Original Effective Date: 08/01/2022
Current Effective Date: 09/28/2022
Last P&T Approval/Version: 07/27/2022
Next Review Due By: 07/2023
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

A. PLAQUE PSORIASIS:
1. a. (i) Documentation of mild psoriasis AND (ii) Documentation of trial and failure of topical corticosteroids, tacrolimus or pimecrolimus
   OR
   b. (i)Documented diagnosis of moderate to severe psoriasis (BSA $\geq$ 5%) OR ≤10% body surface 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, sulfasalazine, 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. ALL INDICATIONS:
   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 (documentation required)
      AND
   2. Documentation of no 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 within initial request and reauthorization requests]

AGE RESTRICTIONS:
18 years of age and older

QUANTITY:
Member's BSA effected <10%- maximum 60 grams/ 25 days
Member's BSA effected >10%- maximum of 180 grams/25 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

APPENDIX:

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

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
(Discussion of disease state, current standard care, criteria drug's place in therapy, clinical studies that led to approval, etc., if needed)

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

OTHER SPECIAL CONSIDERATIONS:

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

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:
Vtama CREAM 1%

REFERENCES

1. Vtama (tapinarof) [prescribing information]. Long Beach, CA: Dermavant Sciences Inc; May 2022
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
NEW CRITERIA	Q3 2022