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<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	July 1, 2022
<b>Subsection:</b>	Topical Products	<b>Original Policy Date:</b>	January 29, 2021
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**Last Review Date:** June 16, 2022

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## Klisyri

### Description

Klisyri (tirbanibulin) ointment

### Background

Klisyri (tirbanibulin) is a microtubule inhibitor. Its mechanism of action for the topical treatment of actinic keratosis is unknown (1).

### Regulatory Status

FDA-approved indications: Klisyri ointment is indicated for the topical treatment of actinic keratosis (AK) of the face or scalp (1).

Klisyri should be applied to the face or scalp once daily for 5 consecutive days using 1 single-dose packet per application (1).

Klisyri may cause eye irritation and transfer of the drug into the eyes and to the periorcular area during and after application should be avoided. Patients should wash their hands immediately after application (1).

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

### Related policies

Aldara, Solaraze, Zyclara

### Policy

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

Klisyri 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.

Klisyri may be 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 **BOTH** of the following:
  - a. Topical purine analog (e.g., fluorouracil)
  - b. 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. Patient had improvement in lesion(s) from their last course of therapy

## Policy Guidelines

### Pre - PA Allowance

None

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## Prior - Approval Limits

**Quantity** 5 packets

**Duration** 12 months

## Prior – Approval *Renewal* Limits

Same as above

## Rationale

### Summary

Klisyri (tirbanibulin) is a microtubule inhibitor. Its mechanism of action for the topical treatment of actinic keratosis is unknown. Safety and effectiveness of Klisyri 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 Klisyri while maintaining optimal therapeutic outcomes.

### References

1. Klisyri [package Insert]. Exton, PA: Almirall, LLC; December 2020.

## Policy History

Date	Action
January 2021	Addition to PA
June 2022	Annual review

## Keywords

**This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 16, 2022 and is effective on July 1, 2022.**