Clinical Policy: Omadacycline (Nuzyra)

Reference Number: ERX.NPA.108
Effective Date: 03.01.19
Last Review Date: 02.22
Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Omadacycline (Nuzyra™) 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 *Chlamydophila 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.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ 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 ≥ 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 ≥ 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 ≥ 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: Duration of request or up to 14 days of total treatment, whichever is less

B. Other diagnoses/indications
1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 or b):
   a. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
   b. 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 ≥ 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. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 14 days (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 policy – ERX.PA.01 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 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® (generic) when the drug is available by brand name only and generic (Brand name®) 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	Loading dose: Day 1: 200 mg IV over 60 minutes *OR* 100 mg IV over 30 minutes twice *OR* 300 mg PO twice Maintenance dose: 100 mg IV over 30 minutes QD *OR* 300 mg PO QD Total duration of treatment: 7-14 days	See regimen
ABSSSI	Loading dose: Day 1: 200 mg IV over 60 minutes *OR* 100 mg IV over 30 minutes twice *OR* Day 1 and Day 2: 450 mg PO QD Maintenance dose: 100 mg IV over 30 minutes QD *OR* 300 mg PO QD Total duration of treatment: 7-14 days	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 September 27, 2021.
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

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	11.20.18	02.19
1Q 2020 annual review: no significant changes; references reviewed and updated.	10.31.19	02.20
1Q 2021 annual review: no significant changes; references reviewed and updated.	11.11.20	02.21
1Q 2022 annual review: no significant changes; added initial Day 1 oral dosing and quantity limits for CABP per updated prescribing information; references reviewed and updated.	09.27.21	02.22

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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.