

SmartPA Criteria Proposal

Drug/Drug Class:	Actinic Keratosis Agents – Topical PDL Edit
First Implementation Date:	July 13, 2017
Proposed Date:	March 19, 2020
Prepared For:	MO HealthNet
Prepared By:	MO HealthNet/Conduent
Criteria Status:	<input checked="" type="checkbox"/> Existing Criteria <input 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: Actinic keratosis 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. There are no widely accepted guidelines for the treatment of actinic keratosis published in the United States, but treatment recommendations are provided in the 2015 guideline from the International League of Dermatological Societies. The treatment recommendations include topical diclofenac, fluorouracil, imiquimod, or ingenol mebutate but preference for one agent over others is not provided. 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
	<ul style="list-style-type: none"> Fluorouracil 5% Crm (gen Efudex®) Fluorouracil Soln Imiquimod (gen Aldara®) 	<ul style="list-style-type: none"> Aldara® Carac® Diclofenac 3% Gel Efudex® Fluorouracil 0.5% Crm (gen Carac®) Imiquimod 3.75% (gen Zyclara® Pump) Picato® Solaraze® Tolak™ 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

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 **AND**
 - Participant currently not pregnant **AND**
 - 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 no approval criteria are met
- Documented diagnosis of molluscum contagiosum

Required Documentation

Laboratory Results:
MedWatch Form:

Progress Notes:
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: “Topical Agents for Actinic Keratosis – Therapeutic Class Review”, Conduent Business Services, L.L.C., Richmond VA; January 2020.
2. Evidence-Based Medicine Analysis: “Topical Agents for Actinic Keratosis”, UMKC-DIC; January 2020.
3. Werner RN, Stockfleth E, Connolly SM, et al. Evidence- and consensus-based (S3) guidelines for the treatment of actinic keratosis – International League of Dermatological Societies in cooperation with the European Dermatology Forum – short version. *J Eur Acad Dermatol Venereol.* 2015;29(11):2069-2079.
4. Lippincott, Williams, Wilkins. PDR Electronic Library, Montvale NJ; 2020.
5. USPDI, Micromedex; 2020.
6. Facts and Comparisons eAnswers (online); 2020 Clinical Drug Information, LLC.

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