

UnitedHealthcare Pharmacy Clinical Pharmacy Programs

| Program Number | 2024 P 1342-4 |
|-------------------|-----------------------------------|
| Program | Prior Authorization/Notification |
| Medication | Zilxi® (minocycline) |
| P&T Approval Date | 12/2020, 12/2021, 12/2022, 1/2024 |
| Effective Date | 4/1/2024 |

1. Background:

Zilxi is FDA approved for the treatment of inflammatory lesions of rosacea in adults. This formulation of minocycline has not been evaluated in the treatment of infections.

2. Coverage Criteria:

A. Initial Authorization

- 1. **Zilxi** will be approved based on the following criterion:
 - a. Diagnosis of rosacea with inflammatory lesions.

Authorization will be issued for 12 months.

B. Reauthorization

- 1. **Zilxi** will be approved for continuation of therapy based on the following criterion:
 - a. Documentation of a positive clinical response to therapy

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- 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.
- Step Therapy and Supply limits may be in place.

4. References:

1. Zilxi [package insert]. Bridgewater, NJ: Vyne Pharmaceuticals Inc; September 2022.



| Program | Prior Authorization/Notification - Zilxi | |
|----------------|------------------------------------------|--|
| Change Control | | |
| 12/2020 | New program | |
| 12/2021 | Annual review. Updated reference. | |
| 12/2022 | Annual review. Updated reference. | |
| 1/2024 | Annual review. No changes. | |