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 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*
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 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 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
Prior - Approval Limits

<table>
<thead>
<tr>
<th>Quantity</th>
<th>5 packets</th>
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<tbody>
<tr>
<td>Duration</td>
<td>12 months</td>
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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**


### Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tr>
<td>January 2021</td>
<td>Addition to PA</td>
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**Keywords**

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 12, 2021 and is effective on April 1, 2021.