Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines:
Dermatological Immunomodulators

Effective: July 1, 2024

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☒ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration – Approved Indications

I. **Topical Calcineurin Inhibitors Step Therapy Program**
The plan has implemented a step therapy program for **Elidel (pimecrolimus)** and **Protopic (tacrolimus)** to encourage the use of first line therapy with topical corticosteroid agents.
   a. Elidel (pimecrolimus) cream and Protopic (tacrolimus) ointment are indicated as second-line therapies for the short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in non-immunocompromised adults and children 2 years of age and older, who have failed to respond adequately to other topical prescription treatments, or when those treatments are not advisable.
   b. Protopic (tacrolimus)

II. **Vtama (tapinarof) cream** is an aryl hydrocarbon receptor agonist indicated for the topical treatment of plaque psoriasis in adults.

III. **Zoryve (roflumilast) cream** is a topical phosphodiesterase-4 (PDE-4) inhibitor indicated for plaque psoriasis in patients aged 6 years and older.

Clinical Guideline Coverage Criteria

I. Topical Calcineurin Inhibitors Step Therapy Program

Note: Prescriptions that meet the initial step therapy requirements, will adjudicate at the point of sale. If the patient does not meet the initial step therapy criteria, then the prescription will deny at the point of service with a message indicating that prior authorization (PA) is required. Refer to the Coverage Criteria below and submit prior authorization requests to the plan for patient who do not meet the step therapy criteria at the point of service.

Please refer to the table below for medications subject to this policy:

Drug	
Step-1	
topical corticosteroids	Covered as listed on formulary (see Appendix)
Step-2	
pimecrolimus	Requires prior use of two (2) Step-1 drugs of medium or greater potency
tacrolimus	

Automated Step Therapy Coverage Criteria

The following stepped approach applies to Elidel (pimecrolimus) and Protopic (tacrolimus) coverage by the plan:

Step 1: Medications on Step-1 are covered without prior authorization (See Appendix)

Step 2: The plan may cover medications on Step-2 if the following criteria are met:

a. The patient has had a trial of at least two (2) Step-1 medications of medium or greater potency or one Step-2 medication within the previous 180 days as evidenced by a paid claim under the prescription benefit administered by the plan

Coverage Criteria for Patients Not Meeting the Automated Step Therapy Coverage Criteria at the Point of Sale

The following stepped approach applies to Step-2 medications covered by the plan:

Step 2: The plan may cover Step-2 medications if the following criteria are met:

a. The patient has had a trial of at least two (2) Step-1 formulary topical steroid medications of medium or greater potency or one Step-2 medication within the previous 180 days as evidenced by physician documented use, excluding the use of samples

OR

b. The patient has a physician documented contraindication or intolerance to **ALL** Step-1 medications

Note: The plan may cover medications on Step-2 if a patient has received a non-formulary medication, containing the same therapeutic ingredient, as evidenced by physician documented use, excluding the use of samples.

Note: The plan may authorize coverage of Elidel (pimecrolimus) or Protopic (tacrolimus) for facial or intertriginous psoriasis for patients when the following criteria are met:

1. The patient has the diagnosis of mild to moderate atopic dermatitis (eczema) or facial or intertriginous psoriasis

AND

2. Documentation of one of the following:
   a. The patient is not a candidate for medium to high potency corticosteroid therapy (e.g., eyelid dermatitis, facial dermatitis, or dermatitis associated with genital area eruptions)

   OR

   b. The patient has a contraindication to topical corticosteroids

II. Vtama cream

The plan may authorize coverage of Vtama (tapinarof) cream for patients when all of the following criteria are met:

Initial therapy

1. Documented diagnosis of plaque psoriasis

AND

2. Patient is 18 year of age or older

AND

3. Prescribed by or in consultation with a dermatologist

AND

4. Documentation of one (1) of the following:
    a. Trial and failure or inadequate response to one of the following generic therapies:
        i. A medium to very high potency topical corticosteroids (examples: betamethasone dipropionate 0.05% lotion/cream, triamcinolone 0.5% cream/ointment, betamethasone dipropionate augmented 0.05% gel/lotion/ointment)
        ii. A topical vitamin D analog (examples: calcipotriene 0.005% cream, calcitriol 3 mcg/g ointment)
        iii. A topical tazarotene (examples: tazarotene 0.1% cream, tazarotene 0.05% gel)

    OR

    b. Contraindication to all of the following generic therapies: topical corticosteroids, topical vitamin D analog and topical tazarotene

Reauthorization:

1. Documentation that the patient has shown improvement on the requested medication

III. Zoryve cream

The plan may authorize coverage of Zoryve (roflumilast) cream for patients when all of the following criteria are met:

Initial therapy

1. Documented diagnosis of plaque psoriasis

AND

2. Patient is 6 year of age or older

AND

3. Prescribed by or in consultation with a dermatologist

AND

5. Documentation of one (1) of the following:
    c. Trial and failure or inadequate response to one of the following generic therapies:
        i. A medium to very high potency topical corticosteroids (examples: betamethasone dipropionate 0.05% lotion/cream, triamcinolone 0.5% cream/ointment, betamethasone dipropionate augmented 0.05% gel/lotion/ointment)
        ii. A topical vitamin D analog (examples: calcipotriene 0.005% cream, calcitriol 3 mcg/g ointment)
        iii. A topical tazarotene (examples: tazarotene 0.1% cream, tazarotene 0.05% gel)

    OR

    d. Contraindication to all of the following generic therapies: topical corticosteroids, topical vitamin D analog and topical tazarotene

Reauthorization:

2. Documentation that the patient has shown improvement on the requested medication

Appendix: Formulary Topical Corticosteroids

Low Potency	Medium Potency	High Potency	Very High Potency
alclometasone 0.05% cream, ointment	betamethasone dipropionate 0.05% lotion	betamethasone dipropionate augmented 0.05% cream	betamethasone dipropionate augmented 0.05% gel, lotion, ointment
betamethasone valerate 0.1% lotion	betamethasone valerate 0.1% cream	betamethasone dipropionate 0.05% cream, ointment	clobetasol 0.05% cream, cream (emollient), foam, gel, lotion, ointment, shampoo, solution, spray
desonide 0.05% cream, lotion, ointment	fluocinolone 0.025% ointment	betamethasone valerate 0.1% ointment, 0.12% foam	fluocinonide 0.1% cream
fluocinolone 0.01% oil (body and scalp), shampoo, solution	fluticasone 0.05% cream	desoximetasone 0.25% cream, ointment, spray	halobetasol 0.05% cream, ointment
hydrocortisone 0.5% cream, ointment; 1% cream, gel, lotion, ointment, solution; 2.5% cream, lotion, ointment	hydrocortisone valerate 0.2% cream, ointment	fluocinonide 0.05% cream, cream (emulsified), gel, ointment, solution	
	mometasone 0.1% cream, solution (lotion)	fluticasone 0.005% ointment	
	prednicarbate 0.1% ointment	mometasone 0.1% ointment	
	triamcinolone 0.025% and 0.1% cream, lotion, ointment, 0.147 mg/g spray	triamcinolone 0.5% cream, ointment	

Limitations

- Vtama and Zoryve will be authorized for 12 months.
- Medications on Step-2 are not covered unless the above step therapy criteria are met.
- Step therapy point of service coding does not apply to any non-formulary medications.
- Previous use of samples or vouchers/coupons for brand name medications will not be considered for authorization.
- For a non-formulary medication request, please refer to the Pharmacy Medical Necessity Guidelines for Formulary Exceptions and submit a formulary exception request to the plan as indicated.

Codes

None

References

1. AHFS Drug Information. Available with subscription at: http://www.ashp.org. Accessed August 29, 2009.
2. Elidel (pimecrolimus) [package insert]. Bridgewater, NJ: Bausch Health US, LLC; September 2020.
3. Protopic (tacrolimus) [package insert]. Madison, NJ: LEO Pharma Inc. June 2022.
4. Lebwohl, M. et al. Tacrolimus ointment is effective for facial and intertriginous psoriasis. Journal of the American Academy of Dermatology 51.5 (2004):723-30.
5. UpToDate [database on the Internet]. Wolters Kluwer. Updated periodically. uptodate.com [available with subscription]. Accessed 2016 September 9.
6. Micromedex Solutions [database online]. Greenwood Village, CO: Truven Health Analytics Inc. Updated periodically. micromedexsolutions.com [available with subscription]. Accessed June 2014.
7. Vtama cream [prescribing information]. Long Beach, CA: Dermavant; May 2022.
8. 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 Dermato l 2021; 84:432.
9. Zoryve [package insert], Westlake Village, CA: Arcutis Biotherapeutics Inc; October 2023.

Approval And Revision History

September 13, 2022: Reviewed by the Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- May 9, 2023: List of preferred topical corticosteroids updated to include: clobetasol 0.05% cream, foam, gel, ointment, solution; desoximetasone 0.25% cream, ointment; fluocinolone 0.01% oil (body and scalp), shampoo, solution; fluocinonide 0.05% solution, gel, ointment, 0.1% cream; halobetasol 0.05% ointment; hydrocortisone valerate 0.2% cream.
- January 9, 2024: Added ‘Step Therapy Program’ to title of MNG. Updated verbiage of preferred Step-1 medications to topical corticosteroids of medium or greater potency that are covered as listed on the formulary. Added the following to the list of formulary topical corticosteroids in MNG: betamethasone dipropionate 0.05% ointment; betamethasone valerate 0.12% foam; clobetasol 0.05% cream (emollient), lotion, shampoo, spray; desonide 0.05% cream, lotion; desoximetasone 0.25% spray; hydrocortisone 1% gel, solution; hydrocortisone valerate 0.2% ointment; triamcinolone 0.147 mg/g spray. Removed the following from the list of formulary topical corticosteroids in MNG: fluocinolone 0.025% and 0.01% cream; prednicarbate 0.1% cream; triamcinolone 0.05% ointment (effective 1/15/24).
- April 9, 2024: Consolidated Vtama cream and Zoryve cream MNGs with Dermatological Immunomodulators MNG. Administrative updates made. Removed ‘Step Therapy Program’ from title of MNG. (effective July 1, 2024)

Background, Product and Disclaimer Information

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.