



Federal Employee Program.

Blue Cross Blue Shield Association
750 9th St NW, Suite 900
Washington, D.C. 20001
1-800-624-5060
Fax 1-877-378-4727

5.90.046

Section:	Prescription Drugs	Effective Date:	October 1, 2024
Subsection:	Topical Products	Original Policy Date:	January 29, 2021
Subject:	Klisyri	Page:	1 of 3

Last Review Date: September 6, 2024

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 indication: 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 periocular 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** if the conditions indicated below are met.

Klisyri 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 **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; June 2024.

Policy History

Date	Action
January 2021	Addition to PA
June 2022	Annual review
June 2023	Annual review and reference update. Changed policy number to 5.90.046
September 2023	Annual review
June 2024	Annual review
September 2024	Annual review and reference update

Keywords

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