RXADVANCE
2 Park Central Drive
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Clinical Policy Title:	omadacycline
Policy Number:	RxA.422
Drug(s) Applied:	Nuzyra®
Original Policy Date:	01/2020
Last Review Date:	09/14/2020
Line of Business Policy Applies to:	All lines of business

Background

Omadacycline (Nuzyra®) is a tetracycline class antibacterial. It 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.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
omadacycline (Nuzyra)	CABP	Loading dose: Day 1: 200 mg IV over 60 minutes *OR* 100 mg IV over 30 minutes twice Maintenance dose: 100 mg IV over 30 minutes QD *OR* 300 mg PO QD Total duration of treatment: 7-14 days	See regimen
omadacycline (Nuzyra)	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

Dosage Forms

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

Clinical Policy

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

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 all are contraindicated or clinically significant adverse effects are experienced;
         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 all are contraindicated or clinically significant adverse effects are experienced;
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) on Day 1
      ii. Maintenance dose: 100 mg IV (1 vial) per day or 300 mg PO (2 tablets) per day.

Approval Duration
Commercial: 14 days
Medicaid: 14 days

II. Continued Therapy Approval

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 that has been authorized by Rxadvance or member has previously met initial approval criteria listed in this policy;
   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
Commercial: 14 days
Medicaid: 14 days

III. Appendices

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® (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

APPENDIX D: General Information
- Not Applicable

References
1. Nuzyra Prescribing Information. Boston, MA: Paratek Pharmaceuticals, Inc; April 2020. Available at: https://www.nuzyra.com. Accessed June 12, 2020.
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; Jul 15;59(2):147-59.
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.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: 1. Clinical Policy Title was updated. 2. Drug(s) Applied was updated. 3. Line of Business Policy Applies to was updated. 4. Continued Therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance..." 5. Commercial approval duration and Medicaid approval duration updated from up to 14 days to 14 days. 6. References were updated.	06/12/2020	09/14/2020