# NUZYRA® (omadacycline) PRIOR AUTHORIZATION CHECKLIST

**This checklist highlights information that may be needed to initiate a prior authorization (PA) decision from an insurer.** The information is general in nature and is not intended to be comprehensive nor replace the guidance of a qualified professional advisor,* but it does provide a step-by-step guide intended to provide general information that may be needed for a PA to be submitted correctly to a health plan.

*Determination of coverage and reimbursement parameters, and appropriate coding for patient and/or procedure, is the responsibility of the provider. The information provided here is not a guarantee of coverage or reimbursement for Paratek Pharmaceuticals products. Paratek Pharmaceuticals makes no guarantees regarding the timeliness or appropriateness of this information for a particular use, given the frequent changes in public and private payer-specific requirements.

## Important Information

☐ **Patient's name, date of birth, insurance policy number (pharmacy benefit e.g., RxBin and Rx Group Number), and other requested information**

☐ **Physician and facility information**

- Name, provider NPI, address (city and state), phone and fax numbers

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

POWERED BY covermymeds®

## Medical Details

**Include a rationale for treatment – a summary statement of medical need and the reason NUZYRA is being requested.**

☐ **Summary of patient's diagnosis**

- ICD-10 code that applies to the need for NUZYRA

**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

- Antibiotic history:
  - List previous antibiotics tried and failed (include dates)
  - Allergies or sensitivities to other antibiotics (e.g., sulfa, penicillin)
  - Specific contraindications
  - Reason for failure (e.g., lack of clinical response)
  - Any additional rationale to support the clinical decision
  - At risk of *C. Difficile*

☐ **Summary of patient's history**

- Current severity of the patient's condition, including any comorbidities or intolerance to other therapies

KEY POINT

**If available, provide diagnostic test results (i.e., culture and susceptibility)**

## Submission

**When CoverMyMeds® and our Specialty Pharmacy Network are used, the specialty pharmacy will initiate the PA on your behalf.**

☐ **Submit all necessary information to the specialty pharmacy**

- The specialty pharmacy will then enter the information into CoverMyMeds®
- When the entry is complete, the office will receive a key code
- After the office reviews the completed form in CoverMyMeds®, the office **must hit the "Send to Plan" button**

**NUZYRA is an acute care product, so please ensure the PA is submitted for expedited review.**

☐ **Remind patients they will receive a call from the specialty pharmacy to confirm insurance coverage and shipment details**

If submitting a PA without CoverMyMeds®, click here for more information.

## INDICATIONS and USAGE

NUZYRA is indicated for the treatment of adult patients with community-acquired bacterial pneumonia (CABP) and acute bacterial skin and skin structure infections (ABSSSI) caused by certain susceptible microorganisms. **See complete Indications and Usage.**

**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.

*Please see Important Safety Information and full Prescribing Information at NUZYRA.com.*

NUZYRA® SurePATH™

once-daily NUZYRA® (omadacycline) 100 mg for injection 150 mg tablets

# PRIOR AUTHORIZATION CHECKLIST

**If submitting a PA request without using CoverMyMeds®, you can submit directly to the insurer.**

## ✓ Submission

☐ **Submit the PA request form to the insurer***

- PA forms can be obtained through the insurer's website or by contacting their customer service

*Insurers may have specific PA forms for different products or therapeutic areas. Always verify that the correct form for NUZYRA has been completed.

**KEY POINT**

**Always review the PA guidelines on the insurer's website or contact their customer service for process information, including forms and contacts.**

**NOTE:** Many insurers use a Pharmacy Benefits Manager (PBM) for patient prescription benefits, so you may be communicating with the PBM and not the insurer. This information can be found on the back of the patient's insurance card.

**If submitting a PA with CoverMyMeds®, click here for more information.**

***If you need additional support with PA policies or support for CoverMyMeds®, reach out to NUZYRA Central® to speak with our reimbursement experts.***

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

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## INDICATIONS and USAGE

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.

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, 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.



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