

## **Clinical Policy: Omadacycline (Nuzyra)**

Reference Number: CP.PMN.188

Effective Date: 03.01.19

Last Review Date: 08.24

Line of Business: Commercial, HIM, Medicaid

[Coding Implications](#)

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

### **Description**

Omadacycline (Nuzyra<sup>™</sup>) is a tetracycline class antibacterial.

### **FDA Approved Indication(s)**

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

- Community-acquired bacterial pneumonia (CABP)
  - *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)
  - *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.

### **Policy/Criteria**

*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of health plans affiliated with Centene Corporation<sup>®</sup> that Nuzyra is **medically necessary** when the following criteria are met:

#### **I. Initial Approval Criteria**

##### **A. Acute Bacterial Skin and Skin Structure Infections, Community-Acquired Bacterial Pneumonia (must meet all):**

1. Diagnosis of ABSSSI or CABP;
2. Age  $\geq$  18 years;
3. Member meets one of the following (a or b):
  - a. Request is for continuation of therapy initiated in an acute care hospital from which member was discharged;
  - b. Both of the following (i and ii):

- i. Culture and sensitivity (C&S) report for the current infection shows isolated pathogen is an organism susceptible to omadacycline, unless provider submits documentation that obtaining a C&S report is not feasible;
  - ii. Member meets one of the following (a, b, or c):
    - a) Failure of  $\geq 2$  formulary antibiotics to which the isolated pathogen is susceptible (if available) per C&S report, unless clinically significant adverse effects are experienced or all are contraindicated;
    - b) C&S report shows resistance or lack of susceptibility of the isolated pathogen to all formulary antibiotics FDA-approved for member's diagnosis;
    - c) If provider documents that obtaining a C&S report is not feasible: Failure of  $\geq 2$  formulary antibiotics indicated for member's diagnosis (if available), unless clinically significant adverse effects are experienced or all are contraindicated;
4. Dose does not exceed one of the following (a or b):
- a. ABSSSI:
    - i. Loading dose: 200 mg IV (2 vials) on Day 1 or 450 mg PO (3 tablets) per day on Days 1 and 2;
    - ii. Maintenance dose: 100 mg IV (1 vial) per day or 300 mg PO (2 tablets) per day;
  - b. CABP:
    - i. Loading dose: 200 mg IV (2 vials) or 600 mg PO (4 tablets) on Day 1;
    - ii. Maintenance dose: 100 mg IV (1 vial) per day or 300 mg PO (2 tablets) per day.

**Approval duration: Up to 14 days of total treatment**

**B. Other diagnoses/indications (must meet 1 or 2):**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
  - a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
  - b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

## II. Continued Therapy

### A. Acute Bacterial Skin and Skin Structure Infections, Community-Acquired Bacterial Pneumonia (must meet all):

1. Member meets one of the following (a, b, or c):
  - a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
  - b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B*);
  - c. Request is for continuation of therapy initiated in an acute care hospital from which member was discharged;
2. Member is responding positively to therapy;
3. Member has not received  $\geq$  14 days of therapy for current infection;
4. If request is for a dose increase, new dose does not exceed one of the following (a or b):
  - a. 100 mg IV (1 vial) per day;
  - b. 300 mg PO (2 tablets) per day.

**Approval duration: Up to 14 days of total treatment**

### B. Other diagnoses/indications (must meet 1 or 2):

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
  - a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
  - b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

## III. Diagnoses/Indications for which coverage is NOT authorized:

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace and CP.PMN.53 for Medicaid or evidence of coverage documents.

**IV. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

ABSSSI: acute bacterial skin and skin structure infections

CABP: community-acquired bacterial pneumonia

C&S: culture and sensitivity

FDA: Food and Drug Administration

*Appendix B: Therapeutic Alternatives*

*This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.*

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Therapeutic alternatives include formulary antibiotics that are indicated for member's diagnosis and have sufficient activity against the offending pathogen at the site of the infection.		

*Therapeutic alternatives are listed as Brand name<sup>®</sup> (generic) when the drug is available by brand name only and generic (Brand name<sup>®</sup>) when the drug is available by both brand and generic.*

*Appendix C: Contraindications/Boxed Warnings*

- Contraindication(s): known hypersensitivity to omadacycline, tetracycline-class antibacterial drugs or any of the excipients in Nuzyra
- Boxed warning(s): none reported

**V. Dosage and Administration**

Indication	Dosing Regimen	Maximum Dose
CABP	<p>Loading dose: Day 1: 200 mg IV over 60 minutes <i>OR</i> 100 mg IV over 30 minutes twice <i>OR</i> 300 mg PO twice</p> <p>Maintenance dose: 100 mg IV over 30 minutes QD <i>OR</i> 300 mg PO QD</p> <p>Total duration of treatment: 7-14 days</p>	See regimen
ABSSSI	<p>Loading dose: Day 1: 200 mg IV over 60 minutes <i>OR</i> 100 mg IV over 30 minutes twice <i>OR</i> Day 1 and Day 2: 450 mg PO QD</p> <p>Maintenance dose: 100 mg IV over 30 minutes QD <i>OR</i> 300 mg PO QD</p> <p>Total duration of treatment: 7-14 days</p>	See regimen

**VI. Product Availability**

- Single dose vial: 100 mg omadacycline (equivalent to 131 mg omadacycline tosylate)
- Tablet: 150 mg omadacycline (equivalent to 196 mg omadacycline tosylate)

**VII. References**

1. Nuzyra Prescribing Information. Boston, MA: Paratek Pharmaceuticals, Inc; May 2021. Available at: <https://www.nuzyra.com>. Accessed May 9, 2024.
2. 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; April 14;59(2):10-52
3. Mandell LA, Wunderink RG, Anzueto A, et al. Infectious Diseases Society of America/American Thoracic Society Consensus guidelines on the management of community-acquired pneumonia in adults. Clinical Infectious Diseases. 2007; 44(Suppl 2): S27-72.
4. Metlay J, Waterer G, Long A, 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 American. American Thoracic Society Documents. Oct 2019; 200(7): e45-67.
5. Stets, Roman, Popescu, M, Gonong J, et al. Omadacycline for Community-Acquired Bacterial Pneumonia. The New England Journal of Medicine. Feb 2019;380(6):517-527

**Coding Implications**

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J0121	Injection, omadacycline, 1 mg
J8499	Prescription drug, oral, non chemotherapeutic, nos

Reviews, Revisions, and Approvals	Date	P&T Approval Date
1Q 2021 annual review: no significant changes; references to HIM.PHAR.21 revised to HIM.PA.154; added coding implications; references reviewed and updated.	11.11.20	02.21
1Q 2022 annual review: added initial Day 1 oral dosing and quantity limits for CABP per updated prescribing information; references reviewed and updated.	09.27.21	02.22
Template changes applied to other diagnoses/indications and continued therapy section.	10.05.22	
1Q 2023 annual review: no significant changes; references reviewed and updated.	10.05.22	02.23
3Q 2023 annual review: no significant changes; added HCPCS code J8499; references reviewed and updated.	04.12.23	08.23
3Q 2024 annual review: no significant changes; references reviewed and updated.	05.09.24	08.24

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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**Note:**

**For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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