

PRIOR AUTHORIZATION CRITERIA

BRAND NAME
(generic)

NUZYRA
(omadacycline)

Status: CVS Caremark® Criteria

Type: Initial Prior Authorization with Quantity Limit

POLICY

FDA-APPROVED INDICATIONS

Community-Acquired Bacterial Pneumonia (CABP)

Nuzyra is indicated for the treatment of adult patients with community-acquired bacterial pneumonia (CABP) caused by the following susceptible microorganisms: *Streptococcus pneumoniae*, *Staphylococcus aureus* (methicillin-susceptible isolates), *Haemophilus influenzae*, *Haemophilus parainfluenzae*, *Klebsiella pneumoniae*, *Legionella pneumophila*, *Mycoplasma pneumoniae*, and *Chlamydia pneumoniae*.

Acute Bacterial Skin and Skin Structure Infections (ABSSSI)

Nuzyra is indicated for the treatment of adult patients with acute bacterial skin and skin structure infections (ABSSSI) caused by the following susceptible microorganisms: *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*.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of Nuzyra and other antibacterial drugs, Nuzyra should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

COVERAGE CRITERIA

Authorization for the requested drug may be granted when the following criteria is met:

- The patient is being converted from intravenous (IV) omadacycline (Nuzyra) as prescribed by or in consultation with an Infectious Disease specialist

Acute Bacterial Skin and Skin Structure Infections (ABSSSI)

Authorization may be granted when the requested drug is being prescribed for the treatment of an adult patient with an acute bacterial skin and skin structure infection (ABSSSI) when ALL of the following criteria are met:

- The infection is caused by ANY of the following susceptible microorganisms: *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*, *Klebsiella pneumoniae*
- The infection is proven or strongly suspected to be caused by susceptible bacteria
- The patient meets ONE of the following:
 - The patient has experienced an inadequate treatment response, intolerance, or contraindication to alternative therapies
 - The bacteria are NOT susceptible to any other antibiotics

Nuzyra PA with Limit Policy 4363-C UDR 01-2024.docx

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Community-Acquired Bacterial Pneumonia (CABP)

Authorization may be granted when the requested drug is being prescribed for the treatment of an adult patient with community-acquired bacterial pneumonia (CABP) when ALL of the following criteria are met:

- The infection is caused by ANY of the following susceptible microorganisms: *Streptococcus pneumoniae*, *Staphylococcus aureus* (methicillin-susceptible isolates), *Haemophilus influenzae*, *Haemophilus parainfluenzae*, *Klebsiella pneumoniae*, *Legionella pneumophila*, *Mycoplasma pneumoniae*, *Chlamydophila pneumoniae*
- The infection is proven or strongly suspected to be caused by susceptible bacteria
- The patient meets ONE of the following:
 - The patient has experienced an inadequate treatment response, intolerance, or contraindication to alternative therapies
 - The bacteria are NOT susceptible to any other antibiotics

QUANTITY LIMITS APPLY

QUANTITY LIMIT

<u>Drug</u>	<u>Limit*</u>
Nuzyra (omadacycline) 150mg tablet	30 tablets / 14 days
Nuzyra (omadacycline) 100mg vial	15 vials / 14 days

* These drugs are for short-term acute use.

DURATION OF APPROVAL (DOA)

- 4363-C: DOA: 14 days

REFERENCES

1. Nuzyra [package insert]. Boston, MA: Paratek Pharmaceuticals, Inc.; May 2021.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2023. <https://online.lexi.com>. Accessed December 7, 2023.
3. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 12/07/2023).
4. Metlay JP, Waterer GW, Long AC, et al. Diagnosis and Treatment of Adults with Community-acquired Pneumonia. An Official Practice Guideline of the American Thoracic Society and Infectious Diseases Society of America. *Am J Respir Crit Care Med*. 2019;200(7):e45-67.
5. Stevens DL, Bisno AL, Chambers HF, et al. Practice Guidelines for the Diagnosis and Management of Skin and Soft Tissue Infections: 2014 Update by the Infectious Diseases Society of America. *Clin Infect Dis*. 2014;59(2):e10-52.