



UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 3155-4
Program	Step Therapy
Medication	Klisyri [®] (tirbanibulin)
P&T Approval Date	6/2021, 6/2022, 7/2023, 8/2024
Effective Date	11/1/2024

1. Background:

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

Step Therapy programs are utilized to encourage the use of lower cost alternatives for certain therapeutic classes.

2. Coverage Criteria^a:

A. Klisyri will be approved based on the following criterion:

1. History of failure, contraindication, or intolerance to **two** of the following:
 - a) diclofenac 3% gel (generic Solaraze[®])
 - b) topical fluorouracil (e.g. generic Efudex[®])
 - c) imiquimod 5% cream (e.g. generic Aldara[®])

Authorization will be issued for 1 month.

^a State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Programs:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may also be in place.

4. References:

1. Klisyri [package insert]. Malvern, PA: Almirall, LLC; April 2024.
2. Efudex [package insert]. Bridgewater, NJ: Bausch Health US, LLC; October 2021.
3. Aldara [package insert]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; June 2022.

4. McIntyre, WJ et al. Treatment Options for Actinic Keratoses. Am Fam Physicians. 2007. Sept 1;76(5):667-571.
5. Eisen, DB et al. Guidelines of care for the management of actinic keratosis. J am Acad Dermatol 2021;85:e209-33.

Program	Step Therapy – Klisyri
Change Control	
6/2021	New program.
6/2022	Annual review. Updated references.
7/2023	Annual review. Updated references.
8/2024	Annual review. Removed Cerac from examples, as this product is typically excluded from benefit coverage. Updated references.