be red with silvery-white scales; for others, plaques may appear as purple or discolored skin. Plaques may itch, burn, or sting and typically appear over the scalp, trunk, and extensor body surface, although any area of skin may be involved.

The severity of plaque psoriasis is generally defined by the total body surface area (BSA) involved, although different definitions have been proposed. The Joint American Academy of Dermatology–National Psoriasis Foundation (JAAD–NPF) guidelines consider BSAs of <3%, 3% to 10%, and >10% as mild, moderate, and severe disease, respectively. The Physician Global Assessment (PGA) is a 5 point assessment of overall disease severity using the clinical characteristics of erythema, scaling and plaque thickness as guidelines. The higher the PGA score, the more severe disease.

There are 4 broad categories of treatments for plaque psoriasis:
Topical therapies such as corticosteroids; vitamin D analogs; retinoids; AhR agonist Vtama (tapinarof); PDE4 inhibitor Zoryve (roflumilast)
Phototherapies such as narrowband ultraviolet B (UVB) or psoralen plus ultraviolet A (PUVA)
Conventional oral agents such as cyclosporine, methotrexate, or acitretin
Targeted immunomodulators (TIMs) including biologics that target IL-17, IL-23, IL-12/IL-23, or tumor necrosis factor (TNF)-alpha; and oral agents including PDE4 inhibitor, Otezla, or TYK2 inhibitor, Sotyktu (deucravacitinib)
The choice of therapy depends on several factors including disease severity and location of affected areas, previous treatment failures, comorbidities, patient preference (e.g., cost, convenience, desired amount of disease control), provider preference, and the efficacy and safety profile of each therapy

option.

Vtama (tapinarof) cream is the first FDA approved aryl hydrocarbon receptor (AhR) agonist. The specific mechanism of action by which tapinarof exerts therapeutic effect in psoriasis is unknown, but it is thought to down regulate IL-17 and other interleukin inflammatory cytokines, and promote skin barrier normalization.

The safety and efficacy of Vtama were evaluated in two identical Phase 3 trials: PSOARING 1 (NCT03956355) and PSOARING 2 (NCT03983980). In these randomized, double-blind, vehicle-controlled trials, a total of 1025 adult patients with mild to severe chronic plaque psoriasis were randomized to receive Vtama 1% cream or vehicle cream, applied once daily for 12 weeks to any lesion regardless of anatomic location. Study participants had a baseline 5-point Physician Global Assessment (PGA) score of 2 (mild) to 4 (severe) (on a scale from 0 to 4, with higher scores indicating more severe psoriasis) and a total affected BSA of 3% to 20%. About 80% of patients who participated in the trials had moderate disease. Concomitant use of other medications for psoriasis, including systemic agents and other topicals, was prohibited. In both trials, the primary endpoint was met, with a higher PGA response observed in the Vtama group compared to the placebo group at Week 12 (P <0.001 for both comparisons). Results for secondary endpoints and patient-reported outcomes were generally in the same direction as those for the primary endpoint.

Adverse effects that occurred in ≥1% of patients treated with Vtama and at a greater rate than in patients treated with vehicle in PSOARING 1 or PSOARING 2 included folliculitis, nasopharyngitis, contact dermatitis, headache, pruritus, and influenza. Adverse reactions leading to treatment discontinuation in >1% of subjects who received Vtama were contact dermatitis (2.9%) and folliculitis (2.8%). There were no serious adverse events that were considered by the investigators to be related to Vtama or vehicle cream in either trial. The safety of Vtama was also established in the LTE PSOARING 3 trial, wherein Vtama demonstrated safety and tolerability consistent with PSOARING 1 and PSOARING 2. The most frequent adverse events were folliculitis (22.7%), contact dermatitis (5.5%), and upper respiratory tract infection (4.7%). Burning, itching, or stinging were rated as low by 86%–92% of patients over the 40- week LTE trial.

Vtama is a once daily cream that does not have limitations on the duration of treatment or body area where it may be applied. Long term safety studies beyond 1 year are lacking.

Vtama was approved for use in atopic dermatitis in December 2024 based on safety and efficacy data from two multicenter, randomized, double-blind, vehicle-controlled trials – ADORING 1 and ADORING 2. Baseline disease severity was graded using the 5-point validated Investigator's Global Assessment (vIGA-AD). The primary efficacy endpoint in both trials was the proportion of subjects who achieved treatment success, defined as a vIGA-AD score of "Clear" (0) or "Almost Clear" (1) and at least a 2-grade improvement from baseline. Efficacy was also assessed using a ≥ 4-point improvement in PP-NRS score in subjects 12 years of age and older. Vtama cream had statistically significant improvements in both endpoints over placebo. Once subjects achieved complete disease clearance, they had Vtama withdrawn. The median time to first worsening was 57 days. Study duration included initial 8 weeks plus additional 48 weeks of follow up.

The most common adverse reactions in the atopic dermatitis studies were upper respiratory infection, folliculitis, lower respiratory tract infection, headache, asthma, vomiting, ear infection, pain in extremity, and abdominal pain.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Vtama (tapinarof) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to Vtama (tapinarof) include: No labeled contraindications.

OTHER SPECIAL CONSIDERATIONS:

CODING/BILLING INFORMATION

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.*

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:
Vtama CREA 1% 60 gram tube

REFERENCES

1. Vtama (tapinarof) cream, for topical use [prescribing information]. Long Beach, CA: Dermavant Sciences Inc; December 2024.
2. Menter A, Korman N, Elmets C, et al. Guidelines of Care for the Management of Psoriasis and Psoriatic Arthritis. Section 3. Guidelines of Care for the Management and Treatment of Psoriasis with Topical therapies. J Am Acad Dermatol 2009; 60:643-59.
3. 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; 84:432.
4. Sidbury R, Alikhan A, Bercovitch L, Cohen DE, Darr JM, Drucker AM, Eichenfield LF, Frazer- Green L, Paller AS, Schwarzenberger K, Silverberg JI, Singh AM, Wu PA, Davis DMR, Guidelines of care for the management of atopic dermatitis in adults with topical therapies, Journal of the American Academy of Dermatology (2023), doi: https://doi.org/10.1016/j.jaad.2022.12.029.

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information Prescriber Requirements Appendix References	Q2 2025

REVISION- Notable revisions: Coding/Billing Information Template Diagnosis Update Required Medical Information Continuation of Therapy Age Restrictions FDA-Approved Uses Background References	Q1 2025
REVISION- Notable revisions: Required Medical Information Duration of Approval	Q2 2024
REVISION- Notable revisions: Continuation of Therapy Quantity Appendix Background Contraindications/Exclusions/Discontinuation	Q2 2023
NEW CRITERIA	Q3 2022