NUZYRA® (omadacycline)

BILLING AND CODING GUIDE

Vial and tablets not shown at actual size.

Paratek Pharmaceuticals, Inc. is pleased to provide this billing and coding resource to help healthcare providers appropriately bill for NUZYRA and its administration. This resource contains relevant information and guidance for claims submitted to commercial/private payers and government-sponsored insurance plans, including Medicare and Medicaid.

This Billing and Coding Guide is intended to provide general information only, and Paratek Pharmaceuticals, Inc. cannot guarantee payment of any claim. Coding, coverage, and reimbursement may vary significantly by payer, plan, patient, and setting of care. Actual coverage and reimbursement decisions are made by individual payers following the receipt of claims. For additional information, customers should consult with their payers for all relevant coding, reimbursement, and coverage requirements. It is the sole responsibility of the healthcare provider to select the proper code and ensure the accuracy of all claims used in seeking reimbursement. All services must be medically appropriate and properly supported in the patient medical record.

NUZYRA CENTRAL®

Questions? Call NUZYRA Central® Support Services at
1-877-4-NUZYRA (1-877-468-9972),
Mon-Fri, 8 AM to 8 PM ET to speak with a representative.

Please see Indications, Usage, and Important Safety Information on page 2 and full Prescribing Information in pocket.

NUZYRA®
(omadacycline)
100 mg for injection / 150 mg tablets

INDICATIONS AND IMPORTANT SAFETY INFORMATION

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, 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.

Please see full Prescribing Information in pocket.

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2 BIOEQUIVALENT FORMULATIONS, **ONCE-DAILY DOSING IN ABSSSI AND CABP[1]***

NUZYRA dosage and administration

DOSAGE OF NUZYRA IN ADULT PATIENTS WITH CABP OR ABSSSI — TREATMENT DURATION: 7-14 DAYS

INFECTION	LOADING DOSES	MAINTENANCE DOSE
CABP	Day 1: 200 mg by intravenous infusion over 60 minutes **OR** 100 mg by intravenous infusion over 30 minutes twice	100 mg by intravenous infusion over 30 minutes once daily **OR** 300 mg orally once daily
CABP (NUZYRA tablets only)	Day 1: 300 mg orally twice	300 mg orally once daily
ABSSSI	Day 1: 200 mg by intravenous infusion over 60 minutes **OR** 100 mg by intravenous infusion over 30 minutes twice	100 mg by intravenous infusion over 30 minutes once daily **OR** 300 mg orally once daily
ABSSSI (NUZYRA tablets only)	Days 1 and 2: 450 mg orally once daily	300 mg orally once daily

*For treatment of CABP, the oral loading dose is 300 mg twice on Day 1.[1]

IMPORTANT CONSIDERATIONS WHEN PRESCRIBING NUZYRA[1]

FOR NUZYRA **IV**

- Do NOT administer with any solution containing multivalent cations (eg, calcium and magnesium) through the same intravenous line
- The compatibility of NUZYRA with other drugs and infusion solutions other than 5% Dextrose Injection, USP, or 0.9% Sodium Chloride Injection, USP, has not been established
- Alternative IV loading dose: 100 mg over 30 minutes twice on Day 1

Vial is not actual size.

FOR NUZYRA **ORAL**

- Fast for at least 4 hours and then take with water – NUZYRA can be taken at bedtime or upon waking
- Do not eat or drink (except water) for 2 hours after dosing
- No dairy products, antacids, or multivitamins for 4 hours after dosing
- Patients taking anticoagulant therapy may require downward adjustment of their anticoagulant dosage while taking NUZYRA

Tablets are not actual size.

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ICD-10-CM DIAGNOSTIC CODING FOR NUZYRA

ICD-10-CM codes are used by physicians to report a patient's diagnosis. The following may apply to conditions covered within the approved Prescribing Information for NUZYRA. Paratek Pharmaceuticals, Inc. does not guarantee payment with respect to any particular code and we do not intend through this information to suggest a prescribing decision for any patient. Those decisions are within the prescriber's individual judgment. Below is a list of codes that may be helpful.

Acute Bacterial Skin And Skin Structure Infections (ABSSSI)[2]

ICD-10-CM CODE	DESCRIPTION
A46	Erysipelas
A49.0	Staphylococcal infection, unspecified site
A49.01	Methicillin-susceptible *Staphylococcus aureus* infection, unspecified site
A49.02	Methicillin-resistant *Staphylococcus aureus* infection, unspecified site
A49.1	Streptococcal infection, unspecified site
A49.9	Bacterial infection, unspecified
B95.0	*Streptococcus* group A as the cause of diseases classified elsewhere
B95.2	*Enterococcus* as the cause of diseases classified elsewhere
B95.4	Other *Streptococcus* as the cause of diseases classified elsewhere
B95.5	Unspecified *Streptococcus* as the cause of diseases classified elsewhere
B95.61	Methicillin-susceptible *Staphylococcus aureus* infection as the cause of diseases classified elsewhere
B95.62	Methicillin-resistant *Staphylococcus aureus* infection as the cause of diseases classified elsewhere
B95.8	Unspecified *Staphylococcus* as the cause of diseases classified elsewhere
H60.00-H60.03	Abscess of external ear
H60.10-H60.13	Cellulitis of external ear
J34.0	Abscess, furuncle and carbuncle of nose
L02.01-L02.03	Cutaneous abscess, furuncle and carbuncle of face
L02.11-L02.13	Cutaneous abscess, furuncle and carbuncle of neck
L02.211-L02.239	Cutaneous abscess, furuncle and carbuncle of abdominal wall
L02.31-L02.33	Cutaneous abscess, furuncle and carbuncle of buttock
L02.411-L02.439	Cutaneous abscess, furuncle and carbuncle of limb
L02.511-L02.539	Cutaneous abscess, furuncle and carbuncle of hand
L02.611-L02.639	Cutaneous abscess, furuncle and carbuncle of foot
L02.811-L02.818	Cutaneous abscess, furuncle and carbuncle of other sites
L02.91-L02.93	Cutaneous abscess, furuncle and carbuncle, unspecified
L03.011-L03.019	Cellulitis of finger
L03.031-L03.039	Cellulitis of toe
L03.1-L03.119	Cellulitis of other parts of limb
L03.211	Cellulitis of face
L03.221	Cellulitis of neck
L03.311-L03.319	Cellulitis of trunk
L03.811-L03.818	Cellulitis of other sites
L03.90	Cellulitis, unspecified
L08-L08.9	Other local infections of skin and subcutaneous tissue
N61.1	Abscess of the breast and nipple

Community-Acquired Bacterial Pneumonia (CABP)[2]

ICD-10-CM CODE	DESCRIPTION
A49.0	Staphylococcal infection, unspecified site
A49.01	Methicillin-susceptible *Staphylococcus aureus* infection, unspecified site
A49.1	Streptococcal infection, unspecified site
A49.3	*Mycoplasma* infection, unspecified site
B95.0	*Streptococcus* group A as the cause of diseases classified elsewhere
B95.3	*Streptococcus pneumoniae* as the cause of diseases classified elsewhere
B95.4	Other *Streptococcus* as the cause of diseases classified elsewhere
B95.5	Unspecified *Streptococcus* as the cause of diseases classified elsewhere
B96.0	*Mycoplasma pneumoniae* as the cause of diseases classified elsewhere
B96.1	*Klebsiella pneumoniae* as the cause of diseases classified elsewhere
B96.3	*Haemophilus influenzae* as the cause of diseases classified elsewhere
J13	Pneumonia due to *Streptococcus pneumoniae*
J14	Pneumonia due to *Haemophilus influenzae*
J15	Bacterial pneumonia, not elsewhere classified
J15.7	Pneumonia due to *Mycoplasma pneumoniae*
J16.0	Chlamydial pneumonia
J18.0	Bronchopneumonia, unspecified organism
J18.1	Lobar pneumonia, unspecified organism
J18.8	Other pneumonia, unspecified organism
J18.9	Pneumonia unspecified organism

ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification.

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HEALTHCARE COMMON PROCEDURE CODING SYSTEM (HCPCS) J-CODE

Below are relevant codes related to submitting claims for NUZYRA. Effective 10/1/19, the permanent HCPCS J-Code J0121 may allow for reimbursement of NUZYRA IV. A sample HCPCS form is available in the back pocket of this guide.

HCPCS CODE	DESCRIPTION
J0121	Injection, omadacycline, 1 mg*

*Based on lowest divisible dose per infusion (1 mg/mL).

Vial is not shown at actual size.

Beginning January 1, 2023, Centers for the Medicare & Medicaid Services (CMS) will require all outpatient providers to include the modifier "JZ" on all Medicare claim forms for NUZYRA when the entire vial is administered to the patient and none was discarded. If less than a full dose of NUZYRA IV is administered to a patient for any reason and, therefore, there is a discarded amount, providers should bill for the amount administered to the patient on a single claim line with the JZ modifier and bill for the discarded amount on a separate claim line with the modifier "JW." Beginning October 1, 2023, claim forms that do not include the JZ modifier may be returned to providers by local Medicare Administrative Contractors (MACs) for reprocessing.

CURRENT PROCEDURAL TERMINOLOGY (CPT®) CODES

Created by the AMA, these codes indicate professional medical procedures and services.

CPT CODE	DESCRIPTION
96365	IV infusion for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour
96366	IV infusion for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour
99601	Home infusion/specialty drug administration, per visit (up to 2 hours)
99602	Each additional hour (list separately in addition to code for primary procedure)

AMA=American Medical Association.

NUZYRA NDC CODES

NUZYRA packaging with National Drug Codes (NDCs)

NUZYRA PACKAGING	NDC
100 mg individual vial Carton containing 10 vials	71715-001-02
Blister package of 6 Blister package of 30	71715-002-21 71715-002-27

Some payers require physicians to report 11-digit NDCs when listing a drug on a claim form. To do this, add a zero to the middle section.

NUZYRA 10-DIGIT NDC	NUZYRA 11-DIGIT NDC WITH LEADING ZERO
71715-001-02	71715-0001-02

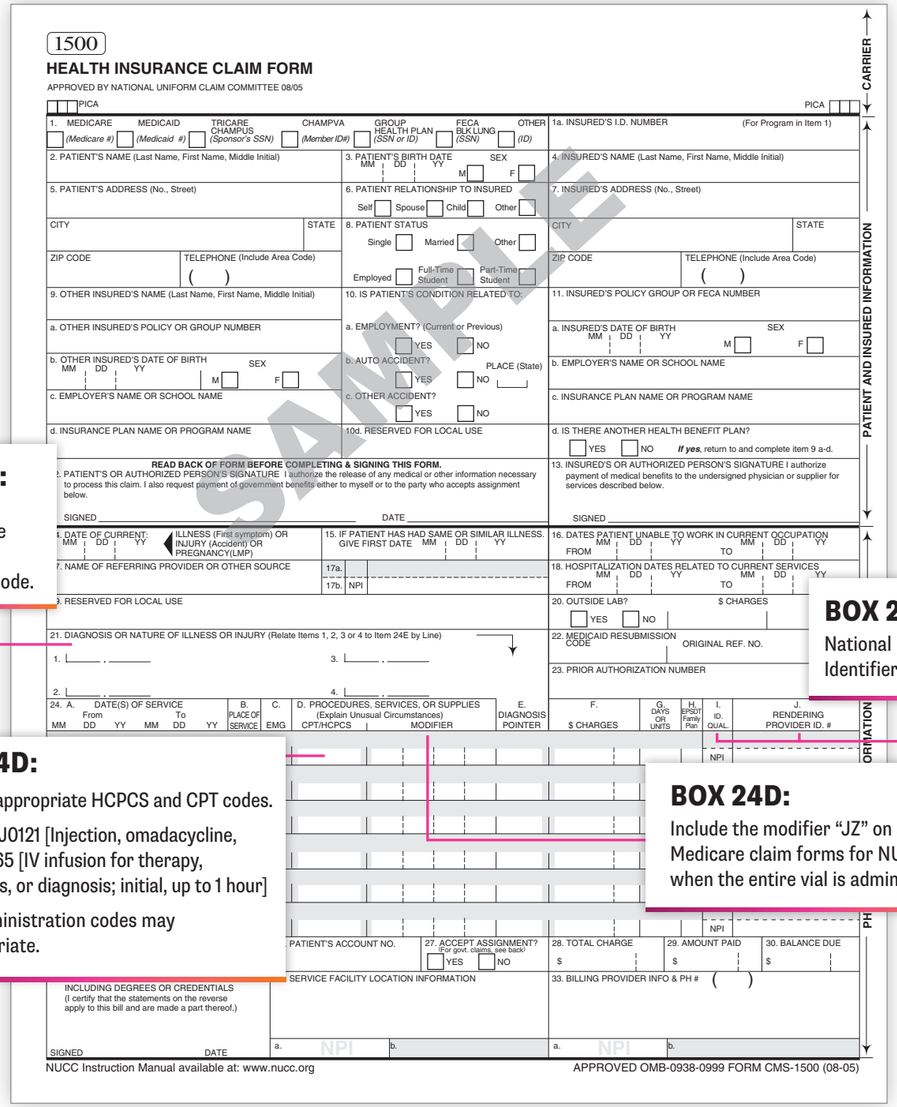
Vial and product packaging are not shown at actual size.

Please see Indications, Usage, and Important Safety Information on page 2 and full Prescribing Information in pocket.

SAMPLE CLAIM FORMS

CMS-1500 Claim Form – Physician Office

The Form CMS-1500 is the basic form prescribed by CMS for the Medicare and Medicaid programs for claims from suppliers and non-institutional providers that qualify for a waiver from the Administrative Simplification Compliance Act (ASCA) requirement for electronic submission of claims. It has also been adopted by the TRICARE Program. For detailed guidance on completing the CMS-1500 items, please see the Medicare Claims Processing Manual, Pub. 100-04, Chapter 26, available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c26.pdf



BOX 21:
Enter the appropriate ICD-10-CM diagnosis code.

BOX 24I & J:
National Provider Identifier.

BOX 24D:
Enter the appropriate HCPCS and CPT codes.

Example: J0121 [Injection, omadacycline, 1 mg] 96365 [IV infusion for therapy, prophylaxis, or diagnosis; initial, up to 1 hour]

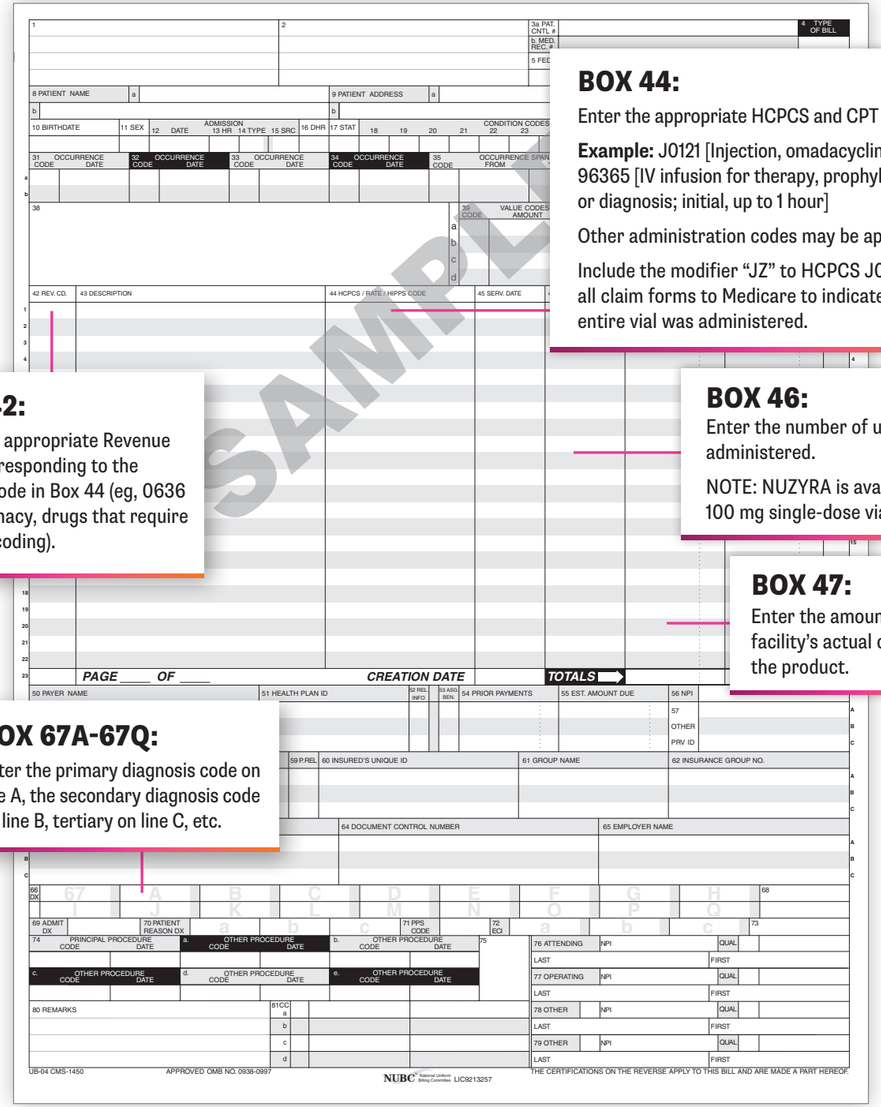
Other administration codes may be appropriate.

BOX 24D:
Include the modifier "JZ" on all Medicare claim forms for NUZYRA when the entire vial is administered.

Please see Indications, Usage, and Important Safety Information on page 2 and full Prescribing Information in pocket.

CMS-1450 (UB-04) Claim Form – Institutional or Hospital Billing

Note: For certain payers, providers must also include the NDC number in Box 43. Specific instructions for formatting this field are available in the Medicare Claims Processing Manual, Chapter 25, available at: http://www.cms.hhs.gov/manuals/downloads/clm104c25.pdf



BOX 42:
Enter the appropriate Revenue Code corresponding to the HCPCS code in Box 44 (eg, 0636 for pharmacy, drugs that require detailed coding).

BOX 44:
Enter the appropriate HCPCS and CPT codes.

Example: J0121 [Injection, omadacycline, 1 mg] 96365 [IV infusion for therapy, prophylaxis, or diagnosis; initial, up to 1 hour]

Other administration codes may be appropriate.

Include the modifier "JZ" to HCPCS J0121 on all claim forms to Medicare to indicate that the entire vial was administered.

BOX 46:
Enter the number of units administered.

NOTE: NUZYRA is available in 100 mg single-dose vials.

BOX 47:
Enter the amount of the facility's actual charges for the product.

BOX 67A-67Q:
Enter the primary diagnosis code on line A, the secondary diagnosis code on line B, tertiary on line C, etc.

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THE MAJORITY OF ELIGIBLE PATIENTS PAY AS LITTLE AS [$0]*

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

*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.

NUZYRA CENTRAL® IS A RESOURCE THROUGHOUT THE PATIENT JOURNEY

NUZYRA Central® provides patient support and resources

REIMBURSEMENT SUPPORT SERVICES

PATIENT RESOURCES

PATIENT ACCESS AND AFFORDABILITY PROGRAMS†

†For eligible patients.

NUZYRA CENTRAL®

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Mon-Fri, 8 AM to 8 PM ET to speak with a representative.

We're here to help

Scan this code to access diagnosis, procedure, and NDC billing codes and more on **NUZYRA.com**.

QR Code drives to: https://www.nuzyra.com/hcp/billing-and-coding/

Please see Indications, Usage, and Important Safety Information on page 2 and full Prescribing Information in pocket.

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

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