

Clinical Policy: Tapinarof (Vtama)

Reference Number: CP.PMN.283

Effective Date: 12.01.22

Last Review Date: 11.22

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 \geq 18 years;
4. Member has \leq 20% body surface area involvement;
5. Member meets one of the following (a or b):
 - a. Failure of both of the following used concurrently (i and ii), unless clinically significant adverse effects are experienced or all are contraindicated:
 - 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. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
Approval duration: Duration of request or 12 months (whichever is less); or
2. 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
3. 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 acetone 0.05% cream, ointment, gel, solution | | |
| triamcinolone acetone 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 | | |
| Combination Corticosteroid + (Vitamin D Analog or Retinoid) | | |
| Enstilar [®] (calcipotriene 0.005% and betamethasone dipropionate 0.064%) foam | Apply topically to affected areas QD for up to 4 weeks. Avoid use on face, groin, axillae, skin treatment site with atrophy present, or with occlusive dressing unless directed by a healthcare provider | 60 g/4 days |
| Duobrii [®] (halobetasol propionate 0.01% and tazarotene 0.045%) lotion | Apply a thin layer of lotion once daily to affected areas until control is achieved | 50 g/week |
| Topical Calcineurin Inhibitors | | |
| tacrolimus (Protopic [®]) (off-label) | Apply twice daily to psoriatic lesions of the face and intertriginous areas | 2 applications/day |
| pimecrolimus (Elidel [®]) (off-label) | 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.

Appendix C: Contraindications/Boxed Warnings

None reported

Appendix D: General Information

- The 2021 American Academy of Dermatology (AAD) and National Psoriasis Foundation (NPF) recommendations:
 - 2.1 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
 - 2.2 The off-label use of pimecrolimus for inverse psoriasis for 4-8 weeks is recommended

- 3.4 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
- 3.5 Use of combination products with calcipotriol and corticosteroids is recommended for the treatment of psoriasis
- 4.4 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
- 4.5 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 August 15, 2022.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2022. Available at: <http://www.clinicalpharmacology-ip.com/>. Accessed August 24, 2022.
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, Tallman A and Armstrong A. 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 |

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.

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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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