SmartPA Criteria Proposal

Drug/Drug Class:	Atopic Dermatitis Agents – Immunomodulators PDL Edit
First Implementation Date:	July 11, 2013
Proposed Date:	March 19, 2020
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, 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
• Elidel®	• Eucrisa™ • 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 (Immunomodulators)
- Age range: All appropriate MO HealthNet participants aged 2 years or older

Approval Criteria

- ~~**Participant aged 2 years or older AND**~~
- 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
  - Documented ADE/ADR to preferred agents
- For Eucrisa:
  - **Quantity limit of 240 grams in 365 days AND**
  - **Participants aged 3 months to 17 years: adequate therapeutic trial of an emollient/moisturizer AND topical low potency corticosteroid OR Elidel OR**
  - **Participants aged 18 years and older: adequate therapeutic trial of an emollient/moisturizer AND topical medium or high potency corticosteroid OR Elidel**

Denial Criteria

- Lack of adequate trial on required preferred agents
- Therapy will be denied if no approval criteria are met

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

1. Evidence-Based Medicine and Fiscal Analysis: “Atopic Dermatitis – Therapeutic Class Review”, Conduent Business Services, L.L.C., Richmond, VA; February 2020.
2. Evidence-Based Medicine Analysis: “Topical Immunomodulators (AKA Atopic Dermatitis Agents)”, UMKC-DIC; January 2020.
3. Lippincott, Williams, Wilkins. PDR Electronic Library, Montvale NJ; 2020.
4. USPDI, Micromedex; 2020.
5. Facts and Comparisons eAnswers (online); 2020 Clinical Drug Information, LLC.