

**RX.PA.061.MPC Nuzyra® (omadacycline) for Injection**

The purpose of this policy is to define the prior authorization process for Nuzyra® (omadacycline)

Nuzyra® (omadacycline) is indicated for the treatment of acute and bacterial skin and skin structure infections (ABSSSI) as well as for the treatment of community acquired bacterial pneumonia (CABP).

**Procedure****A. Initial Authorization Criteria:**

- Must have a documented diagnosis of Acute bacterial skin and skin structure infections (ABSSSI) or Community acquired bacterial pneumonia (CABP)
- Member must be 18 years of age or older
- Nuzyra must be prescribed by or in consultation with an infectious disease specialist
- Must provide documentation of bacterial culture and susceptibility to doxycycline/minocycline/tetracyclines
- Member must have had a previous trial and failure of either doxycycline or minocycline
- Member must have had a previous trial and failure with Linezolid unless the member has documentation of intolerance/contraindication
- Member must have had a trial and failure with two additional drug classes other than doxycycline/minocycline/tetracyclines. If member has not tried two additional drug classes, must provide documentation of intolerance/contraindication to at least two additional drug classes listed below.

Examples for CABP are penicillins, cephalosporins, macrolides, fluoroquinolones

Examples for ABSSSI are penicillins, cephalosporins, sulfonamides, lincosamides, oxazolidinones

- Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc) listed in the FDA approved labeling
- Nuzyra will be considered investigational or experimental for any other use and will not be covered.

**B. Approved Dosing:**

- Acute bacterial skin and skin structure infections (ABSSSI):
  - Initial dose: 200mg IV x1 or 100mg IV twice daily x1
  - Maintenance dose: 100mg IV once daily
- Community acquired bacterial pneumonia (CABP):
  - Initial dose: 200mg IV x1 or 100mg IV twice daily x1
  - Maintenance dose: 100mg IV once daily

**C. Approval Duration:**

- Initial Therapy: 14 days

**D. Reauthorization Criteria:**

- Not applicable – each occurrence requires a new prior authorization

**CPT Code(s):**

CPT Code	Description
J0121	Injection, omadacycline, 1mg

**References:**

1. Nuzyra® (omadacycline) for injection [prescribing information]. Boston, MA: Paratek Pharmaceuticals, Inc.; May 2021.

**REVIEW HISTORY**

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
<i>Annual Review</i>	<i>02/2023</i>
<i>P&amp;T</i>	<i>12/2022</i>
<i>New policy</i>	<i>10/2022</i>