Clinical Policy: Tapinarof (Vtama)

Reference Number: CP.PMN.283
Effective Date: 12.01.22
Last Review Date: 11.24
Line of Business: Commercial, HIM, Medicaid Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Tapinarof (Vtama®) is an aryl hydrocarbon receptor agonist.

FDA Approved Indication(s)

Vtama is indicated for the topical treatment of plaque psoriasis in adults.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Vtama is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Plaque Psoriasis (must meet all)**:**

1. Diagnosis of plaque psoriasis;
2. Prescribed by or in consultation with a dermatologist or rheumatologist;
3. Age ≥ 18 years;
4. Member has ≤ 20% body surface area involvement;
5. Member meets one of the following (a or b):
   a. Failure of both of the following used concurrently, unless clinically significant adverse effects are experienced or all are contraindicated (i and ii):
      i. Medium to ultra-high potency topical corticosteroid (*see Appendix B);*
      ii. Calcipotriene, calcitriol, or tazarotene;
   b. For face or intertriginous areas (e.g., genitals, armpits, forearms, and groin): Failure of a topical calcineurin inhibitor* (*see Appendix B),* unless contraindicated or clinically significant adverse effects are experienced;
      **Prior authorization may be required for topical calcineurin inhibitors*
6. Request does not exceed 1 tube per month.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business:

CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or

b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Plaque Psoriasis (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 1 tube per month.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1, 2, or 3)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
AAD: American Academy of Dermatology
FDA: Food and Drug Administration
NPF: National Psoriasis Foundation

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
calcipotriene (Dovonex®) cream, ointment, solution	Apply topically to the affected area(s) BID	100 g/week
calcitriol (Vectical™) ointment	Apply topically to the affected area(s) BID	200 g/week
tazarotene (Tazorac®) gel, cream	Apply topically to the affected area(s) QHS	Once daily application
Ultra-High Potency Topical Corticosteroids		
augmented betamethasone dipropionate 0.05% (Diprolene®, Alphatrex®) ointment, gel	Apply topically to the affected area(s) BID	Should not be used for longer than 4 consecutive weeks
clobetasol propionate 0.05% (Temovate®, Temovate E®) cream, ointment, gel, solution		
diflorasone diacetate 0.05% (Apexicon®) ointment		
halobetasol propionate 0.05% (Ultravate®) cream, ointment		
High Potency Topical Corticosteroids		
augmented betamethasone dipropionate 0.05% (Diprolone®, Diprolene® AF) cream, lotion	Apply topically to the affected area(s) BID	Should not be used for longer than 4 consecutive weeks
betamethasone dipropionate 0.05% ointment		
desoximetasone (Topicort®) 0.25%, 0.05% cream, ointment, gel		
diflorasone 0.05% (Apexicon E®) cream		
fluocinonide acetonide 0.05% cream, ointment, gel, solution		
triamcinolone acetonide 0.5% (Aristocort®, Kenalog®) cream, ointment		

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Medium/Medium to High Potency Topical Corticosteroids		
betamethasone dipropionate 0.05% cream	Apply topically to the affected area(s) BID	Should not be used for longer than 4 consecutive weeks
desoximetasone 0.05% (Topicort®) cream, ointment, gel		
fluocinolone acetonide 0.025% (Synalar®) cream, ointment		
fluticasone propionate 0.05% (Cutivate®) cream		
mometasone furoate 0.1% (Elocon®) cream, lotion, ointment		
triamcinolone acetonide 0.1%, 0.25%,0.5% (Aristocort®, Kenalog®) cream, ointment		
Topical Calcineurin Inhibitors		
tacrolimus (Protopic®)†	Apply twice daily to psoriatic lesions of the face and intertriginous areas	2 applications/day
pimecrolimus (Elidel®)†	Apply twice daily to affected intertriginous areas	2 applications/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.
†Off-label indication

Appendix C: Contraindications/Boxed Warnings
None reported

Appendix D: General Information
- The 2021 American Academy of Dermatology (AAD) and National Psoriasis Foundation (NPF) recommendations:
  - The off-label usage of 0.1% tacrolimus for psoriasis involving the face as well as inverse psoriasis for up to 8 weeks can be considered
  - The off-label use of pimecrolimus for inverse psoriasis for 4-8 weeks is recommended
  - Use of combination treatments with vitamin D analogues and potent class II and class III topical corticosteroids up to 52 weeks is recommended for the treatment of psoriasis
  - Use of combination products with calcipotriol and corticosteroids is recommended for the treatment of psoriasis
  - The use of mid- or high-potency topical corticosteroids in combination with tazarotene for 8-16 weeks is more effective than monotherapy and is recommended for the treatment of mild to moderate psoriasis
  - The use of topical corticosteroids along with tazarotene is recommended to decrease the duration of treatment as well as increase the length of remission

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Plaque psoriasis	Apply a thin layer to affected areas QD	1 application/day

VI. Product Availability

Cream: 1%, each gram of Vtama cream contains 10 mg of tapinarof

VII. References

1. Vtama Prescribing Information. Long Beach, CA: Dermavant Sciences Inc.; May 2022. Available at: https://www.vtama.com/hcp/PI/. Accessed July 19, 2024.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2023. Available at: https://www.clinicalkey.com/pharmacology/. Accessed August 12, 2024.
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(2):432-70.
4. Bissonnette R, Stein Gold L, Rubenstein DS, et al. Tapinarof in the treatment of psoriasis: a review of the unique mechanism of action of a novel therapeutic aryl hydrocarbon receptor – modulating agent. J Am Acad Dermatol 2021; 84(4):1059-1067.
5. Lebwohl MG, Stein Gold L, Strober B, et al. Phase 3 trials of tapinarof cream for plaque psoriasis. N Engl J Med 2021;385(24):2219-2229.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	09.06.22	11.22
4Q 2023 annual review: updated Appendix B by removing Enstilar and Duobrii therapeutic alternatives since agents are not redirected to and are non-formulary for Commercial, HIM, and Medicaid lines of business; references reviewed and updated.	08.01.23	11.23
4Q 2024 annual review: no significant changes; for continued therapy other diagnosis/indications section, corrected template changes; references reviewed and updated.	07.19.24	11.24

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.