SmartPA Criteria Proposal

Drug/Drug Class:	Actinic Keratosis Agents, Topical PDL Edit
First Implementation Date:	July 13, 2017
Revised Date:	July 13, 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: Actinic Keratosis (AK) is a premalignant condition of the skin that manifests as small, thick, scaly patches of the skin resulting from years of exposure to ultraviolet (UV) light and is the most common type of precancer. In the United States, the prevalence is approximately 10% in people between 20 and 30 years of age and more than 90% in people over 80 years of age. Treatments for AK include topical medications, photodynamic therapy, and medical procedures including cryotherapy, curettage and desiccation, laser, dermabrasion, or chemical peels. Topical fluorouracil and imiquimod are generally considered first-line agents and can be self-administered, which makes them preferable for some patients.

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% (gen Aldara®)	• Carac® • Diclofenac 3% Gel • Efudex® • Fluorouracil 0.5% Crm (gen Carac®) • Imiquimod 3.75% (gen Zyclara®) • Zyclara®

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

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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

- Evidence-Based Medicine and Fiscal Analysis: “Topical Agents for Actinic Keratosis – Therapeutic Class Review”, Conduent Business Services, L.L.C., Richmond VA; Jan 2022.
- Evidence-Based Medicine Analysis: “Topical Agents for Actinic Keratosis”, UMKC-DIC; Last updated January 2022.
- Eisen DB, Asgari MM, Bennett DD, et al. Guidelines of care for the management of actinic keratosis. J Am Acad Dermatol. 2021;85(4):e209-e233. doi:10.1016/j.jaad.2021.02.082
- USPDI, Micromedex; 2023.
- Facts and Comparisons eAnswers (online); 2023 Clinical Drug Information, LLC.

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