Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 02/01/2020**
Policy Number: PA.CP.PMN.188	**Effective Date: 01/01/2018** **Revision Date: 01/15/2020**
Policy Name: Omadacycline (Nuzyra)	

Type of Submission – Check all that apply:

- ☐ **New Policy**
- ✓ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ☐ **Statewide PDL -** *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

Loading dose changes for both indications to reflect oral loading dose for ABSSSI, and no oral loading dose for CABP

Name of Authorized Individual (Please type or print): **Francis G. Grillo, MD**	**Signature of Authorized Individual:**

Clinical Policy: Omadacycline (Nuzyra)

Reference Number: PA.CP.PMN.188
Effective Date: 01.19
Last Review Date: 01.15.20

Coding Implications
Revision Log

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.

It is the policy of health plans affiliated with PA Health & Wellness® 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 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: Duration of request or up to 14 days of total treatment, whichever is less

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53.

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 Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
   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 Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.
   Approval duration: Duration of request or 14 days (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53.

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 – PA.CP.PMN.53 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® (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 Maintenance dose: 100 mg IV over 30 minutes QD *OR* 300 mg PO QD Total duration of treatment: 7-14 days	See regimen

Indication	Dosing Regimen	Maximum Dose
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; October 2018. Available at: https://www.nuzyra.com. Accessed October 8, 2018.
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.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
1Q 2019 Policy created	01.19	
1Q 2020 annual review: Loading dose changes for both indications to reflect oral loading dose for ABSSSI, and no oral loading dose for CABP; references reviewed and updated.	01/2020	