

Federal Employee Program.

# KLISYRI (tirbanibulin ointment)

## **RATIONALE FOR INCLUSION IN PA PROGRAM**

## 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).

#### 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.