

## Commercial/Healthcare Exchange PA Criteria

*Effective: May 8<sup>th</sup>, 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:**

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