Solaraze

Description

Solaraze (diclofenac sodium)

Background
Solaraze 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 indications: 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 under 18 years of age has not been established (1).

Related policies
Aldara, 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 in patients 18 years of age or older with actinic keratosis (AK) and if the conditions indicated below are met.
Solaraze is considered **investigational** in patients less than 18 years of age and for all other indications.

**Prior-Approval Requirements**

**Age**

18 years of age or older

**Diagnosis**

Patient must have the following:

Actinic keratosis (AK)

**AND ALL** of the following:

1. Inadequate treatment response, intolerance, or contraindication to a topical purine analog and topical antineoplastic

**Prior – Approval Renewal Requirements**

**Age**

18 years of age or older

**Diagnosis**

Patient must have the following:

Actinic keratosis (AK)

**AND ALL** of the following:

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

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**Policy Guidelines**

**Pre - PA Allowance**

None

**Prior - Approval Limits**

**Duration**

3 month
Prior – Approval **Renewal Limits**

**Duration** 3 month (One renewal only)

**Rationale**

**Summary**
Solaraze 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. AKs can be linked to the development of skin cancer. Safety and effectiveness of Solaraze in pediatric patients under 18 years of age has 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**

**Policy History**

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<td>July 2015</td>
<td>Addition to PA</td>
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<td>September 2015</td>
<td>Annual review</td>
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<tr>
<td>December 2016</td>
<td>Annual review and reference update. Addition of age requirement to renewal section. Policy number change from 5.14.16 to 5.90.16</td>
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<td>September 2017</td>
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**Keywords**

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 13, 2019 and is effective on October 1, 2019.