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Omadacycline

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Related Coverage Resources

INSTRUCTIONS FOR USE

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Overview

This policy supports medical necessity review for omadacycline (Nuzyra®).

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Omadacycline (Nuzyra) is considered medically necessary when ONE of the following is met:

- 1. Treatment of Community-Acquired Bacterial Pneumonia (CABP). Individual meets BOTH of the following criteria:
A. Age 18 years or older
B. ONE of the following:
i. Continuation of Nuzyra to complete a course of therapy already started
ii. The individual's infection is resistant to tetracycline antibiotics (for example, doxycycline, tetracycline)

- iii. Documentation of failure, contraindication, or intolerance to an appropriate first-line therapy (for example: amoxicillin, doxycycline, macrolide [i.e., azithromycin or clarithromycin], respiratory fluoroquinolone [i.e., levofloxacin or moxifloxacin] or combination therapy with amoxicillin/clavulanate or cephalosporin AND a macrolide or doxycycline)

2. **Treatment of Acute Bacterial Skin and Skin Structure Infections (ABSSSI).** Individual meets **BOTH** of the following criteria:

- A. Age 18 years or older
- B. **ONE** of the following:
  - i. Continuation of Nuzyra to complete a course of therapy already started
  - ii. The individual's infection is resistant to tetracycline antibiotics (for example, doxycycline, tetracycline)
  - iii. Documentation of failure, contraindication, or intolerance to an appropriate first-line therapy (for example: ceftriaxone, cefazolin, cephalixin, clindamycin, linezolid, piperacillin-tazobactam, sulfamethoxazole-trimethoprim [SMX-TMP], or vancomycin)

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

## Reauthorization Criteria

Not applicable for continuation beyond initial approval duration.

## Authorization Duration

Initial approval duration: up to 1 month.

Reauthorization approval duration: Not applicable for continuation beyond initial approval duration.

## Conditions Not Covered

Any other use is considered experimental, investigational, or unproven.

## Background

### OVERVIEW

Nuzyra, a tetracycline-class antibiotic, is indicated for the treatment of adult patients with the following infections caused by susceptible microorganisms<sup>1</sup>:

- Community-acquired bacterial pneumonia (CABP)
- Acute bacterial skin and skin structure infections (ABSSSI)

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.

### Guidelines

The Infectious Diseases Society of America (IDSA) and the American Thoracic Society (ATS) have developed treatment guidelines for the management of CABP (2019 version).<sup>2</sup> Preferred regimens for the outpatient management of CABP in otherwise healthy individuals include amoxicillin, doxycycline, or a macrolide (azithromycin, clarithromycin). In the presence of comorbidities, in regions with macrolide-resistant *Streptococcus pneumoniae*, risk for drug-resistant *S. pneumoniae*, or for the inpatient non-intensive care unit treatment of CABP, the guidelines recommend the use of combination therapy with amoxicillin/clavulanate or a

cephalosporin plus a macrolide (azithromycin or clarithromycin) or doxycycline, or monotherapy with a respiratory fluoroquinolone (moxifloxacin, gemifloxacin, or levofloxacin).

The IDSA developed treatment guidelines for the management of skin and soft tissue infections (2014 version).<sup>3</sup> Treatment recommendations for erysipelas/cellulitis include penicillin, amoxicillin, amoxicillin-clavulanate, dicloxacillin, cephalexin, or clindamycin. Abscesses should be treated with incision and drainage, and if antibiotics are needed, recommended treatment options include oxacillin, clindamycin, dicloxacillin, cephalexin, doxycycline, trimethoprim/sulfamethoxazole, vancomycin, linezolid, daptomycin, or ceftaroline. Treatment recommendations for surgical wound infections include ticarcillin-clavulanate; piperacillin-tazobactam; imipenem-cilastatin; meropenem; ertapenem; metronidazole plus one of ceftriaxone, ciprofloxacin, or levofloxacin; or ampicillin-sulbactam plus gentamicin or tobramycin.

## References

1. Nuzyra™ for injection for intravenous use and tablets [prescribing information]. Boston, MA: Paratek Pharmaceuticals; May 2021.
2. Metlay JP, Waterer GW, Long AC, et al. Diagnosis and Treatment of Adults with Community-acquired Pneumonia. An Official Practice Guideline of the American Thoracic Society and Infectious Diseases Society of America. *Am J Respir Crit Care Med*. 2019;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.

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