Vtama (tapinarof) Prior Authorization Program Summary

This program applies to FlexRx Closed, FlexRx Open, FocusRx, GenRx Closed, GenRx Open, Health Insurance Marketplace and KeyRx formularies.

This is a FlexRx Standard and GenRx Standard program.

The BCBS MN Step Therapy Supplement also applies to this program for all Commercial/HIM lines of business.

POLICY REVIEW CYCLE

Effective Date	**Date of Origin**
02-01-2024	01-01-2023

FDA APPROVED INDICATIONS AND DOSAGE

Agent(s)	FDA Indication(s)	Notes	Ref#
Vtama® (tapinarof) Cream	Treatment of plaque psoriasis in adults		1

See package insert for FDA prescribing information: https://dailymed.nlm.nih.gov/dailymed/index.cfm

CLINICAL RATIONALE

Psoriasis (PS)	Psoriasis (PS) is a chronic inflammatory skin condition that is often associated with systemic manifestations, especially arthritis. Diagnosis is usually clinical, based on the presence of typical erythematous scaly patches, papules, and plaques that are often pruritic and sometimes painful. Treatment goals for psoriasis include improvement of skin, nail, and joint lesions plus enhanced quality of life.(2)
	
	The American Academy of Family Physicians (AAFP) categorizes psoriasis severity into mild to moderate (less than 5% of body surface area [BSA]) and moderate to severe (5% or more of BSA). The AAFP psoriasis treatment guidelines recommend basing treatment on disease severity:(2)
	
	• Mild to moderate (less than 5% of BSA and sparing the genitals, hands, feet, and face):
	  ○ Candidate for intermittent therapy: topical corticosteroids, vitamin D analogs (calcipotriene and calcitriol), or tazarotene (Tazorac)
	  ○ Candidate for continuous therapy: calcineurin inhibitors (tacrolimus and pimecrolimus)
	• Severe (5% or more of BSA or involving the genitals, hands, feet, and face):
	  ○ Less than 20% of BSA affected: vitamin D analogs (calcipotriene and calcitriol) with or without phototherapy. These agents have a slower onset of action but a longer disease-free interval than topical corticosteroids
	  ○ 20% or more of BSA affected: systemic therapy with MTX, cyclosporine, acitretin, or biologics. Biologics are recommended for those with concomitant PsA
	• Less commonly used topical therapies include non-medicated moisturizers, salicylic acid, coal tar, and anthralin

	The American Academy of Dermatology (AAD) and National Psoriasis Foundation (NPF) categorize psoriasis severity as limited or mild (less than 3% of BSA), moderate (3% to 10% of BSA), or severe (greater than 10% of BSA). The AAD/NPF guidelines also note that psoriasis can be considered severe irrespective of BSA when it occurs in select locations (e.g., hands, feet, scalp, face, or genital area) or when it causes intractable pruritus.(4) The AAD psoriasis treatment guidelines recommend the following:(3,6)
	
	• Limited disease (less than 5% of BSA):
	  ○ Topical corticosteroids are first line as either monotherapy or in conjunction with non-steroidal topical agents
	  ○ Vitamin D analogs, calcipotriene, calcipotriol, and calcitriol, are other first line agents and are often used in combination with topical corticosteroids
	  ○ Tazarotene is a corticosteroid sparing agent and can be used in combination with topical corticosteroids to produce a synergistic effect and longer durations of treatment benefit and remission
	  ○ Phototherapy is another first line option for limited disease, and allows for selective targeting of localized lesions and resistant areas such as the scalp and skin folds, leaving surrounding, non-lesional skin unaffected
	  ○ Calcineurin inhibitors (tacrolimus and pimecrolimus) may also be considered first line for intertriginous, inverse, face, and genital psoriasis
	  ○ Systemic agents are considered second line and only for short term use
	• Moderate to severe disease without PsA (more than 5% of BSA or psoriasis in vulnerable areas [e.g., face, genitals, hands, and feet] that adversely affects quality of life):
	  ○ UV-therapy is considered first line as monotherapy or in combination with acitretin or MTX
	  ○ If UV-therapy is unavailable, first line therapies include MTX, cyclosporine, acitretin, and biologics
	  ○ Second line systemic agents include leflunomide, sulfasalazine, and tacrolimus
	• Biologics are routinely used when one or more traditional systemic agents fail to produce adequate response, but are considered first line in patients with moderate to severe psoriasis with concomitant severe PsA
	
	The National Psoriasis Foundation (NPF) medical board recommend a treat-to-target approach to therapy for psoriasis that include the following:(5)
	
	• The preferred assessment instrument for determining disease severity is BSA
	• Target response after treatment initiation should be BSA less than or equal to 1% after 3 months
	• Acceptable response is either a BSA less than or equal to 3% or a BSA improvement greater than or equal to 75% from baseline at 3 months after treatment initiation

Efficacy (1)	Two multicenter, randomized, double-blind, vehicle-controlled trials were conducted to evaluate the safety and efficacy of Vtama cream for the treatment of adults with plaque psoriasis (PSOARING 1 [NCT03956355] and PSOARING 2 [NCT03983980]). These trials were conducted in a total of 1025 subjects randomized 2:1 to Vtama cream or vehicle cream applied once daily for 12 weeks to any lesion regardless of anatomic location. Baseline disease severity was graded using the 5-point Physician's Global Assessment (PGA). The majority of subjects had "Moderate" disease (82%), while 10% had "Mild" disease, and 8% had "Severe" disease at baseline. The extent of disease involvement assessed by mean body surface area (BSA), excluding the scalp, palms, and soles, was 8% (range 3 to 20%).

	The primary efficacy endpoint in both studies was the proportion of subjects who achieved treatment success, defined as a PGA score of "Clear" (0) or "Almost Clear" (1) and at least a 2-grade improvement from baseline. At week 12, patients treated with Vtama achieved treatment success at a 29% greater rate than placebo in PSOARING 1 and at a 34% greater rate than placebo in PSOARING 2. Following 12 weeks of treatment, 73 subjects randomized to Vtama achieved complete disease clearance (PGA 0) and had Vtama withdrawn. These subjects were followed for up to 40 additional weeks with a median time to first worsening (PGA greater than or equal to 2 ["Mild"]) of 114 days (95% CI: 85, 142).
Safey(1)	Vtama does not have any FDA labeled contraindications for use.

REFERENCES

Number	Reference
1	Vtama prescribing information. Dermavent Sciences Inc. May 2022.
2	Weigle, Nancy, M.D., et al. Psoriasis. American Academy of Family Physicians. May 2013. 87 (9): 626-633.
3	Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. J Am Acad Dermatol. 2011;65(1):137–174.
4	Menter, Alan et al. (2019). Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. Journal of the American Academy of Dermatology. doi: https://doi.org/10.1016/j.jaad.2018.11.057.
5	Armstrong AW, Siegel MP, Bagel J, et al. From the medical board of the National Psoriasis Foundation: treatment targets for plaque psoriasis. Journal of the American Academy of Dermatology. 2017;76(2):290-298. doi: 10.1016/j.jaad.2016.10.017.
6	Menter A, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 1. Overview of psoriasis and guidelines of care for the treatment of psoriasis with biologics. Journal of the American Academy of Dermatology. 2008; 58:826–850. doi: 10.1016/j.jaad.2008.02.039.

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Vtama	tapinarof cream	1 %	M ; N ; O ; Y	N		

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Vtama	tapinarof cream	1 %	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met:

Module	Clinical Criteria for Approval
	1. ONE of the following A. The patient has a diagnosis of plaque psoriasis AND ALL of the following: 1. The patient's affected body surface area (BSA) is less than or equal to 20% **AND** 2. ONE of the following: A. The patient has tried and had an inadequate response to a topical corticosteroid **OR** B. The patient has an intolerance or hypersensitivity to therapy with topical corticosteroids **OR** C. The patient has an FDA labeled contraindication to ALL topical corticosteroids **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that topical corticosteroids cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 3. ONE of the following: A. The patient has tried and had an inadequate response to another topical psoriasis agent with a different mechanism of action (e.g., vitamin D analogs, calcineurin inhibitors, tazarotene) **OR** B. The patient has an intolerance or hypersensitivity to another topical psoriasis agent with a different mechanism of action **OR** C. The patient has an FDA labeled contraindication to ALL other topical psoriasis agents with a different mechanism of action **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL other topical psoriasis agents with a different mechanism of action cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** B. The patient has another FDA approved indication for the requested agent and route of administration **AND** 2. If the patient has an FDA approved indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., dermatologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent

Module	Clinical Criteria for Approval
	Length of Approval: 12 months **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. The patient has had clinical benefit with the requested agent **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., dermatologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months

