

Clinical Policy Title:	tirbanibulin
Policy Number:	RxA.667
Drug(s) Applied:	Klisyri®
Original Policy Date:	03/09/2021
Last Review Date:	03/09/2021
Line of Business Policy Applies to:	All lines of business

Background

Klisyri® is a microtubule inhibitor indicated for the topical treatment of actinic keratosis of the face or scalp.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
tirbanibulin (Klisyri®)	Actinic keratosis	Using 1 single-dose packet per application, apply a sufficient amount of ointment to evenly cover up to 25 cm ² treatment field on the face or scalp once daily for 5 consecutive days.	25 cm ² or 2.5 mg (1 single-dose packet) topically per application once daily.

Dosage Forms

- Ointment: 1% tirbanibulin, single-dose packets

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

I. Initial Approval Criteria

A. Actinic Keratosis (must meet all):

1. Diagnosis of AK;
2. Prescribed by or in consultation with a dermatologist;
3. Member is 18 years of age or older;
4. Prescribed for use on face or scalp only;
5. Member has tried and failed at least two preferred topical agents used to treat AK including fluorouracil and imiquimod unless contraindications or clinically significant adverse reactions were experienced;
6. Dose does not exceed 2.5 mg (one packet) per application once daily

Approval Duration

Commercial: 5 days

Medicaid: 5 days

II. Continued Therapy Approval

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

A. Actinic Keratosis (must meet all):

1. Member is currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;
2. Member responded positively to previous Klisyri therapy;
3. Prescribed for treating new lesion/s;
4. Dose does not exceed 2.5 mg (one packet) per application once daily.

Approval Duration

Commercial: 5 days

Medicaid: 5 days

III. Appendices

APPENDIX A: Abbreviation/Acronym Key

AK: Actinic Keratosis

FDA: Food and Drug Administration

APPENDIX B: Therapeutic Alternatives

Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen	Maximum Dose
Solaraze® (diclofenac sodium)	Apply twice daily for 60–90 days	0.5 g of gel on each 5-cm × 5-cm lesion site
Aldara® (imiquimod)	Apply 2 times per week for 16 weeks to one defined treatment area.	Up to one contiguous area of about 25 cm ² on face or scalp. Only one area can be treated at a time. No more than 36 packets per 16-week treatment period.
Zyclara® 3.75% cream (imiquimod) Zyclara® Pump (imiquimod) 3.75% cream; 2.5% cream	Apply once daily before bedtime for two 2-week treatment cycles, separated by a 2-week no-treatment period.	No more than 2 packets or 2 full pump actuations can be applied to a treatment area with each use. No more than 2 boxes (56 packets) or 2 pump bottles (7.5 gm in each bottle) for the total 2-cycle treatment course.
Carac® 0.5% cream (fluorouracil)	Apply once daily for up to 4 weeks.	Not applicable
Tolak® 4% cream (fluorouracil)	Apply once daily for up to 4 weeks.	Not applicable
Ameluz® 10% gel (aminolevulinic acid hydrochloride)	Applied to lesion(s) or field followed by 3 hours of occlusion. Area is illuminated for 10 minutes with the BF-RhodoLED red light source. Can retreat incompletely resolved lesions after 3 months.	Area should not exceed 20 cm ² and no more than 2 grams of Ameluz (one tube) at one time.
Levulan® Kerastick® 20% solution (aminolevulinic acid hydrochloride)	Applied to individual lesion(s). Then it sets or incubates on the skin for 14 to 18 hours for face or scalp and for 3 hours with occlusion for upper extremities. Area is illuminated for 16 minutes 40	Multiple lesions located within one region can be treated in one session; multiple regions should not be treated simultaneously.

Drug Name	Dosing Regimen	Maximum Dose
	seconds with the BLU-U blue light source. Can retreat incompletely resolved lesions after 8 weeks.	
Fluoroplex® 1% cream (fluorouracil)	Apply twice daily for 2–6 weeks; may need a longer duration for areas other than the head and neck.	Not applicable
Efudex® (fluorouracil) 5% cream; 5% solution; 2% solution	Apply twice daily for 2–4 weeks. Off-label studies show once-daily application is also effective.	Not applicable

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
 - None.

- Boxed Warning(s):
 - None.

APPENDIX D: General Information

None.

References

1. Klisyri® Prescribing information, December 2020; Exton, PA. Almirall, LLC. Available at: [https://www.klisyri.com/assets/klisyri-prescribing-information](https://www.klisyri.com/assets/klisyri-prescribing-information.pdf) .pdf. Accessed on February 26, 2021.
2. Berman B. Treatment of actinic keratosis. In: UpToDate. Dellavalle RP, Robinson JK, eds. Waltham, MA: UpToDate Inc. Updated November 4, 2020. <https://www.uptodate.com/contents/treatment-of-actinic-keratosis> . Accessed on February 26, 2021.
3. New Drug Review: Klisyri. In: IPD Analytics. Aventura, FL. IPD Analytics, LLC. Published January 14, 2021. Available at <https://www.ipdanalytics.com/> . Accessed on February 26, 2021.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	03/09/2021	03/09/2021