

# STEPS

## New Drug Reviews

# Tirbanibulin (Klisyri) for the Treatment of Actinic Keratosis

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Tirbanibulin (Klisyri) is a topical ointment labeled for the treatment of actinic keratosis (AK) on the face and scalp.<sup>1</sup> It inhibits cell division by disrupting microtubules, similar to some types of chemotherapy. The goal of tirbanibulin therapy is resolution of lesions and prevention of recurrence.

### Safety

Adverse effects associated with tirbanibulin include vesiculation/pustulation (mild: 7%, moderate: less than 1%, severe: less than 1%) and erosion/ulceration (mild: 9%, moderate: 3%, severe: 0%) localized to the treated area of skin. These symptoms have been shown to resolve with discontinuation of therapy.<sup>1</sup> There are no data on the use of tirbanibulin in pregnant patients or its effects on breastfed infants, milk production, or levels of tirbanibulin in breast milk.<sup>1</sup> Animal studies indicate there are no adverse effects on offspring.

### Tolerability

The most common adverse effects of tirbanibulin are localized skin reactions at the site of application. These reactions range from mild to severe and consist of erythema, flaking or scaling, crusting, and swelling.<sup>1</sup> Overall, 91% of patients treated with tirbanibulin reported erythema and 82% reported flaking and scaling.<sup>2</sup> Patients treated with tirbanibulin also reported pain (10%) and pruritus (9%) at the application site.<sup>2</sup> The use of corticosteroids to minimize the

inflammatory reaction caused by tirbanibulin has not been studied.

### Effectiveness

Two premarketing randomized placebo-controlled trials of 353 patients with AK who were treated with tirbanibulin demonstrated a statistically significant clearance rate of 44% in trial 1 and 54% in trial 2 for areas of skin smaller than 25 cm<sup>2</sup> (i.e., about the size of a baseball). Most of the participants were White men 70 years or older with Fitzpatrick skin types I and II. The estimated recurrence rate in those with complete response to tirbanibulin was 47%.<sup>2</sup>

Although not directly compared, the clearance rates with tirbanibulin are lower than the 70% to 75% clearance rates of fluorouracil, imiquimod (Aldara), and ingenol mebutate (Picato).<sup>3</sup> Treatment of areas larger than 25 cm<sup>2</sup> has not been studied with tirbanibulin but has been studied for the other AK medications.<sup>3</sup> Currently, no clinical trials compare tirbanibulin with other AK treatments.<sup>2</sup>

Drug	Dosage	Dose form	Cost*
Tirbanibulin (Klisyri)	Apply to the affected area on the face or scalp for five consecutive days	Single-dose packets of tirbanibulin 1% ointment	\$1,000

\*—Estimated retail price of one course of treatment based on information obtained at <https://www.goodrx.com> (accessed September 9, 2021; zip code: 66211).

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### Price

A five-day course of tirbanibulin (five single-dose packets) costs about \$1,000. This is comparable to ingenol mebutate, which costs about \$1,100, but it is substantially more expensive than imiquimod and fluorouracil, which are approximately \$30 to \$80.

### Simplicity

Tirbanibulin 1% ointment is applied daily for five days to the entire scalp or face area up to 25 cm<sup>2</sup> where lesions are visible. Occlusive bandaging should not be applied over the application area. Patients using tirbanibulin should avoid contact with their eyes, in the periocular area, or in or near the mouth and lips due to risk of irritation. Tirbanibulin should not be used on broken or unhealed skin.

### Bottom Line

The cost and effectiveness profile of tirbanibulin make it a last-line option compared with

current first-line therapies such as fluorouracil and imiquimod, which are less expensive and have a higher clearance rate of AK lesions.<sup>3</sup> Further trials comparing the effectiveness of tirbanibulin and other AK medications are needed.

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