# **STEP THERAPY CRITERIA**

### BRAND NAME (generic)

## ACTICLATE (BRAND ONLY) (doxycycline hyclate)

Status: CVS Caremark Criteria Type: Initial Step Therapy; Post Step Therapy Prior Authorization

### POLICY

#### FDA-APPROVED INDICATIONS

Acticlate is indicated for:

- Rickettsial infections
- Sexually transmitted infections
- Respiratory tract infections
- Specific bacterial infections
- Ophthalmic infections
- Anthrax, including inhalational anthrax (post-exposure)
- Alternative treatment for selected infections when penicillin is contraindicated
- · Adjunctive therapy for acute intestinal amebiasis and severe acne
- Prophylaxis of malaria

To reduce the development of drug-resistant bacteria and maintain the effectiveness of Acticlate and other antibacterial drugs, Acticlate should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

#### **INITIAL STEP THERAPY<sup>4</sup>**

<sup>+</sup>Include Rx and OTC products unless otherwise stated.

If the patient has filled a prescription for at least a 7-day supply of generic doxycycline (do not include brand or generic Oracea or Periostat) within the past 60 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 patient has experienced an intolerance to generic doxycycline (not including generic Oracea or Periostat) due to an adverse event (examples: rash, nausea, vomiting, anaphylaxis) that is thought to be due to an inactive ingredient

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#### **REFERENCES**

- 1. Acticlate [package insert]. Exton, PA: Almirall, LLC; March 2020.
- 2. Doxycycline Hyclate 20 mg Tablets [package insert]. Laurelton, NY: Epic Pharma, LLC; September 2019.
- 3. Oracea [package insert]. Fort Worth, TX: Galderma Laboratories, L.P; August 2017.
- 4. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, OH: UpToDate, Inc.; 2021; Accessed January 12, 2021.
- 5. Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: https://www.micromedexsolutions.com. Accessed January 8, 2021.

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