SmartPA Criteria Proposal

Drug/Drug Class:	Actinic Keratosis Agents, Topical PDL Edit
First Implementation Date:	July 13, 2017
Proposed Date:	March 18, 2021
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: Actinic Keratosis (AK) is a premalignant condition of the skin that manifests as small, thick, scaly patches of the skin. It is seen mostly in sun-exposed areas of the skin and should be treated due to its potential to progress into a squamous cell carcinoma. A United States-based actinic keratosis guideline is not available, but the 2015 guideline from the International League of Dermatological Societies provides recommendations for the treatment options of actinic keratosis. The guideline mentions that topical diclofenac, fluorouracil, imiquimod, or ingenol mebutate are options for the treatment of actinic keratosis but does not provide a preference for one agent over others. The comparative evidence among the agents remains limited as most studies had a small sample size and were conducted in a single center. The results of these studies are conflicting, and clear evidence for a certain agent having a superior efficacy and safety is lacking.

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

Program-Specific Information:

Preferred Agents	Non-Preferred Agents
• Fluorouracil 5% Crm (gen Efudex®) • Fluorouracil Soln • Imiquimod 5% Crm (gen Aldara®)	• Aldara® • Carac® • Diclofenac 3% Gel • Efudex® • Fluorouracil 0.5% Crm (gen Carac®) • Imiquimod 3.75% Crm (gen Zyclara®) • Picato® • Solaraze® • Tolak® • Zyclara®

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: Actinic Keratosis Agents, Topical
- Age range: All appropriate MO HealthNet participants

Approval Criteria

- 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 imiquimod:
  - Participant aged 12 years or older
  - Participant currently not pregnant
  - Dosage within approved dosage limitations:
    - Quantity limits of 1 Zyclara pump or ≤ 28 Zyclara packets with history of < 2 months of total therapy
    - For Aldara:
      - For first claim only: quantity limit of ≤ 12 packets
      - With documented diagnosis of actinic keratosis in the past year:
        - Quantity limit of ≤ 4 packets of Aldara per claim
        - History of < 4 months of total Aldara therapy
      - With documented diagnosis of genital or perianal warts in the past year:
        - Quantity limit of ≤12 packets of Aldara per claim
        - History of < 4 months of total Aldara therapy
      - With documented diagnosis of superficial basal cell carcinoma in the past year:
        - Quantity limit of ≤ 36 packets of Aldara per claim
        - History of < 2 months of total Aldara therapy

Denial Criteria

- Lack of adequate trial on required preferred agents
- Therapy will be denied if all approval criteria are not met

Required Documentation

Laboratory Results:	☐	Progress Notes:	☐
MedWatch Form:	☐	Other:	☐

Disposition of Edit

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

References

1. Evidence-Based Medicine and Fiscal Analysis: “Topical Agents for Actinic Keratosis – Therapeutic Class Review”, Conduent Business Services, L.L.C., Richmond VA; March 2021.
2. Evidence-Based Medicine Analysis: “Topical Agents for Actinic Keratosis”, UMKC-DIC; January 2021.
3. Lippincott, Williams, Wilkins. PDR Electronic Library, Montvale NJ; 2021.
4. USPDI, Micromedex; 2021.
5. Facts and Comparisons eAnswers (online); 2021 Clinical Drug Information, LLC.