

Program Number	2024 P 2124-9
Program	Prior Authorization/Medical Necessity
Medication/Therapeutic Class	minocycline extended-release tablet (generic Solodyn™)*, Minolira™* (minocycline extended-release tablet), Solodyn* (minocycline extended-release tablet), Ximino®* (minocycline extended-release capsule)
P&T Approval Date	3/2017, 8/2017, 4/2018, 2/2019, 2/2020, 2/2021, 2/2022, 2/2023, 2/2024
Effective Date	5/1/2024

**1. Background:**

Systemic antibiotics are an option for the treatment of acne. They are indicated for use in moderate to severe inflammatory acne and should be used in combination with a topical retinoid, benzoyl peroxide, and/or a topical antibiotic.

Minolira\*, Solodyn\* and Ximino\* are indicated to treat inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 12 years of age and older. They did not demonstrate any effect on non-inflammatory acne lesions. The safety of Minolira\*, Solodyn\* and Ximino\* has not been established beyond 12 weeks of use.

This program requires a member to try minocycline immediate-release capsule (generic Minocin) and minocycline extended-release (generic Solodyn)\* prior to receiving coverage for Minolira\*, Solodyn\* or Ximino\*. In addition, it requires a member to try minocycline immediate-release capsule (generic Minocin®) prior to receiving coverage for minocycline extended-release tablet (generic Solodyn)\*.

**2. Coverage Criteria<sup>a</sup>:**

**A. Minocycline Extended-Release (generic Solodyn)\*** will be approved based on **all** of the following criteria:

1. Diagnosis of moderate to severe inflammatory acne vulgaris

**-AND-**

2. **One** of the following:

- a. Submission of medical records (e.g., chart notes) documenting an inadequate response to a four-week trial of minocycline immediate-release capsule (generic Minocin)

**-OR-**

- b. Submission of medical records (e.g., chart notes) documenting an intolerance to minocycline immediate-release capsule (generic Minocin) which is unable to be resolved with attempts to minimize the adverse effects where appropriate (e.g.,

dose reduction)

**Authorization will be issued for 3 months.**

**B. Minolira\*, Solodyn\* and Ximino\*** will be approved based on **all** of the following criteria:

1. Diagnosis of moderate to severe inflammatory acne vulgaris

**-AND-**

2. **One** of the following:

a. Submission of medical records (e.g., chart notes) documenting an inadequate response to a four-week trial of minocycline immediate-release capsule (generic Minocin)

**-OR-**

b. Submission of medical records (e.g., chart notes) documenting an intolerance to minocycline immediate-release capsule (generic Minocin) which is unable to be resolved with attempts to minimize the adverse effects where appropriate (e.g., dose reduction)

**-AND-**

3. **One** of the following:

a. Submission of medical records (e.g., chart notes) documenting an inadequate response to a four-week trial of minocycline extended-release (generic Solodyn)\*

**-OR-**

b. Submission of medical records (e.g., chart notes) documenting an intolerance to minocycline extended-release (generic Solodyn)\* which is unable to be resolved with attempts to minimize the adverse effects where appropriate (e.g., dose reduction)

**Authorization will be issued for 3 months.**

<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.

\*Typically excluded from coverage

### 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.

**4. References:**

1. Minolira [package insert]. Charleston, SC: EPI Health, LLC; June 2018.
2. Solodyn [package insert]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC.; September 2017.
3. Ximino [package insert]. New Brunswick, NJ: Ohm Laboratories Inc.; January 2021.
4. Zaenglein AL, Pathy AL, Schlosser BJ, Alikhan A, Baldwin HE, Berson DS, et al. Guidelines of care for the management of acne vulgaris. *J Am Acad Dermatol*. 2016 Feb 15.

Program	Prior Authorization/Medical Necessity - Minocycline ER
<b>Change Control</b>	
Date	Change
3/2017	New program.
8/2017	Added minocycline extended-release to criteria.
4/2018	Ximino added to the criteria
2/2019	Minolira added to the criteria
2/2020	Annual review. Updated references.
2/2021	Annual review. Updated references.
2/2022	Annual review. Updated references.
2/2023	Annual review. No changes.
2/2024	Annual review. No changes.