

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>02/2026</i>
<i>Annual Review</i>	<i>02/2025</i>
<i>Annual Review</i>	<i>02/2024</i>
<i>Annual Review</i>	<i>02/2023</i>
<i>P&T</i>	<i>12/2022</i>
<i>New policy</i>	<i>10/2022</i>