

STEP THERAPY CRITERIA

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

Status: CVS Caremark Criteria

Type: Initial Step Therapy; Post Step Therapy Prior Authorization

POLICY

FDA-APPROVED INDICATION

Minolira, Solodyn, Ximino

Minolira, Solodyn, and Ximino are 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

These formulations of minocycline have 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, Solodyn, and Ximino should be used only as indicated.

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 delayed-release OR generic doxycycline immediate-release within the past 365 days under 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

The requested drug will be covered with prior authorization when the following criteria are met:

- The requested drug is being prescribed for the treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris in a patient 12 years of age or older

AND

- 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

- The patient has experienced an inadequate treatment response to generic doxycycline (immediate-release or delayed-release)
- OR**
- The patient has experienced an intolerance to generic doxycycline (immediate-release or delayed-release)

REFERENCES

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2. Minocycline Hydrochloride Tablet, Extended Release [package insert]. Baltimore, MD: Lupin Pharmaceuticals, Inc.; December 2020.
3. Minolira [package insert]. Devunipalavalasa Village, Andhra Pradesh, India: Dr. Reddy's Laboratories Limited; June 2018.
4. Oracea [package insert]. Fort Worth, Texas: Galderma Laboratories, L.P.; August 2017.
5. Solodyn [package insert]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; September 2017.
6. Ximino [package insert]. New Brunswick, NJ: Ohm Laboratories Inc.; January 2021.
7. Lexicomp Online, AHFS DI (Adult and Pediatric) Online, Hudson, Ohio: UpToDate, Inc.; 2021; Accessed February 22, 2021.
8. Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: <https://www.micromedexsolutions.com>. Accessed February 24, 2021.
9. Zaenglein A, Pathy A, Schlosser B, et al. Guidelines of Care for Acne Vulgaris Management. *J Am Acad Dermatol*. 2016; 74(5):945-73.
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.
11. Eichenfield L, Krakowski A, Piggott C, et al. Evidence-Based Recommendations for the Diagnosis and Treatment of Pediatric Acne. *Pediatrics*. 2013; 131:S163–S186.