TUFTS Health Plan

Pharmacy Medical Necessity Guidelines: Nuzyra (omadacycline) tablets

Effective: May 12, 2020

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:

Commercial Products

☐ Tufts Health Plan Commercial products – large group plans
☐ Tufts Health Plan Commercial products – small group and individual plans
☐ Tufts Health Freedom Plan products – large group plans
☐ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:
RXUM:
617.673.0988

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 ludgenensis, Streptococcus pyogenes, Streptococcus anginosus* grp (includes *S. anginosus, S. intermedius,* and *S. constellatus), Enterococcus facealis, 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. The Member was started on Nuzyra (omadacycline) in the inpatient setting

OR

1. The Member has a diagnosis of community-acquired bacterial pneumonia (CABP) or acute bacterial skin and skin structure infection (ABSSSI)

AND

The microorganism is susceptible to omadacycline

AND

The 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; February 2020.

APPROVAL HISTORY

July 9, 2019: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:
1. May 12, 2020: 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.