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Section:	Prescription Drugs	**Effective Date:**	July 1, 2024
Subsection:	Anti-infective Agents	**Original Policy Date:**	September 27, 2019
Subject:	Nuzyra	**Page:**	1 of 5

Last Review Date: June 13, 2024

Nuzyra

Description

Nuzyra (omadacycline)

Background
Nuzyra (omadacycline) is an aminomethylcycline antibacterial within the tetracycline class of antibacterial drugs. Nuzyra binds to the 30S ribosomal subunit and blocks protein synthesis. Nuzyra is active in vitro against Gram positive bacteria expressing tetracycline resistance active efflux pumps (*tetK* and *tet L*) and ribosomal protection proteins (*tet M*). In general, Nuzyra is considered bacteriostatic; however, Nuzyra has demonstrated bactericidal activity against some isolates of *S. pneumoniae* and *H. influenzae* (1).

Regulatory Status
FDA-approved indications: Nuzyra is a tetracycline class antibacterial indicated for the treatment of adult patients with the following infections caused by susceptible microorganisms: (1)

1. Community-acquired bacterial pneumonia (CABP)
2. Acute bacterial skin and skin structure infections (ABSSSI)

To reduce the development of drug-resistant bacteria and maintain the effectiveness of Nuzyra and other antibacterial drugs, Nuzyra should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria (1).

The safety and efficacy of Nuzyra formulations given for longer than 14 days have not been evaluated in controlled clinical trials (1).

The use of Nuzyra during the second and third trimester of pregnancy, infancy and childhood up to the age of 8 years may cause reversible inhibition of bone growth. All tetracyclines form a stable calcium complex in any bone-forming tissue. A decrease in fibula growth rate has been observed in premature infants given oral tetracycline in doses of 25 mg/kg every 6 hours. This reaction was shown to be reversible when the drug was discontinued. Advise the patient of the potential risk to the fetus if Nuzyra is used during the second or third trimester of pregnancy (1).

Nuzyra is structurally similar to tetracycline-class of antibacterial drugs and may have similar adverse reactions. Adverse reactions including photosensitivity, pseudotumor cerebri, and anti-anabolic action which has led to increased BUN, azotemia, acidosis, hyperphosphatemia, pancreatitis, and abnormal liver function tests, have been reported for other tetracycline-class antibacterial drugs, and may occur with Nuzyra. Discontinue Nuzyra if any of these adverse reactions are suspected (1).

Clostridium difficile associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon leading to overgrowth of C. difficile. C. difficile produces toxins A and B which contribute to the development of CDAD. Hypertoxin producing strains of C. difficile cause increased morbidity and mortality, as these infections can be refractory to antimicrobial therapy and may require colectomy. CDAD must be considered in all patients who present with diarrhea following antibacterial drug use. Careful medical history is necessary since CDAD has been reported to occur over two months after the administration of antibacterial agents. If CDAD is suspected or confirmed, ongoing antibacterial drug use not directed against C. difficile may need to be discontinued. Appropriate fluid and electrolyte management, protein supplementation, antibacterial drug treatment of C. difficile, and surgical evaluation should be instituted as clinically indicated. (1).

The safety and effectiveness of Nuzyra in pediatric patients below the age of 18 years have not been established. Due to the adverse effects of the tetracycline-class of drugs, including Nuzyra on tooth development and bone growth, use of Nuzyra in pediatric patients less than 8 years of age is not recommended (1).

Related policies
Baxdela, Sivextro, Xenleta, Zyvox

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claim

Nuzyra may be considered **medically necessary** if the conditions indicated below are met.

Nuzyra may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnoses

Patient must have an infection caused by **OR** strongly suspected to be caused by **ONE** of the following:

1. Community-Acquired Bacterial Pneumonia (CABP)
   Streptococcus pneumoniae
   Staphylococcus aureus (methicillin-susceptible)
   Haemophilus influenzae
   Haemophilus parainfluenzae
   Klebsiella pneumoniae
   Legionella pneumophila
   Mycoplasma pneumoniae
   Chlamydophila pneumoniae

2. Acute Bacterial Skin and Skin Structure Infections (ABSSSI)
   Staphylococcus aureus (methicillin-susceptible)
   Staphylococcus aureus (methicillin-resistant)
   Staphylococcus lugdunensis
   Streptococcus pyogenes
   Streptococcus anginosus grp. (includes *S. anginosus*, *S. intermedius*, and *S. constellatus*)
   Enterococcus faecalis
   Enterobacter cloacae
   Klebsiella pneumoniae

AND the following:

1. Inadequate treatment response, intolerance, or contraindication to a first-line antibiotic, such as a macrolide, fluoroquinolone, beta-lactam, or tetracycline

Prior – Approval *Renewal* Requirements

Same as above

Policy Guidelines

Pre - PA Allowance

Quantity 14 day supply every 365 days

Prior - Approval Limits

Duration 12 months

Prior - Approval *Renewal* Limits

Same as above

Rationale

Summary

Nuzyra is an aminomethylcycline antibacterial within the tetracycline class of antibacterial drugs. To reduce the development of drug-resistant bacteria and maintain the effectiveness of Nuzyra and other antibacterial drugs, Nuzyra should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. Nuzyra is structurally similar to tetracycline-class of antibacterial drugs and may have similar adverse reactions. Adverse reactions including photosensitivity, pseudotumor cerebri, and anti-anabolic action which has led to increased BUN, azotemia, acidosis, hyperphosphatemia, pancreatitis, Clostridium difficile associated diarrhea (CDAD), and abnormal liver function tests, have been reported for other tetracycline-class antibacterial drugs, and may occur with Nuzyra. The safety and effectiveness of Nuzyra in pediatric patients below the age of 18 years have not been established. Due to the adverse effects of the tetracycline-class of drugs, including Nuzyra on tooth development and

bone growth, use of Nuzyra in pediatric patients less than 8 years of age is not recommended (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Nuzyra while maintaining optimal therapeutic outcomes.

References

1. Nuzyra [package insert]. Boston, MA: Paratek Pharmaceuticals, Inc.; May 2021.

Policy History

Date	Action
September 2019	Addition to PA
December 2019	Annual review. Revised requirement to be infection caused by or strongly suspected to be caused by one of the following organisms per SME. Also revised requirement to t/f Bactrim to be for ABSSSI only per SME
March 2020	Annual review and reference update. Revised t/f statement to t/f one first-line antibiotic per SME
September 2021	Annual review and reference update
September 2022	Annual review
June 2023	Annual review
June 2024	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 13, 2024 and is effective on July 1, 2024.