UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2022 P 2124-7
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
Effective Date	5/1/2022; Oxford only: 5/1/2022

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[a]:**

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.

[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.

*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
Change Control	
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.