

### Clinical Pharmacy Program Guidelines for Nuzyra

Program	Prior Authorization
Medication	Nuzyra (omadacycline) oral tablets
Markets in Scope	Arizona, Colorado, Hawaii, Maryland, New Jersey, New York, New York EPP, Nevada, Pennsylvania-CHIP, Rhode Island, California, South Carolina
Issue Date	5/2019
Pharmacy and Therapeutics Approval Date	1/2021
Effective Date	3/2021

#### 1. Background:

Nuzyra is indicated for the treatment of adult patients with community-acquired bacterial pneumonia (CABP) caused by the following susceptible microorganisms: *Streptococcus pneumoniae*, *Staphylococcus aureus* (methicillin-susceptible isolates), *Haemophilus influenzae*, *Haemophilus parainfluenzae*, *Klebsiella pneumoniae*, *Legionella pneumophila*, *Mycoplasma pneumoniae*, and *Chlamydophila pneumoniae*. It is also indicated for the treatment of adult patients with acute bacterial skin and skin structure infections (ABSSSI) caused by the following susceptible microorganisms: *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*.

#### 2. Coverage Criteria:

<p><b>A. <u>Community-acquired bacterial pneumonia</u></b></p> <p>1. <b>Nuzyra</b> will be approved based on the following:</p> <p style="padding-left: 40px;">a. <b><u>One</u></b> of the following:</p> <p style="padding-left: 80px;">(1) For continuation of therapy upon hospital discharge</p> <p style="text-align: center;"><b>-OR-</b></p> <p style="padding-left: 80px;">(2) As continuation of therapy when transitioning from intravenous antibiotics that are shown to be sensitive to the cultured organism for the requested indication.</p>
-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

**-OR-**

(3) All of the following:

(a) Diagnosis of community-acquired bacterial pneumonia (CABP)

**-AND-**

(b) Infection caused by an organism that is confirmed to be or likely to be susceptible to treatment with Nuzyra

**-AND-**

(c) History of failure, contraindication, or intolerance to **three** of the following antibiotics or antibiotic regimens:

- Amoxicillin
- A macrolide
- Doxycycline
- A fluoroquinolone
- Combination therapy with amoxicillin/clavulanate or cephalosporin AND a macrolide or doxycycline

**Authorization will be issued for up to 14 days.**

**B. Acute Bacterial Skin and Skin Structure Infections**

1. Nuzyra will be approved based on the following:

a. **One** of the following:

(1) For continuation of therapy upon hospital discharge

**-OR-**

(2) As continuation of therapy when transitioning from intravenous antibiotics that are shown to be sensitive to the cultured organism for the requested indication.

**-OR-**

(3) All of the following:

(a) One of the following diagnoses:

i. Both of the following:

- Acute bacterial skin and skin structure infections
- Infection caused by methicillin-resistant *Staphylococcus aureus* (MRSA) documented by culture and sensitivity report

**-OR-**

ii. Both of the following:

- Empirical treatment of patients with acute bacterial skin and skin structure infections
- Presence of MRSA infection is likely

**-AND-**

(b) History of failure, contraindication, or intolerance to linezolid (generic Zyvox)

**-AND-**

(c) History of failure, contraindication, or intolerance to **one** of the following antibiotics:

- Sulfamethoxazole-trimethoprim (SMZ-TMP)
- A tetracycline
- Clindamycin

**-OR-**

(4) All of the following:

(a) Diagnosis of acute bacterial skin and skin structure infections

**-AND-**

(b) Infection caused by an organism that is confirmed to be or likely to be susceptible to treatment with Nuzyra

**-AND-**

(c) History of failure, contraindication, or intolerance to **three** of the following antibiotics:

- A penicillin
- A cephalosporin
- A tetracycline

- Sulfamethoxazole-trimethoprim (SMZ-TMP)
- Clindamycin

**Authorization will be issued for up to 14 days.**

**C. Off-Label Uses**

1. **Nuzyra** will be approved based on one of the following:

a. For continuation of therapy upon hospital discharge

**-OR-**

b. As continuation of therapy when transitioning from intravenous antibiotics that are shown to be sensitive to the cultured organism for the requested indication

**-OR-**

c. The drug has been recognized for treatment of the indication by the Infectious Diseases Society of America (IDSA).

**Authorization duration based on provider and IDSA recommended treatment durations, up to 6 months.**

**3. Additional Clinical Rules:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

**4. References:**

1. Nuzyra [package insert]. Boston, MA: Paratek Pharmaceuticals, Inc.; October 2020.
2. 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 Disease Society of America, *Am J Respir Crit Care Med*. 2019 Oct; 200(7): e45-67.
3. 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;59(2):e10-52.

Program	Prior Authorization –Nuzyra (omadacycline)
<b>Change Control</b>	
Date	Change
5/2019	New policy
7/2019	Updated number of step therapy drugs for MRSA from two to one, plus linezolid.
1/2020	Added continuation of therapy when transitioning from IV antibiotics to CABP section. Updated step therapy drugs to match IDSA recommended regimens. Updated references.
1/2021	Annual review, updated references.