



UnitedHealthcare Pharmacy  
Clinical Pharmacy Programs

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| Program Number    | 2025 P 3155-5                          |
| Program           | Step Therapy                           |
| Medication        | Klisyri <sup>®</sup> (tirbanibulin)    |
| P&T Approval Date | 6/2021, 6/2022, 7/2023, 8/2024, 9/2025 |
| Effective Date    | 11/16/2025                             |

**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<sup>a</sup>:**

**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<sup>®</sup>)
  - b) topical fluorouracil (e.g. generic Efudex<sup>®</sup>)
  - c) imiquimod 5% cream (e.g. generic Aldara<sup>®</sup>)

**Authorization will be issued for 1 month.**

<sup>a</sup> 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; June 2024.
2. Efudex [package insert]. Bridgewater, NJ: Bausch Health US, LLC; March 2024.
3. McIntyre, WJ et al. Treatment Options for Actinic Keratoses. Am Fam Physicians. 2007. Sept 1;76(5):667-571.

4. Eisen, DB et al. Guidelines of care for the management of actinic keratosis. J am Acad Dermatol 2021;85:e209-33.

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| Program               | Step Therapy – Klisyri   |
| <b>Change Control</b> |  |
| 6/2021                | New program.   |
| 6/2022                | Annual review. Updated references.   |
| 7/2023                | Annual review. Updated references.   |
| 8/2024                | Annual review. Removed Carac from examples, as this product is typically excluded from benefit coverage. Updated references. |
| 9/2025                | Annual review. Updated references.   |