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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

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.

A. PLAQUE PSORIASIS:

1. a. (i) Documentation of mild psoriasis AND (ii) Documentation of trial and failure of topical corticosteroids, tacrolimus or pimecrolimus (see Appendix)
OR
b. (i) Documented diagnosis of moderate to severe psoriasis (BSA \geq 5%) OR \leq 10% body surface

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area with plaque psoriasis that involves sensitive areas of the body or areas that would significantly impact daily function (ex. face, neck, hands, feet, genitals)

AND

(ii) ONE of the following: (1) Documentation of treatment failure with or a clinical contraindication to TWO of the following systemic therapies for ≥ 3 months: Methotrexate (oral or IM at a minimum dose of 15 mg/week), cyclosporine, acitretin, azathioprine, hydroxyurea, leflunomide, mycophenolate mofetil, or tacrolimus OR (2) Documentation of treatment failure to Phototherapy for ≥ 3 months with either psoralens with ultraviolet A (PUVA) or ultraviolet B (UVB) radiation (provider to submit documentation of duration of treatment, dates of treatment, and number of sessions; contraindications include type 1 or type 2 skin, history of photosensitivity, treatment of facial lesions, presence of premalignant lesions, history of melanoma or squamous cell carcinoma, or physical inability to stand for the required exposure time)

AND

2. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal

CONTINUATION OF THERAPY:

A. PLAQUE PSORIASIS:

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

DURATION OF APPROVAL:

Initial authorization: 6 months, Continuation of Therapy: 12 months

PRESCRIBER REQUIREMENTS:

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

AGE RESTRICTIONS:

18 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.

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

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- 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; postinflammatory 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.

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

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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 $\geq 1\%$ 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.

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:

None

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPDS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:

Vtama CREAM 1%

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REFERENCES

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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.

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Continuation of Therapy Quantity Appendix Background Contraindications/Exclusions/Discontinuation	Q2 2023
NEW CRITERIA	Q3 2022