Nuzyra™ (omadacycline)
Effective 02/01/2020

Plan | MassHealth | Commercial/Exchange | Program Type | Prior Authorization | Quantity Limit | Step Therapy
--- | --- | --- | --- | --- | --- | ---
Benefit | Pharmacy Benefit | Medical Benefit (NLX) | | |

Specialty Limitations | N/A

<table>
<thead>
<tr>
<th>Plan</th>
<th>Specialty Medications</th>
<th>Non-Specialty Medications</th>
<th>Medical Specialty Medications (NLX)</th>
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<tbody>
<tr>
<td>MassHealth</td>
<td>Phone: 866-814-5506</td>
<td>Fax: 866-249-6155</td>
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<tr>
<td>Commercial</td>
<td>Phone: 877-433-7643</td>
<td>Fax: 866-255-7569</td>
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<tr>
<td>Exchange</td>
<td>Phone: 800-294-5979</td>
<td>Fax: 888-836-0730</td>
<td></td>
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<tr>
<td>All Plans</td>
<td>Phone: 855-582-2022</td>
<td>Fax: 855-245-2134</td>
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| 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 (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
- Klebsiella pneumoniae

Limitations
1. All authorizations will be for a total of 14 days of treatment, including number of days of inpatient intravenous use.
2. The following quantity limits apply:
   
   **Nuzyra** #30 tablets (150mg) per request

References
1. Nuzyra (omadacycline) [prescribing information]. Boston, MA: Paratek Pharmaceuticals Inc; July 2020

Review History
11/20/19 – Reviewed at P&T
11/18/2020-Reviewed at P+T

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