



Effective Date: 02/2019  
Last P&T Approval/Version: 01/27/2021  
Next Review Due By: 01/2023  
Policy Number: C15914-A

## Nuzyra (omadacycline tosylate)

### PRODUCTS AFFECTED

Nuzyra (omadacycline)

### COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines

#### **Documentation Requirements:**

Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive

#### **DIAGNOSIS:**

Community-acquired bacterial pneumonia (CABP), acute bacterial skin and skin structure infections (ABSSSI)

#### **REQUIRED MEDICAL INFORMATION:**

This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review

#### **A. FOR ALL INDICATIONS:**

1. Documentation member has an infection caused by or strongly suspected to be caused by a type of pathogen and site of infection within the FDA label or compendia supported.  
AND
2. (a) Documentation of inadequate treatment response, intolerance, contraindication, or non-susceptibility to a first-line antibiotic treatment:

## Drug and Biologic Coverage Criteria

- i. [Community-acquired bacterial pneumonia-(e.g., PO azithromycin, PO or IV moxifloxacin or levofloxacin, IV ceftriaxone, IV ertapenem, IV vancomycin, IV Linezolid);  
OR
  - ii. [acute bacterial skin and skin structure infections- (e.g., IV/PO linezolid, IV vancomycin, PO TMP/SMX, PO doxycycline, PO nafcillin, IV cefazolin, PO clindamycin, PO dicloxacillin or PO cephalexin, PO penicillin)
- OR
- (b) Request is for a continuation of therapy that was started at an in-patient setting (within the last 14 days) and member is at time of request transitioning to an outpatient site of care [DISCHARGE DOCUMENTATION REQUIRED WHICH INCLUDES INFECTIOUS DISEASE PRESCRIBER RECOMMENDED DURATION OF THERAPY; START AND END DATE]
- AND
3. FOR IV REQUESTS ONLY: Member must have medical documentation of medically necessary use of IV Nuzyra (Omadacycline Tosylate) for the current active infection instead of oral Nuzyra (Omadacycline Tosylate)

### CONTINUATION OF THERAPY:

NA

### DURATION OF APPROVAL:

Initial authorization: 14 days, Continuation of Therapy: NA

### PRESCRIBER REQUIREMENTS:

Prescribed by or in consultation with an infectious disease specialist. [If prescribed in consultation, consultation notes must be submitted within initial request and reauthorization requests]

### AGE RESTRICTIONS:

18 years of age and older

### QUANTITY:

200 mg IV once or 100 mg IV twice daily as loading dose on day 1, then 100 mg IV once daily for up to 14 days OR After IV loading dose, 300 mg PO once daily for up to 14 days.

### PLACE OF ADMINISTRATION:

The recommendation is that oral medications in this policy will be for pharmacy benefit coverage and patient self-administered.

The recommendation is that infused medications in this policy will be for pharmacy or medical benefit coverage administered in a place of service that is a non-inpatient hospital facility-based location.

## DRUG INFORMATION

### ROUTE OF ADMINISTRATION:

Oral or Intravenous

### DRUG CLASS:

Tetracyclines

### FDA-APPROVED USES:

NUZYRA is indicated for the treatment of adult patients with the following infections caused by susceptible microorganisms:

## Drug and Biologic Coverage Criteria

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

*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*

### COMPENDIAL APPROVED OFF-LABELED USES:

None

## APPENDIX

### APPENDIX:

	CABP	ABSSI
Gram Positive Bacteria	Streptococcus pneumoniae Staphylococcus aureus (methicillin-susceptible isolates)	Enterococcus faecalis S aureus (methicillin-susceptible and-resistant isolates) Staphylococcus lugdunensis Streptococcus anginosus grp. (includes S anginosus, Streptococcus intermedius, and Streptococcus constellatus) Streptococcus pyogenes
Gram Negative Bacteria	Haemophilus influenzae Haemophilus parainfluenzae Klebsiella pneumoniae	Enterobacter cloacae K pneumoniae
Other	Chlamydophila pneumoniae Legionella pneumophila Mycoplasma pneumoniae	

## BACKGROUND AND OTHER CONSIDERATIONS

### BACKGROUND:

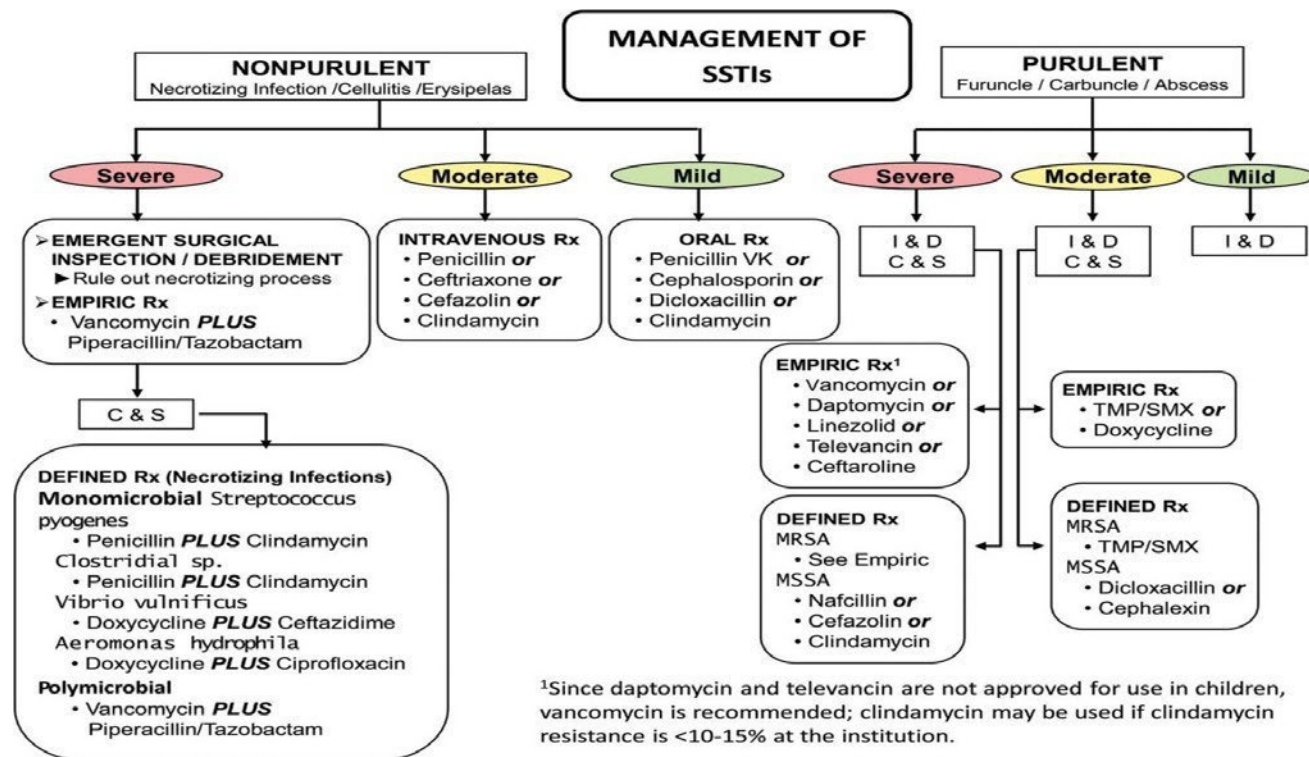
Nuzyra is similar to other tetracyclines (i.e. doxycycline, minocycline, tigecycline) in that it works by binding to the tetracycline binding site on the 30S subunit of the bacterial ribosome. Nuzyra is prepared by chemical modification of minocycline to overcome two common mechanisms of tetracycline resistance (tetracycline efflux mechanism and ribosome protection mechanism).

Nuzyra demonstrates antimicrobial activity in vitro against a range of Gram-positive and Gram-negative bacteria that are commonly associated with CABP and ABSSSI. Nuzyra is available in both intravenous and oral formulations (100 mg intravenous dose = 300 mg oral dose).

### Treatment of ABSSSI

The majority of skin and soft tissue infections have a bacterial cause and are referred to as acute bacterial skin and skin structure infections (ABSSSI). They are classified as purulent (furuncles, carbuncles, abscesses) or non-purulent (erysipelas, cellulitis, necrotizing fasciitis), and then further classified as mild, moderate, or severe. Management of ABSSSI is based on several important diagnostic factors which determine treatment choices, including antibiotic therapy. According to the treatment algorithm included in the 2014 Infectious Diseases Society of America (IDSA) Guidelines for the Management of Skin and Soft Tissue infections, clinicians should first determine if the infection is purulent or non-purulent and whether it is mild, moderate, or severe

## IDSA Treatment Algorithm for Skin and Soft Tissue Infections



Omadacycline is the first amino methylene tetracycline - a modification of minocycline designed to overcome two common resistance mechanisms found in tetracyclines (tetracycline efflux mechanism and ribosome protection mechanism). Due to this modification, omadacycline has a broader spectrum of antimicrobial activity than other tetracyclines (i.e., minocycline, doxycycline).

Omadacycline received FDA approval for treatment of ABSSSI and CABP in October 2018. Product labeling lists the following organisms susceptible to omadacycline in ABSSSI: Staphylococcus aureus (MSSA and MRSA), Staphylococcus lugdunensis, Streptococcus pyogenes, Streptococcus anginosus grp, Enterococcus faecalis, Enterobacter cloacae, and Klebsiella pneumoniae. Efficacy of omadacycline for treatment of ABSSSI was evaluated in two phase-3, double-blind clinical trials compared to treatment with linezolid. In the first trial, patients received either omadacycline 100 mg intravenously every 12 hours for 2 doses followed by 100 mg every 24 hours with the option to switch to 300 mg orally every 24 hours or linezolid 600 mg intravenously every 12 hours with the option to switch to 600 mg orally every 12 hours. In the second trial, patients received either omadacycline 450 mg orally on Days 1 and 2, followed by 300 mg orally once daily or linezolid 600 mg orally every 12 hours. In both trials, efficacy was determined using early clinical response (ECR) at 48 to 72 hours and clinical response at the post-therapy evaluation (PTE) - 7 to 14 days after the last dose. In both trials, efficacy of omadacycline and linezolid were found to be similar. The most common adverse effects for omadacycline in the clinical trials were nausea, vomiting, infusion site reactions, increased alanine aminotransferase, increased gamma-glutamyl transferase, hypertension, headache, diarrhea, insomnia, and constipation. Omadacycline is structurally similar to other tetracyclines and may have similar tetracycline class effects including photosensitivity, pseudotumor cerebri, and anti-anabolic action which has led to increased BUN, azotemia, hyperphosphatemia, pancreatitis, and abnormal liver function tests.

**CABP**

Infectious Disease Society of America (IDSA)/ American Thoracic Society (ATS) guidelines recommend doxycycline as a possible therapeutic option (alternative to a macrolide) for previously healthy patients with no use of antimicrobials in the previous 3 months (macrolide or doxycycline). In other clinical scenarios, doxycycline also could be used as an alternative for patients where a macrolide is preferred

**CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:**

All other uses of Nuzyra (omadacycline) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to Nuzyra (omadacycline) include known hypersensitivity to omadacycline, tetracycline-class antibacterial drugs or any of the excipients in NUZYRA.

**OTHER SPECIAL CONSIDERATIONS:**

None

**CODING/BILLING INFORMATION**

*Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement*

HCPSC CODE	DESCRIPTION
J0121	injection, omadacycline, 1mg
C9051	injection, omadacycline, 1mg

**AVAILABLE DOSAGE FORMS:**

Nuzyra TABS 150MG, Nuzyra SOLR 100MG

**REFERENCES**

1. Nuzyra (omadacycline) injection and tablets [prescribing information]. Boston, MA: Paratek Pharmaceuticals Inc; May 2021
2. Villano S, et al. Omadacycline; development of a novel aminomethylcycline antibiotic for treating drug-resistant bacterial infections. Future Microbiol. 2016. 11(11); 1421- 1434. <http://doi.org/10.2217/fmb-2016-0100>
3. Metlay JP, Waterer GW, Long AC, et al. Diagnosis and treatment of adults with community-acquired pneumonia. An official clinical practice guideline of the American Thoracic Society and Infectious Diseases Society of America. Am J Respir Crit Care Med. 2019;200(7):e45-e67. doi:10.1164/rccm.201908-1581ST
4. Stevens DL, Bisno AL, Chambers HF, et al. ; Infectious Diseases Society of America 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:e10–52