

Nuzyra™ (omadacycline)
Effective 02/01/2020

Plan	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit		
Specialty Limitations	N/A		
Contact Information	Medical Benefit Pharmacy Benefit	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
Exceptions	N/A		

Overview

Nuzyra is a tetracycline class antibacterial indicated for the treatment of adult patients with community-acquired bacterial pneumonia (CABP) or acute bacterial skin and skin structure infections (ABSSSI). Nuzyra should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria.

Coverage Guidelines

Authorization may be granted for members who have been started on Nuzyra in the inpatient setting

OR

Authorization may be granted for members when all the following criteria are met, and documentation is provided:

1. The member is at least 18 years of age
2. A confirmed diagnosis of ONE of the following:
 - Proven or strongly suspected community acquired bacterial pneumonia (CABP) infection caused by susceptible bacteria (See Appendix A)
 - Proven or strongly suspected acute bacterial skin and skin structure (ABSSSI) infection caused by susceptible bacteria (See Appendix B)
3. The member has had an inadequate response or adverse reaction to ALL the following therapy agents:
 - a. **For CABP:**
 - Beta-lactam plus either a macrolide or doxycycline or monotherapy with a respiratory fluoroquinolone (moxifloxacin, Levofloxacin) or monotherapy with an advanced macrolide (azithromycin, clarithromycin)
 - b. **For CABP with MRSA**
 - Linezolid or vancomycin
 - c. **For ABSSSI with no MRSA**
 - Beta-lactam or trimethoprim-sulfamethoxazole or clindamycin
 - d. **For ABSSSI with MRSA, localized mild infection with no systemic symptoms**
 - Trimethoprim-sulfamethoxazole or doxycycline or minocycline

Appendix A: Susceptible Microorganisms for Community-Acquired Bacterial Pneumonia (CABP)

- *Streptococcus pneumoniae*

- *Staphylococcus aureus* (methicillin-susceptible isolates)
- *Haemophilus influenzae*
- *H. parainfluenzae*
- *Klebsiella pneumoniae*
- *Legionella pneumophila*
- *Mycoplasma pneumoniae*
- *Chlamydophila pneumoniae*

Appendix B: Susceptible Microorganisms for Acute Bacterial Skin and Skin Structure Infections (ABSSI)

- *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*
- *Klebsiella pneumoniae*

Limitations

1. All authorizations will be for a total of 14 days of treatment, including number of days of in-patient intravenous use.
2. The following quantity limits apply:

Nuzyra	#30 tablets (150mg) per request
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References

1. Nuzyra (omadacycline) [prescribing information]. Boston, MA: Paratek Pharmaceuticals Inc; July 2020
2. File TM Jr, Eckburg PB, Talbot GH, et al. Macrolide therapy for community-acquired pneumonia due to atypical pathogens: outcome assessment at an early time point. *Int J Antimicrob Agents* 2017; 50:247
3. Stets R, Popescu M, Gonong JR, et al. Omadacycline for Community-Acquired Bacterial Pneumonia. *N Engl J Med* 2019; 380:517
4. Yue J, Dong BR, Yang M, et al. Linezolid versus vancomycin for skin and soft tissue infections. *Cochrane Database Syst Rev* 2016; :CD008056
5. Bowen AC, Carapetis JR, Currie BJ, et al. Sulfamethoxazole-Trimethoprim (Cotrimoxazole) for Skin and Soft Tissue Infections Including Impetigo, Cellulitis, and Abscess. *Open Forum Infect Dis* 2017; 4:ofx232

Review History

11/20/19 – Reviewed at P&T

11/18/2020 – Reviewed at P&T

11/16/2022 – Reviewed for Nov P&T. Separated out MH vs Comm/Exch. No clinical changes.

