SmartPA Criteria Proposal

Drug/Drug Class:	Atopic Dermatitis Agents, Immunomodulators PDL Edit
First Implementation Date:	July 11, 2013
Proposed Date:	July 18, 2023
Prepared For:	MO HealthNet
Prepared By:	MO HealthNet/Conduent
Criteria Status:	☐Existing Criteria ☒Revision of Existing Criteria ☐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 affecting about 16.5 million adults and 9.6 million children in the United States. The rash of atopic dermatitis is red, scaly, very itchy, and has unknown etiology, but is believed to be a combination of environmental and genetic factors. Treatment options include topical therapies, biologics, and oral Janus kinase (JAK) inhibitors. Topical immunomodulating therapies for atopic dermatitis are addressed in this edit including topical calcineurin inhibitors, topical phosphodiesterase-4 (PDE-4) inhibitors, and topical JAK inhibitors. Tacrolimus (Protopic®) and pimecrolimus (Elidel®) are both topical calcineurin inhibitors; 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. Eucrisa® (crisaborole), a topical PDE-4 inhibitor, is approved for the treatment of mild-to-moderate atopic dermatitis in patients 3 months of age and older. Opzelura™ (ruxolitinib), a topical JAK inhibitor, is approved for short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis and also for treatment of nonsegmental vitiligo in patients 12 years of age and older. First line topical treatments for atopic dermatitis include topical corticosteroids and calcineurin inhibitors. Second line topical treatments for atopic dermatitis include Eucrisa and Opzelura. Treatment options for atopic dermatitis after topical therapy include phototherapy, oral immunomodulators, biologics, and oral JAK inhibitors.

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

Program-Specific Information:

Preferred Agents	Non-Preferred Agents
• Elidel®	• Eucrisa® • Opzelura™ • Pimecrolimus • Protopic® • Tacrolimus

Type of Criteria:

☒ **Increased risk of ADE**
☒ **Appropriate Indications**
☒ **Preferred Drug List**
☐ **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

- Claim is for a preferred agent **OR**
- For Opzelura:
  - Documented diagnosis of atopic dermatitis **or vitiligo** in the past year **AND**
  - Participant is aged 12 years or older **AND**
  - Documented therapeutic trial of **topical tacrolimus** **AND**
  - Clinical Consultant Review required
- For all other non-preferred agents:
  - Documented diagnosis of atopic dermatitis in the past year **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 **OR**
  - 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 **OR**

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:

Drug Description	Generic Equivalent	Max Dosing Limitation
EUCRISA 2% OINTMENT	CRISABOROLE	240 g every 365 days
OPZELURA 1.5% CREAM	RUXOLITINIB PHOSPHATE	60 g (1 tube) every 25 days

Required Documentation

Laboratory Results:		Progress Notes:	**X**
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: “Therapeutic Class Review: DERMATOLOGIC AGENTS: Atopic Dermatitis”, Gainwell Technologies; Last updated April 11, 2023.
- Evidence-Based Medicine Analysis: “Topical Immunomodulators (Atopic Dermatitis)”, UMKC-DIC; January 2022.
- IPD Analytics. Dermatology: Atopic Dermatitis. Accessed May 8, 2023.
- USPDI, Micromedex; 2023.
- Clinical Pharmacology [online]. Tampa (FL): Elsevier. 2023.