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5.90.016

Section:	Prescription Drugs	**Effective Date:**	October 1, 2024
Subsection:	Topical Products	**Original Policy Date:**	July 31, 2015
Subject:	Solaraze	**Page:**	1 of 3

Last Review Date: September 6, 2024

Solaraze

Description

Solaraze (diclofenac sodium)

Background
Solaraze (diclofenac sodium) gel is a prescription medicine used on the skin for actinic keratoses. Actinic keratosis (AK), also called solar keratosis, which is a chronic (long-term) condition of the skin caused by a chemical reaction to ultraviolet (UV) rays. Actinic keratosis can be linked to the development of skin cancer (1).

Regulatory Status
FDA-approved indication: Solaraze gel is indicated for the topical treatment of actinic keratoses (AK). Sun avoidance is indicated during therapy (1).

Safety and effectiveness of Solaraze in pediatric patients less than 18 years of age have not been established (1).

Related policies
Aldara, Klysyri, Zyclara

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Solaraze may be considered **medically necessary** if the conditions indicated below are met.

Solaraze may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Actinic keratosis (AK)

AND the following:

1. Inadequate treatment response, intolerance, or contraindication to a topical pyrimidine analog (e.g., fluorouracil) and another topical antineoplastic (e.g., imiquimod)

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Actinic keratosis (AK)

AND the following:

1. Re-evaluation of lesion(s) for improvement

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 3 months

Prior – Approval *Renewal* Limits

Duration 3 months (One renewal only)

Rationale

Summary

Solaraze (diclofenac sodium) gel is a prescription medicine used on the skin for actinic keratoses. Actinic keratosis (AK), also called solar keratosis, which is a chronic (long-term) condition of the skin. It is caused by a chemical reaction to ultraviolet (UV) rays. AK can be linked to the development of skin cancer. Safety and effectiveness of Solaraze in pediatric patients less than 18 years of age have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Solaraze while maintaining optimal therapeutic outcomes.

References

1. Solaraze [package Insert]. Melville, NY: PharmaDerm.; May 2016.

Policy History

Date	Action
July 2015	Addition to PA
September 2015	Annual review
December 2016	Annual review and reference update Addition of age requirement to renewal section. Policy number change from 5.14.16 to 5.90.16
September 2017	Annual editorial review
September 2018	Annual review
September 2019	Annual review
September 2020	Annual review
March 2021	Annual editorial review
September 2022	Annual review
September 2023	Annual review. Per SME, changed purine to pyrimidine, provided try and fail examples for topical pyrimidine and topical antineoplastic
September 2024	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 6, 2024 and is effective on October 1, 2024.