



POLICIES AND PROCEDURE MANUAL

Policy: MBP 203.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Nuzyra (omadacycline) Injection

Applicable line of business:

Commercial	X	Medicaid	X
Medicare	X	ACA	X
CHIP	X		

I. Policy:

Nuzyra (omadacycline) Injection

II. Purpose/Objective:

To provide a policy of coverage regarding Nuzyra (omadacycline) Injection

III. Responsibility:

- A. Medical Directors
- B. Medical Management
- C. Pharmacy Department

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards good medical treatment practiced by the general medical community;
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Commercial

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Medicare

Geisinger Gold Medicare Advantage HMO, PPO, and HMO D-SNP plans are offered by Geisinger Health Plan/Geisinger Indemnity Insurance Company, health plans with a Medicare contract. Continued enrollment in Geisinger Gold depends on contract renewal. Geisinger Health Plan/Geisinger Indemnity Insurance Company are part of Geisinger, an integrated health care delivery and coverage organization.

CHIP

Geisinger Health Plan Kids (GHP Kids) is a Children's Health Insurance Program (CHIP) offered by Geisinger Health Plan in conjunction with the Pennsylvania Department of Human Services (DHS). Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Medicaid

Geisinger Health Plan Family (GHP Family) is a Medical Assistance (Medicaid) insurance program offered by Geisinger Health Plan in conjunction with the Pennsylvania Department of Human Services (DHS). Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Medicaid Business Segment

Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
- iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION:

Nuzyra (omadacycline) Injection is a tetracycline derivative antibiotic that inhibits protein synthesis by binding with the 30S ribosomal subunit of susceptible bacteria.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Nuzyra (omadacycline) will be considered medically necessary for the commercial, exchange, CHIP, and Medicaid lines of business when ALL of the following criteria are met:

- Prescription is written by or in consultation with Infectious Disease **AND**
 - Medical record documentation of member is greater than or equal to 18 years of age **AND**
 - Medical record documentation of one of the following:
 - Diagnosis of Community-acquired bacterial pneumonia caused by *Streptococcus pneumoniae*, *Staphylococcus aureus* (methicillin-susceptible isolates), *Haemophilus influenzae*, *Haemophilus parainfluenzae*, *Klebsiella pneumoniae*, *Legionella pneumophila*, *Mycoplasma pneumoniae*, or *Chlamydophila pneumoniae* **OR**
 - Diagnosis of an acute bacterial skin and skin structure infection (including cellulitis/erysipelas, wound infection, and major cutaneous abscess) caused by *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*, or *Klebsiella pneumoniae*
- AND**
- Medical record documentation of a culture and sensitivity showing the patient's infection is not susceptible to alternative antibiotic treatments **OR** a documented history of previous intolerance to or contraindication to three (3) alternative antibiotics shown to be susceptible on the culture and sensitivity **OR**
 - Medical record documentation that treatment with Nuzyra was initiated during an inpatient setting

QUANTITY LIMITS: Facets RX Count: up to 1500 units (15 vials per 14 days)

AUTHORIZATION DURATION: Approvals will be given for up to 14 days of treatment.

Nuzyra (omadacycline) will be considered medically necessary for the Medicare line of business when ALL of the following criteria are met:

- Prescription is written by or in consultation with Infectious Disease **AND**
- Medical record documentation of member is greater than or equal to 18 years of age **AND**
- Medical record documentation of one of the following:
 - Diagnosis of Community-acquired bacterial pneumonia caused by *Streptococcus pneumoniae*, *Staphylococcus aureus* (methicillin-susceptible isolates), *Haemophilus influenzae*, *Haemophilus parainfluenzae*, *Klebsiella pneumoniae*, *Legionella pneumophila*, *Mycoplasma pneumoniae*, or *Chlamydophila pneumoniae* **OR**
 - Diagnosis of an acute bacterial skin and skin structure infection (including cellulitis/erysipelas, wound infection, and major cutaneous abscess) caused by *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*, or *Klebsiella pneumoniae*.

QUANTITY LIMITS: Facets RX Count: up to 1500 units (15 vials per 14 days)

AUTHORIZATION DURATION: Approvals will be given for up to 14 days of treatment.

Note: For Medicaid (GHP Family), any requests for services that do not meet criteria set in the PARP will be evaluated on a case-by-case basis.

LINE OF BUSINESS:

Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

REFERENCES:

1. Nuzyra [prescribing information]. Boston, MA: Paratek Pharmaceuticals Inc; October 2020.

This policy will be revised as necessary and reviewed no less than annually.

Devised: 11/19/19

Revised: 12/30/20 (per DHS), 10/4/22 (Medicaid PARP statement), 10/2/23 (LOB carve out, Medicaid business segment), 12/29/23 (references added), 10/1/24 (AND added)

Reviewed: 11/2/20, 10/4/21

MA UM Committee approval: 12/31/23, 12/31/24

DHS PARP approval: 11/26/24