Pharmacy Medical Necessity Guidelines:
Nuzyra (omadacycline) tablets

Effective: February 10, 2026

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
These pharmacy medical necessity guidelines apply to the following: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

Nuzyra (omadacycline) is a tetracycline class antibacterial indicated for the treatment of adult patients with the following infections caused by susceptible microorganisms:

- **Community-acquired bacterial pneumonia (CABP)** caused by the following microorganisms: *Streptococcus pneumoniae, Staphylococcus aureus* (methicillin-sensitive isolates), *Haemophilus influenzae, Haemophilus parainfluenzae, Klebsiella pneumoniae, Legionella pneumophila, Mycoplasma pneumoniae,* and *Chlamydophila pneumoniae*
- **Acute bacterial skin and skin structure infections (ABSSSI)** caused by the following microorganisms: *Staphylococcus aureus* (methicillin-susceptible and –resistant isolates), *Staphylococcus lugdunenesis, Streptococcus pyogenes, Streptococcus anginosus* grp (includes *S. anginosus, S. intermedius,* and *S. constellatus), Enterococcus faecalis, Enterobacter cloacae,* and *Klebsiella pneumoniae.*

Nuzyra is available orally as 150 mg tablets.

COVERAGE GUIDELINES

The plan may authorize coverage of Nuzyra (omadacycline) for Members when the following criteria are met and limitations do not apply

1. Member was started on Nuzyra (omadacycline) in the inpatient setting

OR

1. Member meets **ALL** of the following:
   a. Member has a diagnosis of community-acquired bacterial pneumonia (CABP) or acute bacterial skin and skin structure infection (ABSSSI)

AND

   b. The microorganism is proven or strongly suspected to be susceptible to omadacycline

AND

   c. Member has tried and failed at least two other generic oral antibiotics or the provider submits a clinical rationale why treatment with two other generic oral antibiotics is not appropriate for the Member

LIMITATIONS

1. Requests for Nuzyra (omadacycline) will be approved for the length of treatment.

CODES

None

REFERENCES

1. Nuzyra (omadacycline) [prescribing information]. Boston, MA: Paratek Pharmaceuticals; March 2025.

APPROVAL HISTORY

October 11, 2022: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. May 9, 2023: Effective June 1, 2023, minor verbiage update to the susceptibility criteria.
2. February 13, 2024: Effective March 1, 2024, updated fax number for RxUM.

3. February 11, 2025: No changes
4. February 10, 2026: No changes.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.

Provider Services