

Commercial/Healthcare Exchange PA Criteria

Effective: May 8th, 2019

Prior Authorization: Nuzyra

Products Affected: Nuzyra (omadacycline) oral tablets

Medication Description:

Nuzyra (omadacycline) is a tetracycline-class antibiotic, indicated for the treatment of adult patients with community-acquired bacterial pneumonia or acute bacterial skin and skin structure infections (ABSSSI).

Covered Uses: Indicated for adult patients with the following infections caused by susceptible microorganisms:

1. Community-acquired bacterial pneumonia (CABP)
2. Acute bacterial skin and skin structure infections (ABSSSI)

Exclusion Criteria: N/A

Required Medical Information:

1. Diagnosis
2. History of previous therapy tried/failed
3. Chart notes documenting treatment failure or allergy

Age Restrictions: 18 years of age and older

Prescriber Restrictions: Prescribed by, or in consultation with, an Infectious disease specialist.

Coverage Duration: 14 days

Other Criteria:

Approve Nuzyra (omadacycline) for 14 days if the patient meets the following criteria (**A, B, C, AND D**):

- A. Patient is at least 18 years old; **AND**
- B. Patient has a diagnosis of community acquired bacterial pneumonia (CABP) OR acute bacterial skin and skin structure infection (ABSSSI); **AND**
- C. Culture and Sensitivity (C&S) testing shows isolated pathogen that is susceptible to omadacycline [documentation required]:
 - a. **For CABP:** Streptococcus pneumoniae, Staphylococcus aureus (methicillin-susceptible isolates), Haemophilus influenzae, Haemophilus parainfluenzae, Klebsiella pneumoniae, Legionella pneumophila, Mycoplasma pneumoniae, and Chlamydia pneumoniae; OR
 - b. **For ABSSSI:** Staphylococcus aureus (methicillin-susceptible and -resistant isolates), Staphylococcus lugdunensis, Streptococcus pyogenes, Streptococcus anginosus grp. (includes S. anginosus, S. intermedius, and S. constellatus), Enterococcus faecalis, Enterobacter cloacae, and Klebsiella pneumoniae. **AND**
- D. The C&S report shows resistance of the isolated pathogen to ALL formulary antibiotics FDA approved for member's diagnosis

References:

1. Nuzyra™ for injection for intravenous use and tablets [prescribing information]. Boston, MA: Paratek Pharmaceuticals; October 2018.

Policy Revision history:

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	4/30/2019