Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	July 1, 2025

Nuzyra® (omadacycline)

LENGTH OF AUTHORIZATION: Up to 14 days

REVIEW CRITERIA:

- Patient must be ≥ 18 years of age; **AND**
- Nuzyra must be prescribed by or in consultation with an infectious disease specialist; **AND**
- If patient is prescribed intravenous therapy, the patient is not a candidate for oral therapy; **AND**
- Total treatment duration is 7 to 14 days; **AND**
- Patient is initiating therapy and is not a candidate or has failed treatment with ≥ 2 preferred antibiotics from 2 different classes (*documentation required*); **AND**
- Patient has a diagnosis of community-acquired bacterial pneumonia (CABP) **AND** meets the following requirement:
    - Infection is hypothesized or proven to be caused by susceptible pathogens (*Streptococcus pneumoniae*, *Staphylococcus aureus* [methicillin-susceptible isolates; MSSA], *Haemophilus influenzae*, *Haemophilus parainfluenzae*, *Klebsiella pneumoniae*, *Legionella pneumophila*, *Mycoplasma pneumoniae*, and *Chlamydophila pneumoniae*); **OR**
- Patient has a diagnosis of acute bacterial skin and skin structure infections (ABSSSI) **AND** meets the following requirement:
    - Infection is hypothesized or proven to be caused by susceptible pathogens (*S. aureus* [methicillin-susceptible and -resistant isolates], *Staphylococcus lugdunensis*, *Streptococcus pyogenes*, *Streptococcus anginosus* group [includes *S. anginosus*, *S. intermedius*, and *S. constellatus*], *Enterococcus faecalis*, *Enterobacter cloacae*, and *K. pneumoniae*).

CONTINUATION OF THERAPY

- Patient met initial review criteria; **AND**
- Patient's symptoms are clinically improving, as documented by provider; **AND**
- Dosing is appropriate as per labeling or is supported by compendia; **AND**
- Prescriber is extending treatment duration to a total duration of ≤ 14 days; **AND**
- Patient has no treatment-limiting adverse effects (e.g., *Clostridium difficile* associated diarrhea, severe photosensitivity, etc).

DOSING AND ADMINISTRATION:

- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/
- Available as 100 mg lyophilized powder for intravenous infusion and 150 mg tablet.