



INDICATIONS and **USAGE**

INDICATIONS

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: Streptococcus pneumoniae, Staphylococcus aureus (methicillin-susceptible 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:

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, and Klebsiella pneumoniae.

USAGE

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.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

NUZYRA is contraindicated in patients with known hypersensitivity to omadacycline or tetracycline-class antibacterial drugs, or to any of the excipients.

WARNINGS AND PRECAUTIONS

Mortality imbalance was observed in the CABP clinical trial with eight deaths (2%) occurring in patients treated with NUZYRA compared to four deaths (1%) in patients treated with moxifloxacin. The cause of the mortality imbalance has not been established. All deaths, in both treatment arms, occurred in patients >65 years of age; most patients had multiple comorbidities. The causes of death varied and included worsening and/or complications of infection and underlying conditions. Closely monitor clinical response to therapy in CABP patients, particularly in those at higher risk for mortality.

The use of NUZYRA during tooth development (last half of pregnancy, infancy and childhood to the age of 8 years) may cause permanent discoloration of the teeth (yellow-gray-brown) and enamel hypoplasia.

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.

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Hypersensitivity reactions have been reported with NUZYRA. Life-threatening hypersensitivity (anaphylactic) reactions have been reported with other tetracycline-class antibacterial drugs. NUZYRA is structurally similar to other tetracycline-class antibacterial drugs and is contraindicated in patients with known hypersensitivity to tetracycline-class antibacterial drugs. Discontinue NUZYRA if an allergic reaction occurs.

Clostridioides 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. Evaluate if diarrhea occurs.

NUZYRA is structurally similar to tetracycline-class antibacterial drugs and may have similar adverse reactions. Adverse reactions, including photosensitivity, fixed drug eruption, 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.

Prescribing NUZYRA in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

ADVERSE REACTIONS

The most common adverse reactions (incidence ≥2%) are nausea, vomiting, infusion site reactions, alanine aminotransferase increased, aspartate aminotransferase increased, gamma-glutamyl transferase increased, hypertension, headache, diarrhea, insomnia, and constipation.

DRUG INTERACTIONS

Patients who are on anticoagulant therapy may require downward adjustment of their anticoagulant dosage while taking NUZYRA.

Absorption of tetracyclines, including NUZYRA is impaired by antacids containing aluminum, calcium, or magnesium, bismuth subsalicylate and iron containing preparations.

USE IN SPECIFIC POPULATIONS

Lactation: Breastfeeding is not recommended during treatment with NUZYRA.

References: 1. Data on file. Paratek Pharmaceuticals, Inc. 2. Centers for Medicare & Medicaid Services. ICD-10-CM Official Guidelines for Coding and Reporting FY 2019. 3. NUZYRA [Prescribing Information]. Boston, MA: Paratek Pharmaceuticals, Inc.



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COVERAGE AND ACCESS

The vast majority of patients have access to NUZYRA¹

When you prescribe NUZYRA, you're prescribing an antibiotic that's widely covered by commercial and Medicare insurance plans. Broad insurance coverage plus patient and provider resources help facilitate quick prescription fulfillment.

NUZYRA is covered by the majority of insurers in the United States with limited or no restrictions¹ — ask your representative for a list of plans in your area.

After submission of all necessary information, most ePAs are approved in 24 hours or less.1

Powered by COVERNYMEDS®

ePA=electronic prior authorization.





THE MAJORITY OF \$ ELIGIBLE PATIENTS PAY AS LITTLE AS

With the NUZYRA Copay Program, the majority of eligible commercially insured patients may pay as little as \$0.*

INSURERS Commercial Medicare Advantage/Supplemental Low-income Subsidy **Basic Medicare** Medicaid Tricare

When a prior authorization is required, our specialty pharmacy partners are here to help.

Specialty pharmacy will work with providers and patients on prior authorization, if required. Covered with a lower out-of-pocket cost than traditional Medicare Part D. Out-of-pocket costs will vary based on the design of the plan.

Specialty pharmacy will work with providers and patients on prior authorization, if required. Covered with low out-of-pocket cost.

Individuals enrolled in basic Medicare plan may have high out-of-pocket costs for their prescription.

Some states may require documented failure on 1 or 2 antibiotics with clinical notes.

With prior authorization, there is no copay for active-duty service members at a military treatment facility. No prior authorization required if filled through our Specialty Pharmacy Network, however there is a \$76 copay.

*Terms and conditions apply.

Insurance coverage and reimbursement for NUZYRA are not guaranteed. Coverage and reimbursement depend on an individual patient's insurance plan. We recommend that you contact the insurance provider to verify NUZYRA coverage and reimbursement. Certain factors like personal insurance and/or deductibles may impact the price of your prescription. May not be used if the patient is enrolled in a government-funded prescription insurance program.



JUST SELECT, SEND, AND ASK

NUZYRA®

SurePATH

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Follow these steps when you choose to prescribe NUZYRA (omadacycline).



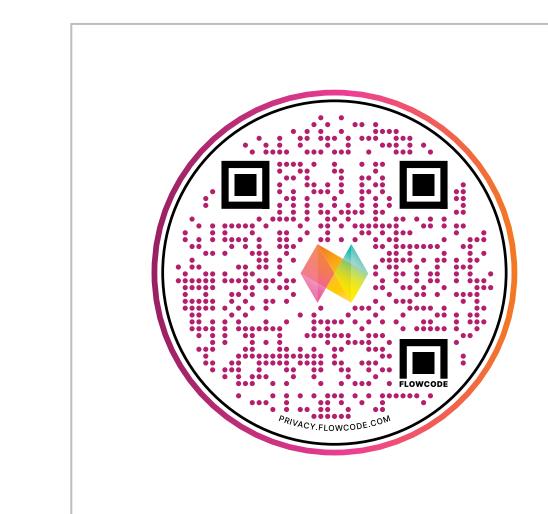
SELECT a NUZYRA network specialty pharmacy* or hospital outpatient specialty pharmacy in your Electronic Health Record (EHR) prescribing system.

Some practical benefits of our Specialty Pharmacy Network

These specialty pharmacy partners can help patients get their NUZYRA-and support your office staff or care coordinator if a prior authorization (PA) is needed.

- Walgreens Specialty Pharmacy
- CVS Specialty
- Kroger Specialty
- Option Care
- Panther
- Perigon Pharmacy 360
- Hospital Outpatient Specialty Pharmacy

*Paratek Pharmaceuticals, Inc. does not recommend or prefer the use of one pharmacy over another. NUZYRA Specialty Pharmacy Network as of 06/24/2024.



Scan this code for a full list of pharmacies.



The majority of patients will receive their medication within 24 hours of the prescription being sent to the pharmacy.¹

After submission of all necessary information.

HOW WE HELP



Benefits of using our Specialty Pharmacy Network or your hospital outpatient specialty pharmacy:

- Pharmacists understand the needs of your acute patients
- Pharmacies have NUZYRA in stock
- They provide PA support, utilizing CoverMyMeds® electronic prior authorization tool
- Our partners can provide patient services like **bridge**, **copay**, and support for our **patient assistance program**

Using CoverMyMeds® can assist in determination of PAs and tracking of submitted and pending PAs

Powered by covermymeds®

QUICK TIP

Our **Bridge Program** provides eligible patients up to a 2-day supply of NUZYRA tablets in the event there is a delay in coverage during the benefits investigation with the patient's insurance.

JUST SELECT, SEND, AND ASK

NUZYRA® SurePATHTM

Follow these steps when you choose to prescribe NUZYRA (omadacycline).

STEP

SEND the prescription to your selected NUZYRA network specialty pharmacy via e-Prescribe or fax.

Specialty pharmacy partners can assist with prior authorization when you include the following information with a prescription:

ICD-10 codes², for example:

ABSSSI:

- L08.9 Local infection of the skin and subcutaneous tissue
- L03.116 Cellulitis of left lower limb
- L03.115 Cellulitis of right lower limb
- L03.119 Cellulitis of unspecified part of limb
- L03.90 Cellulitis unspecified
- A49.9 Bacterial infection, unspecified

CABP:

- J18.9 Pneumonia
- J18.0 Bronchopneumonia, unspecified organism
- J18.1 Lobar pneumonia, unspecified organism
- J18.8 Other pneumonia, unspecified organism
- J15 Bacterial pneumonia, not elsewhere classified



Visit <u>nuzyra.com/billing</u> for a full list of codes.

- Include or attach most recent chart notes and face sheet to help limit exchanges between the pharmacy and your staff or care coordinators. CONSIDER:
- History of therapies or antibiotics tried/failed
- Allergies or sensitivities to other antibiotics (e.g., sulfa, penicillin)
- At risk for *C. difficile* (where fluoroquinolones are not appropriate)
- Contraindications

Dosing information: Oral-only treatment duration (7-14 days)³

For ABSSSI Oral:

Days 1-2 450 mg (3 tablets) once per day

Maintenance Dose 300 mg once daily

Total Tablet Count 16-30



For CABP Oral:

Day 1
300 mg (2 tablets) BID
BID=twice a day

Maintenance Dose 300 mg once daily

Total Tablet Count 16-30



Tablets not shown at actual size.

When prescribing oral NUZYRA, instruct patient to:

- Fast for at least 4 hours and then take with water
 NUZYRA can be taken at bedtime or upon waking
- Not eat or drink (except water) for 2 hours after dosing
- Not consume dairy products, antacids, or multivitamins for 4 hours after dosing Patients on anticoagulant therapy may require downward adjustment of their anticoagulant dosage while also taking NUZYRA.

HOW WE HELP



Provide the information above, and the pharmacy will:

- Initiate the PA if needed
- Complete the PA with all required information
- Prepare the PA for final submission

QUICK TIP

Reimbursement support services, including coverage inquiry and billing and coding support, may be available to eligible patients. Call NUZYRA Central® to be connected with a field reimbursement specialist and to check the status of a patient's medication. **1-877-4NUZYRA** (**1-877-468-9972**)

JUST SELECT, SEND, AND ASK

NUZYRA®

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STEP

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ASK the patient to accept a call from the pharmacy to review insurance coverage, bridge options, and eligibility for the patient assistance program.

It's crucial that the pharmacy connects with the patient to confirm these details

Help ensure your patient speaks to the pharmacy

- Share the specialty pharmacy name and phone number with your patient
- Let your patient know that the specialty pharmacy will make multiple attempts to reach them
- If the patient has not heard from the specialty pharmacy within 24 hours, they should call the pharmacy directly

Specialty pharmacists will evaluate current medications for potential interactions, review dosing and administration, plus coordinate shipping and payment options.

Home delivery via expedited shipping

Whether a prescription comes directly through a specialty pharmacy partner or NUZYRA Central[®], medication will be delivered straight to your patient's doorstep, via expedited shipping—at no extra charge.



Remind patients that the pharmacy calling may not be the one they normally use.

Allow your patient to scan to add the pharmacy phone number to their mobile contacts.

HOW WE HELP



NUZYRA Central® can help with:

- Verification of benefits, typically in 24 hours
- for both oral (tablets) and IV formulations
- for both commercially covered and Medicare Advantage patients
- Insurance forms
- Coordination of prior authorizations

Extra assistance for eligible patients:

Patients may qualify for additional assistance with medication through NUZYRA Central[®], the **NUZYRA**[®] *SurePath*[™] access and affordability offering.

You (or a patient) can connect live to NUZYRA Central® for help at

1-877-4NUZYRA (1-877-468-9972) M-F, 8 AM - 8 PM ET

QUICK TIP

Use NUZYRA Central® eSubmit:

- When planning the discharge of hospitalized patients
- To allow NUZYRA Central® to work on your patient's case and help evaluate all available patient services and medication dispensing

Processing can begin immediately upon submission—even before the patient is discharged.



Visit <u>nuzyra.com/nuzyracentral</u>