Pharmacy Medical Necessity Guidelines: Elidel® (pimecrolimus) & Protopic® (tacrolimus)

Effective: February 11, 2014

Clinical Documentation and Prior Authorization Required	√	Type of Review – Case Management	
Not Covered		Type of Review – Clinical Review Fax: 617-673-0956	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RxUM

Note: This pharmacy medical necessity guideline applies to commercial products. For Tufts Health Plan Medicare Preferred members, please refer to the Tufts Health Plan Medicare Preferred Step Therapy Criteria. Background, applicable product and disclaimer information can be found on the last page.

OVERVIEW

Elidel and Protopic 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.

PHARMACY COVERAGE GUIDELINES

Note: Prescriptions that meet the initial step therapy requirements, will adjudicate at the point of service. If the Member 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 Tufts Health Plan using the Universal Pharmacy Medical Review Request Form for Members who do not meet the step therapy criteria at the point of service.

Members who are currently (within 180 days prior to the effective date) filling prescriptions for a drug affected by this policy under the prescription benefit administered by Tufts Health Plan will be able to continue treatment on such existing drug regimen.

For Members who are new Members of Tufts Health Plan without prior claims history, physicians must provide documentation of prior use of a Step-2 drug to continue treatment on such existing drug regimen.

Automated Step Therapy Coverage Criteria (Commercial, GFF and Rhode Island Formularies)

The following stepped approach applies to Elidel (pimecrolimus) & Protopic (tacrolimus) coverage by Tufts Health Plan:

Step 1: Medications on Step-1 are covered without prior authorization (*See Attachment 1*).

Step 2: Tufts Health Plan may cover medications on Step-2 for Members if the following criteria are met:

- The Member has had previous paid claims for at least two (2) Step-1 topical steroid drugs of medium potency or greater within the previous 180 days as evidenced by a previous paid claim under the prescription benefit administered by Tufts Health Plan.

Coverage Criteria for Members Not Meeting the Automated Step Therapy Coverage Criteria at the Point-of-service

Tufts Health Plan may authorize coverage of Elidel (pimecrolimus) or Protopic (tacrolimus) for Members when the following criteria are met:

- The member has had a trial of least two (2) Step-1 topical steroid drugs of medium potency or greater as evidenced by physician documented use, excluding the use of samples.

Note: Tufts Health Plan may authorize coverage of Elidel (pimecrolimus) or Protopic (tacrolimus) for facial or intertriginous psoriasis for Members when the following criteria are met:

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

AND either of the following:

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

OR

3. The patient has a contraindication to topical corticosteroids

Attachment 1

Potency	Products	Drug Dosage Form	Strength
Very High	Augmented betamethasone dipropionate	Ointment	0.05%
	Clobetasol propionate	Cream, Ointment	0.05%
	Diflorasone diacetate	Ointment	0.05%
	Halobetasol propionate	Cream, Ointment	0.05%
High	Amcinonide	Cream, Lotion, Ointment	0.1%
	Augmented betamethasone dipropionate	Cream	0.05%
	Betamethasone dipropionate	Cream, Ointment	0.05%
	Betamethasone valerate	Ointment	0.1%
	Desoximetasone	Cream, Ointment	0.25%
		Gel	0.05%
	Diflorasone diacetate	Cream, Ointment (emollient base)	0.05%
	Fluocinonide	Cream, Ointment, Gel	0.05%
	Halcinonide	Cream, Ointment	0.1%
	Triamcinolone acetonide	Cream, Ointment	0.5%
Medium	Betamethasone benzoate	Cream, Gel, Lotion	0.025%
	Betamethasone dipropionate	Lotion	0.05%
	Betamethasone valerate	Cream	0.1%
	Clocortolone pivalate	Cream	0.1%
	Desoximetasone	Cream	0.05%
	Fluocinolone acetonide	Cream, Ointment	0.025%
	Flurandrenolide	Cream, Ointment	0.025%
		Cream, Ointment, Lotion	0.05%
		Tape	4 mcg/cm^2
	Fluticasone propionate	Cream	0.05%
		Ointment	0.005%
	Hydrocortisone butyrate	Ointment, Solution	0.1%
	Hydrocortisone valerate	Cream, Ointment	0.2%
	Mometasone furoate	Cream, Ointment	0.1%
	Triamcinolone acetonide	Cream, Ointment, Lotion	0.025%
		Cream, Ointment, Lotion	0.1%

LIMITATIONS

None

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. Novartis Pharmaceuticals. June 2011.
3. Protopic (tacrolimus) [package insert]. Northbrook, IL. Astellas Pharma US, Inc. May 2012.
4. Lebwohl, M. et al. Tacrolimus ointment is effective for facial and intertriginous psoriasis. Journal of the American Academy of Dermatology 51.5 (2004): 723-730.

APPROVAL HISTORY

- September 11, 2009: Reviewed by the Pharmacy and Therapeutics Committee
- January 1, 2010: Removal of Tufts Medicare Preferred language (separate criteria have been created specifically for Tufts Medicare Preferred)
- September 14, 2010: No changes
- November 9, 2010: Removed the listing for fluocinolone cream 0.2%, no longer available. Removed "lotion" from mometasone 0.1%, not available
- May 10, 2011: Added facial or intertriginous psoriasis to the criteria for approval
- September 13, 2011: Added historical look back period of 2 years for physician documented use of Step Therapy pre-requisite drugs
- March 13, 2012: No changes
- June 12, 2012: Administrative Update: removed historical look back period of 2 years for physician documented use of Step Therapy pre-requisite drugs
- March 12, 2013: No changes
- February 11, 2014: No changes

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for Tufts Health Plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. They are used in conjunction with a Member's benefit document and in coordination with the Member's physician(s). Tufts Health 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 Tufts Health Plan service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Tufts Health Plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

Pharmacy Medical Necessity Guidelines apply to all fully insured Tufts Health Plan offerings unless otherwise noted in this policy or the Member's benefit document. Check the applicable formulary in the Pharmacy section of our website at www.tuftshealthplan.com to determine if the drug requires you to get prior authorization. This Pharmacy Medical Necessity Guideline does not apply to Uniformed Services Family Health Plan Members or to certain delegated service arrangements. Unless otherwise noted in the Member's benefit document or applicable Pharmacy Medical Necessity Guideline, Pharmacy Medical Necessity Guidelines do not apply to CareLink℠ Members. For self-insured plans, drug coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a coverage guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. Applicable state or federal mandates will take precedence.

For Tufts Health Plan Medicare Preferred, please refer to Tufts Health Plan Medicare Preferred Step Therapy Criteria.

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.