

SmartPA Criteria Proposal

Drug/Drug Class:	Atopic Dermatitis Agents, Immunomodulators PDL Edit
First Implementation Date:	July 11, 2013
Proposed Date:	March 17, 2022
Prepared For:	MO HealthNet
Prepared By:	MO HealthNet/Conduent
Criteria Status:	<input type="checkbox"/> Existing Criteria <input checked="" type="checkbox"/> Revision of Existing Criteria <input type="checkbox"/> New Criteria

Executive Summary

Purpose: The MO HealthNet Pharmacy Program will implement a state-specific preferred drug list.

Why Issue Selected: Atopic dermatitis is a persistent skin condition, intermittent in nature and affects roughly 35 million people in the United States. It often begins in childhood and has been linked to families with a history of asthma, hay fever, or eczema. The rash of atopic dermatitis is red, scaly, very itchy, and has unknown etiology. It is believed to be a combination of environmental and genetic factors. First-line options include hydration (emollients), moisturizers, and topical corticosteroids. Corticosteroids work by reducing inflammation, constricting blood vessels, and changing the cells of the immune system, but side effects limit the long-term use of these agents. In 2006, the FDA approved tacrolimus (Protopic®) and pimecrolimus (Elidel®), both topical calcineurin inhibitors, as second-line treatments. Pimecrolimus is approved for mild-to-moderate atopic dermatitis in patients who have failed other topical agents, while tacrolimus is approved for moderate-to-severe atopic dermatitis. Crisaborole (Eucrisa®), a topical phosphodiesterase-4 inhibitor product was approved in 2016 for treatment of mild-to-moderate atopic dermatitis. These products can be used intermittently and discontinued after the rash resolves. Other benefits include the ability to be used for repeated courses, not causing thinning of the skin, stretch marks, or spider veins, and the ability to be used anywhere on the body including face, neck, groin, and around the eyes.

Total program savings for the PDL classes will be regularly reviewed.

Program-Specific Information:	Preferred Agents	Non-Preferred Agents
	<ul style="list-style-type: none"> • Elidel® 	<ul style="list-style-type: none"> • Eucrisa® • Opzelura™ • Pimecrolimus • Protopic® • Tacrolimus

Type of Criteria: Increased risk of ADE Preferred Drug List
 Appropriate Indications Clinical Edit

Data Sources: Only Administrative Databases Databases + Prescriber-Supplied

Setting & Population

- Drug class for review: Atopic Dermatitis Agents, Immunomodulators
- Age range: All appropriate MO HealthNet participants

Approval Criteria

- Documented diagnosis of atopic dermatitis **AND**
- Failure to achieve desired therapeutic outcomes with trial on 1 or more preferred agents
 - Documented trial period of preferred agents **OR**
 - Documented ADE/ADR to preferred agents **AND**
 - For Eucrisa:
 - Participants aged 3 months to < 2 years: adequate therapeutic trial of an emollient/moisturizer **AND** topical low potency corticosteroid **OR** Elidel
 - Participants aged 2 years to < 18 years: adequate therapeutic trial of an emollient/moisturizer **AND** topical low potency corticosteroid **AND** Elidel
 - Participants aged 18 years and older: adequate therapeutic trial of an emollient/moisturizer **AND** topical medium or high potency corticosteroid **AND** Elidel
 - **For Opzelura:**
 - **Participant is aged 12 years or older AND**
 - **Documented therapeutic trial of generic Protopic AND**
 - **Clinical Consultant Review required**

Denial Criteria

- Lack of adequate trial on required preferred agents
- Therapy will be denied if all approval criteria are not met
- Claim exceeds maximum dosing limitation for the following:

		240 g every 365 days
		60 g (1 tube) every 25 days

Required Documentation

Laboratory Results: Progress Notes:
MedWatch Form: Other:

Disposition of Edit

Denial: Exception Code "0160" (Preferred Drug List)
Rule Type: PDL

Default Approval Period

1 year

References

- Evidence-Based Medicine and Fiscal Analysis: "Atopic Dermatitis – Therapeutic Class Review", Conduent Business Services, L.L.C., Richmond, VA; January 2022.

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- Evidence-Based Medicine Analysis: “Topical Immunomodulators (AKA Atopic Dermatitis Agents)”, UMKC-DIC; January 2022.
- USPDI, Micromedex; 2022.
- Facts and Comparisons eAnswers (online); 2022 Clinical Drug Information, LLC.

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