tapinarof (Vtama®)

EOCCO POLICY

Policy Type: PA Pharmacy Coverage Policy: EOCCO262

Description

Tapinarof (Vtama) cream is a topical aryl hydrocarbon receptor agonist.

Length of Authorization

- Initial: Six months
- Renewal: 12 months
    i. One three-month quantity exception approval allowed per lifetime, when applicable criteria are met.

Quantity Limits

Product Name	Indication	Dosage Form	Quantity Limit
tapinarof (Vtama)	Plaque Psoriasis	1% topical cream	60 grams/30 days*

**Quantity exceptions not allowed on initial approval*

Initial Evaluation

I. **Tapinarof (Vtama) cream** may be considered medically necessary when the following criteria are met:
   A. Member is 18 years of age or older; **AND**
   B. Diagnosis of plaque psoriasis; **AND**
   C. Treatment with at least one agent from three different topical medication classes below has been ineffective or not tolerated, unless all are contraindicated:
      1. Corticosteroid: High-potency corticosteroid (e.g., betamethasone, clobetasol)
         i. When located on the face or intertriginous areas only, low-potency corticosteroid (e.g., hydrocortisone) accepted
      2. Calcineurin inhibitor: tacrolimus ointment or pimecrolimus cream
      3. Vitamin D analog: calcipotriene cream/ointment or calcitriol ointment
      4. Retinoid: tazarotene cream

II. Tapinarof (Vtama) is considered investigational when used for all other conditions, including but not limited to:
   A. Plaque psoriasis in pediatric or adolescent patients
   B. Atopic dermatitis

Renewal Evaluation

I. Member has received a previous prior authorization approval for this agent through this health plan or has been established on therapy from a previous health plan; **AND**

II. Member is not continuing therapy based off being established on therapy through samples, manufacturer coupons, or otherwise. If they have, initial policy criteria must be met for the member to qualify for renewal evaluation through this health plan; **AND**
   - A. On first renewal: The member has exhibited improvement in extent and/or severity of psoriasis; **OR**
   - B. Upon subsequent renewals: The member has exhibited continued improvement or stability in extent and/or severity of psoriasis; **AND**

III. If quantity requested is greater than 60 grams (1 tube) per 30-day supply, a quantity exception will be considered medically necessary when the following are met:
   - A. Documentation of current body surface area affected by psoriasis; **AND**
   - B. Rationale for need of more than one tube of cream per 30-days; **AND**
   - C. Quantity requested does not exceed the amount needed to cover psoriatic lesions at a frequency of once daily.

Supporting Evidence

I. Tapinarof (Vtama) cream is a non-steroidal topical medication for the treatment of plaque psoriasis and has only been evaluated for safety and efficacy in adults for the treatment of plaque psoriasis. Coverage consideration is limited to those 18 years of age or older. It is being evaluated in pediatric patients in clinical trials, and use of therapy is best monitored in pediatrics and adolescents in a clinical trial setting until sufficient evidence for safety and efficacy in these populations is available.

II. Tapinarof (Vtama) cream is being evaluated in clinical trials for other skin conditions (e.g., atopic dermatitis); however, safety and efficacy have not been sufficiently demonstrated for any condition other than plaque psoriasis. Thus, coverage consideration is limited only to patients with a diagnosis of plaque psoriasis.

III. Tapinarof (Vtama) cream was evaluated as monotherapy in two Phase 3 clinical trials, which showed improvement in extent and severity of psoriasis as well as improvement in patient quality-of-life vs. a placebo vehicle. It was effective and well tolerated when used on the face and intertriginous areas. The extent of efficacy as well as safety when used in combination with other topical or systemic agents for this condition are currently unknown given the use as monotherapy only in clinical trials. Tapinarof (Vtama) cream joins a market of well-established, effective, and generic topical treatment options for psoriasis:

- Topical corticosteroids (TCS) are the mainstay of therapy for plaque psoriasis, with a variety of chemical entities, potencies, and formulations to satisfy patient needs. These are highly effective, and safety concerns or adverse events can be mitigated by proper use (i.e., application to affected areas only), use of products that offer appropriate potency for extent/severity/area of the body, and the correct formulation (e.g., foams, sprays, oils, or shampoos for scalp involvement). Plaque psoriasis on the face or intertriginous areas may require a low potency TCS (e.g., OTC hydrocortisone 1%). Skin atrophy is a common concern for utilizing TCS for extended durations of time; however, this is rarely a concern when TCS are applied to plaques appropriately (e.g., on active current lesions). For patients that experience quick recurrence of plaques after TCS discontinuation, TCS may be restarted intermittently, or steroid-sparing therapy may be considered, which may have synergistic effects with TCS.
- Topical calcineurin inhibitors (TCI): Tacrolimus 0.1% ointment and pimecrolimus 1% cream are the available generic TCI products, and they may be utilized as monotherapy or in combination with other topicals. These are safe and effective and have been evaluated for use on the face and intertriginous areas, as well as, in pediatric patients.
- Vitamin D analogs: Calcipotriene and calcitriol are the available generic products, and they may be utilized as monotherapy or in combination with other topicals. Combination use with TCS may have synergistic efficacy and increases tolerability vs. either agent alone. Monotherapy preparations are available, as well as betamethasone dipropionate-calcipotriene as a generic single preparation combination therapy as various formulations. These are applied once daily.
- Topical retinoid: Tazarotene 0.05% cream and 0.1% cream and foam are available with the 0.1% products being available as generics. Similar to vitamin D analogs, use with TCS may increase improve efficacy and tolerability. A single preparation combination therapy is available for halobetasol-tazarotene (Duobrii).

IV. Tapinarof (Vtama) cream has not proven to be superior in safety or efficacy to established therapies. Given the lack of definitive clinical advantage, as well as, higher cost relative to available generic therapies, use of at least three different classes of standard of care topical medications is required prior to coverage consideration of tapinarof (Vtama) cream.

V. One tube of tapinarof (Vtama) cream contains 60 grams, which should be adequate to cover 8% of the body surface area on average for 30-days when used appropriately (e.g., thin layer, once daily application). This quantity is likely sufficient for patients that have greater than 10% of the body surface area affected as well, given that when efficacy is realized the quantity needed to cover psoriatic plaques will decrease over time. Not all patients will respond to therapy or be able to tolerate therapy. Given these considerations, the plan's quantity limit for initial approval (i.e., first six months) is one tube per month, to minimize risk of medication waste as efficacy, tolerability, and adherence are realized. Upon renewal, a quantity exception may be granted based on medical necessity. The current body surface area affected and provider rationale for

needing increased quantity will be reviewed relative to the labeled dosing recommendations and frequency. A one-time quantity exception may be granted when criteria are met. In clinical trials for patients that respond to therapy, tapinarof (Vtama) has the potential to treat psoriatic lesions and may prevent occurrence of new lesions for several months follow treatment success. If continuous use at excessive quantities of tapinarof (Vtama) cream are required, alternative treatment strategies with greater potential efficacy and favorable cost effectiveness may be more appropriate (e.g., other topical therapies, DMARDS, other systemic agents).

Investigational or Not Medically Necessary Uses

I. Tapinarof (Vtama) has not been FDA-approved, or sufficiently studied for safety and efficacy for the conditions or settings listed below:
   A. Plaque psoriasis in pediatric or adolescent patients
   B. Atopic dermatitis

References

1. 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.
2. 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. Journal of the American Academy of Dermatology. 2021;84(2):432-470.
3. Vtama [Prescribing Information]. Dermavant Sciences Inc. Long Beach, CA. May 2022.

Related Policies

Policies listed below may be related to the current policy. Related policies are identified based on similar indications, similar mechanisms of action, and/or if a drug in this policy is also referenced in the related policy.

Policy Name	Disease state
Chronic Inflammatory Disease Policy	Plaque psoriasis
Systemic Janus Associated Kinase Inhibitors in Chronic Inflammatory Disease Policy	Plaque psoriasis

Policy Implementation/Update:

Action and Summary of Changes	Date
Policy created	08/2022