

# STEP THERAPY CRITERIA

<b>DRUG CLASS</b>	<b>MINOCYCLINE (ORAL) – ACNE ONLY</b>
<b>BRAND NAME (generic)</b>	<b>MINOLIRA</b> (minocycline hydrochloride extended-release)
	<b>SOLODYN</b> (minocycline hydrochloride extended-release)
	<b>XIMINO</b> (minocycline hydrochloride extended-release)

**Status: CVS Caremark® Criteria**

**Type: Initial Step Therapy; Post Step Therapy Prior Authorization**

## POLICY

### FDA-APPROVED INDICATION

#### **Minolira**

Minolira is indicated to treat the inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 12 years of age and older.

#### Limitations of Use

This formulation of minocycline has not been evaluated in the treatment of infections.

To reduce the development of drug-resistant bacteria as well as to maintain the effectiveness of other antibacterial drugs, Minolira should be used only as indicated.

#### **Solodyn**

Solodyn is indicated to treat only inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 12 years of age and older.

#### Limitations of Use

Solodyn did not demonstrate any effect on non-inflammatory acne lesions. Safety of Solodyn has not been established beyond 12 weeks of use. This formulation of minocycline has not been evaluated in treatment of infections.

To reduce the development of drug-resistant bacteria as well as to maintain the effectiveness of other antibacterial drugs, Solodyn should be used only as indicated.

#### **Ximino**

Ximino is indicated to treat only inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 12 years of age and older.

To reduce the development of drug-resistant bacteria as well as to maintain the effectiveness of other antibacterial drugs, Ximino should be used only as indicated.

#### Limitations of Use

Ximino did not demonstrate any effect on non-inflammatory acne lesions. Safety of Ximino has not been established beyond 12 weeks of use. This formulation of minocycline has not been evaluated in the treatment of infections.

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## **INITIAL STEP THERAPY\***

*\*Include Rx and OTC products unless otherwise stated.*

If the patient is 12 years of age or older AND has filled a prescription for at least a 30-day supply of generic minocycline immediate-release OR generic doxycycline (immediate-release or delayed-release, not including brand or generic Oracea or Periostat) within the past 365 days a prescription benefit administered by CVS Caremark, then the requested drug will be paid under that prescription benefit. If the patient does not meet the initial step therapy criteria, then the claim will reject with a message indicating that a prior authorization (PA) is required. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.

## **COVERAGE CRITERIA**

### **Acne Vulgaris**

Authorization may be granted when the requested drug is being prescribed for the treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris when ALL of the following criteria are met:

- The patient is 12 years of age or older
- The patient has experienced an intolerance to generic minocycline (immediate-release) due to an adverse event (examples: rash, nausea, vomiting, anaphylaxis) that is thought to be due to an inactive ingredient and ONE of the following criteria are met:
  - The patient has experienced an inadequate treatment response to generic doxycycline (immediate-release or delayed-release)
  - The patient has experienced an intolerance to generic doxycycline (immediate-release or delayed-release)

## **DURATION OF APPROVAL (DOA)**

- 526-F: DOA: 12 months

## **REFERENCES**

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2. Minocycline Hydrochloride Tablet, Extended Release [package insert]. Baltimore, MD: Lupin Pharmaceuticals, Inc.; December 2021.
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5. Solodyn [package insert]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; September 2017.
6. Ximino [package insert]. New Brunswick, NJ: Ohm Laboratories Inc.; December 2023.
7. Lexicomp Online, Lexi-Drugs Online, Hudson, OH: UpToDate, Inc.; 2024; Accessed February 13, 2024.
8. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 02/13/2024).
9. Reynolds RV, Yeung H, Cheng CE, et al. Guidelines of Care for Acne Vulgaris Management. *J Am Acad Dermatol*. 2024; 1:e1-30.
10. Thiboutot D, Dreno B, et al. Practical Management of Acne for Clinicians: An International Consensus From the Global Alliance to Improve Outcomes in Acne. *J Am Acad Dermatol*. 2018; 78(2):S1-S23.

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