

**Clinical Policy: Tapinarof (Vtama)** 

Reference Number: CP.PMN.283

Effective Date: 12.01.22 Last Review Date: 11.25

Line of Business: Commercial, HIM, Medicaid

Revision Log

See <u>Important Reminder</u> 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
- Atopic dermatitis in adults and pediatric patients 2 years of age and older

#### 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<sup>®</sup> 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  $\geq$  18 years;
  - 4. Member has  $\leq 20\%$  body surface area involvement;
  - 5. Member meets one of the following (a or b):<sup>†</sup>

    †For Illinois HIM requests, the step therapy requirements below do not apply as of 1/1/2026 per IL HB
    5395
    - 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.** Atopic Dermatitis (must meet all):

- 1. Diagnosis of atopic dermatitis:
- 2. Age  $\geq$  2 years;



- 3. Failure of both of the following (a and b), each used for ≥ 2 weeks, unless clinically significant adverse effects are experienced or all are contraindicated:<sup>†</sup>

  †For Illinois HIM requests, the step therapy requirements below do not apply as of 1/1/2026 per IL HB 5395
  - a. Two formulary medium-to-very high potency topical corticosteroids (*see Appendix B*), unless involved areas include the face, neck, or intertriginous areas;
  - b. Topical tacrolimus;

\*Prior authorization may be required for topical tacrolimus

4. Dose does not exceed 1 tube per month.

**Approval duration: 12 months** 

### C. 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. All Indications in Section I (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

BSA: body surface area

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/			
Di ug Name	Dusnig Regimen	Maximum Dose	
DI AQUE BOODIACIO		Maximum Dose	
PLAQUE PSORIASIS			
calcipotriene (Dovonex®)	Apply topically to the affected	100 g/week	
cream, ointment, solution	area(s) BID		
calcitriol (Vectical <sup>™</sup> ) ointment	Apply topically to the affected	200 g/week	
, ,	area(s) BID		
tazarotene (Tazorac®) gel,	Apply topically to the	Once daily application	
cream	affected area(s) QHS		
Ultra-High Potency Topical Con	rticosteroids		
augmented betamethasone	Apply topically to the affected	Should not be used for	
dipropionate 0.05%	area(s) BID	longer than 4	
(Diprolene®, Alphatrex®)		consecutive weeks	
ointment, gel			
clobetasol propionate 0.05%			
(Temovate <sup>®</sup> , Temovate E <sup>®</sup> )			
cream, ointment, gel, solution			
diflorasone diacetate 0.05%			
(Apexicon®) ointment			
halobetasol propionate 0.05%			
(Ultravate®) cream, ointment			



Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
High Potency Topical Corticost	eroids	
augmented betamethasone dipropionate 0.05% (Diprolone®, Diprolene® AF) cream, lotion 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,	Apply topically to the affected area(s) BID	Should not be used for longer than 4 consecutive weeks
ointment  Madium to High Potancy Tonic	al Coutionstaunids	
Medium to High Potency Topica		
betamethasone dipropionate 0.05% cream  desoximetasone 0.05% (Topicort®) cream, ointment, gel fluocinolone acetonide 0.025% (Synalar®) cream, ointment fluticasone propionate 0.05% (Cutivate®) cream mometasone furoate 0.1% cream, lotion, ointment triamcinolone acetonide 0.1%, 0.25%,0.5% (Aristocort®, Kenalog®) cream, ointment	Apply topically to the affected area(s) BID	Should not be used for longer than 4 consecutive weeks
Topical Calcineurin Inhibitors		
tacrolimus (Protopic®) <sup>†</sup>	Apply a thin layer to affected area twice daily	Varies
pimecrolimus (Elidel®) <sup>†</sup>	Apply a thin layer to affected area twice daily	Varies



Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
ATOPIC DERMATITIS		
Very High Potency Topical Cort	ticosteroids	
augmented betamethasone 0.05% (Diprolene® AF) cream, ointment, gel, lotion clobetasol propionate 0.05% (Temovate®) cream, ointment, gel, solution diflorasone diacetate 0.05% (Maxiflor®, Psorcon E®) cream, ointment fluocinonide 0.1% cream	Apply topically to the affected area(s) BID	Varies
halobetasol propionate 0.05% (Ultravate®) cream, ointment		
High Potency Topical Corticoste	roids	
amcinonide 0.1% ointment, lotion	Apply topically to the affected area(s) BID	Varies
augmented betamethasone 0.05% (Diprolene® AF) cream, ointment, gel, lotion betamethasone valerate 0.1%, 0.12% (Luxiq®) ointment, foam clobetasol propionate 0.025% (Impoyz®) cream diflorasone 0.05% (Florone®, Florone E®, Maxiflor®,Psorcon E®) cream fluocinonide acetonide 0.05% (Lidex®, Lidex E®) cream, ointment, gel, solution fluticasone propionate 0.005% cream, ointment halcinonide 0.1% cream, ointment, solution (Halog®) halobetasol propionate 0.01% lotion (Bryhali®) mometasone furoate 0.1% ointment triamcinolone acetonide 0.5% (Aristocort®, Kenalog®) cream, ointment		



Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose		
Medium to High Potency Topica	Medium to High Potency Topical Corticosteroids			
clocortolone pivalate 0.1% cream  desoximetasone 0.05%, 0.025% (Topicort®) cream, ointment, gel fluocinolone acetonide 0.025% (Synalar®) cream, ointment flurandrenolide 0.05% lotion,	Apply topically to the affected area(s) BID	Varies		
ointment (Cordran®) hydrocortisone valerate 0.2% cream mometasone 0.1% cream, ointment, lotion triamcinolone acetonide 0.025%, 0.1% (Aristocort®, Kenalog®) cream, ointment				
Topical Calcineurin Inhibitor				
tacrolimus 0.03%, 0.1% ointment (Protopic®)	Apply a thin layer to affected area twice daily	Varies		

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 for psoriasis:
  - 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
  - o 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	<b>Dosing Regimen</b>	<b>Maximum Dose</b>
Plaque psoriasis	Apply a thin layer to affected areas QD	1 application/day
Atopic dermatitis		

#### 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 2025. Available at: VTAMA® (tapinarof) cream, 1%. Accessed July 17, 2025.
- 2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2025. Available at: https://www.clinicalkey.com/pharmacology/. Accessed July 17, 2025.
- 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 tapinar of cream for plaque psoriasis. N Engl J Med 2021;385(24):2219-2229.
- 6. Sidbury R, Alikhan A, Bercovitch L, et al. Guidelines of care for the management of atopic dermatitis in adults with topical therapies. J Am Acad Dermatol. 2023; 89(1):e1-e20.
- 7. Chu DK, Schneider L, Asiniwasis RN, et al. Atopic dermatitis (eczema) guidelines: 2023 American Academy of Allergy, Asthma and Immunology/American College of Allergy, Asthma and Immunology Joint Task Force on Practice Parameters GRADE- and Institute of Medicine-based recommendations. Ann Allergy Asthma Immunol. 2024 Mar;132(3):274-312. doi: 10.1016/j.anai.2023.11.009.
- 8. Silverberg JI, Eichenfield LF, Hebert AA, et al. Tapinarof cream 1% once daily: Significant efficacy in the treatment of moderate to severe atopic dermatitis in adults and children down to 2 years of age in the pivotal phase 3 ADORING trials. J Am Acad Dermatol. 2024 Sep;91(3):457-465. doi: 10.1016/j.jaad.2024.05.023.

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	08.01.23	11.23
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.		
4Q 2024 annual review: no significant changes; for continued	07.19.24	11.24
therapy other diagnosis/indications section, corrected template		
changes; references reviewed and updated.		
RT4: added newly approved atopic dermatitis indication to criteria.	12.26.24	



Reviews, Revisions, and Approvals	Date	P&T Approval Date
4Q 2025 annual review: no significant changes; added step therapy bypass for IL HIM per IL HB 5395; references reviewed and updated.	07.10.25	11.25

#### **Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

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.



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#### 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.

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