

EFFECTIVE OCTOBER 1, 2024

CMS Approves New Technology Add-On Payment (NTAP) for Inpatient Use of ZEVTERA[®] (ceftobiprole medocaryl sodium for injection)¹

As of October 1, 2025, CMS will provide an additional payment* for ZEVTERA of up to:

- \$16,215.00 for *Staphylococcus aureus* bloodstream infections (SAB) **or**
- \$5,287.50 for acute bacterial skin and skin structure infections (ABSSSI) **or**
- \$5,287.50 for community-acquired bacterial pneumonia (CABP)

*Per qualifying case through the Hospital Inpatient Prospective Payment System (IPPS).^{1†}

THIS PIECE IS FOR EDUCATIONAL PURPOSES ONLY AND NOT TO BE CONSIDERED AS ADVICE.

What is an NTAP?^{2,3}

- NTAPs are temporary payments additional to the Medicare Severity Diagnosis-Related Group (MS-DRG) payments normally made to participating hospitals
- NTAPs are designed to support the use of new medical services and technologies before their cost has been calculated into the MS-DRG bundled payment
- CMS weighs several criteria to determine NTAPs. The product must:
 - ◊ Be new to market, offering a differentiating technology
 - ◊ Offer substantial clinical improvement over previously available technologies
 - ◊ Be inadequately compensated in the current MS-DRG payment bundle
- CMS may extend NTAPs for 2 to 3 IPPS fiscal years

CMS, Centers for Medicare and Medicaid Services

[†]NTAPs are discharged through the hospital IPPS. IPPS-exempt hospitals include critical access hospitals, IPPS-exempt cancer hospitals, long-term care hospitals, Veterans Administration/Department of Defense Hospitals, and hospitals in the state of Maryland.^{4,5}

INDICATIONS & USAGE

Indications

ZEVTERA[®] (ceftobiprole medocaryl sodium for injection), for intravenous use, is indicated for the treatment of:

- Adult patients with *Staphylococcus aureus* bloodstream infections (bacteremia) (SAB), including those with right-sided infective endocarditis, caused by methicillin-susceptible and methicillin-resistant isolates.
- Adult patients with acute bacterial skin and skin structure infections (ABSSSI) caused by susceptible isolates of the following gram-positive and gram-negative microorganisms: *Staphylococcus aureus* (methicillin-susceptible and methicillin-resistant isolates), *Streptococcus pyogenes*, and *Klebsiella pneumoniae*.
- Adult and pediatric patients (3 months to less than 18 years) with community-acquired bacterial pneumonia (CABP) caused by susceptible isolates of the following gram-positive and gram-negative microorganisms: *Staphylococcus aureus* (methicillin-susceptible isolates), *Streptococcus pneumoniae*, *Haemophilus influenzae*, *Haemophilus parainfluenzae*, *Escherichia coli*, and *Klebsiella pneumoniae*.

Usage

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

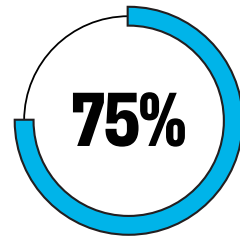
SELECTED IMPORTANT SAFETY INFORMATION

Contraindications: ZEVTERA is contraindicated in patients with a known history of severe hypersensitivity to ZEVTERA, or to other members of the cephalosporin class.

Please see additional Important Safety Information throughout. Before administering, please see the [Full Prescribing Information](#) for ZEVTERA.

 **ZEVTERA[®]**
(ceftobiprole medocaryl sodium for injection)

Determining the amount of an NTAP



ZEVTERA has been designated as a Qualified Infectious Disease Product (QIDP) by the FDA. The use of ZEVTERA will result in an **NTAP payment of up to \$16,215 in addition to the DRG.**

Billing NTAPs for ZEVTERA

The following ICD-10-PCS codes have been assigned for NTAP submission of ZEVTERA on hospital inpatient Medicare claim forms.¹

ICD-10-PCS CODES FOR USE OF ZEVTERA (EFFECTIVE OCTOBER 1, 2024)	
XW0335A	Introduction of ceftobiprole medocartil anti-infective into peripheral vein, percutaneous approach, New Technology Group 10
XW0435A	Introduction of ceftobiprole medocartil anti-infective into central vein, percutaneous approach, New Technology Group 10
USE ONE OF THE CODES ABOVE IN COMBINATION WITH R78.81 + ONE OF THE BELOW ICD-10-CM CODES ⁶	
R78.81	Bacteremia (presence of bacteria in the bloodstream, without systemic inflammatory response)
B95.61	Methicillin-susceptible <i>Staphylococcus aureus</i> infection as the cause of diseases classified elsewhere
B95.62	Methicillin-resistant <i>Staphylococcus aureus</i> infection as the cause of diseases classified elsewhere

ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification;
 ICD-10-PCS, International Classification of Diseases, Tenth Revision, Procedure Coding System.

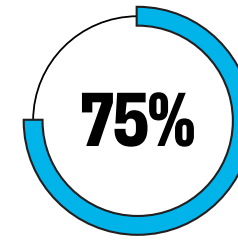
SELECTED IMPORTANT SAFETY INFORMATION

Warnings and Precautions:

- Increased mortality with unapproved use in ventilator-associated bacterial pneumonia (VABP) Patients: **The safety and effectiveness of ZEVTERA for the treatment of VABP has not been established and the use of ZEVTERA for VABP is not approved.**
- Serious hypersensitivity reactions, including anaphylaxis, were observed in ZEVTERA-treated patients in clinical trials. Serious and occasionally fatal hypersensitivity reactions and serious skin reactions have been reported in patients receiving beta-lactam antibacterial drugs. Before therapy with ZEVTERA is instituted, careful inquiry about previous hypersensitivity reactions to other cephalosporins, penicillins, or other beta-lactam antibacterial drugs should be made. Maintain clinical supervision if this product is to be given to a penicillin- or other beta-lactam-allergic patient, because cross sensitivity among beta-lactam antibacterial agents has been established. Discontinue ZEVTERA if a hypersensitivity reaction occurs, and institute appropriate treatment.



Determining the amount of an NTAP



ZEVTERA has been designated as a Qualified Infectious Disease Product (QIDP) by the FDA. The use of ZEVTERA will result in an **NTAP payment of up to \$5,287.50 in addition to the DRG.**

Billing NTAPs for ZEVTERA

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ICD-10-PCS, International Classification of Diseases, Tenth Revision, Procedure Coding System.

When completing Form UB-04 CMS-1450, under column “44 HCPCS / RATE / HIPPS CODE” enter NDC code(s) for ZEVTERA:

68547-578-01 – 667 mg in 1 vial (single-dose)

68547-578-10 – 10 single-dose vials

SELECTED IMPORTANT SAFETY INFORMATION

Warnings and Precautions (cont’d):

- Seizures and other adverse central nervous system (CNS) reactions have been reported during treatment with ZEVTERA and other cephalosporins. If CNS adverse reactions, including seizures, occur, evaluate patients to determine whether ZEVTERA should be discontinued.
- Clostridioides difficile*-associated diarrhea (CDAD) has been reported with nearly all systemic antibacterial agents, including ZEVTERA, and may range in severity from mild diarrhea to fatal colitis. If CDAD is suspected or confirmed, the risk/benefit of continuing treatment with ZEVTERA should be assessed.

Please see additional Important Safety Information throughout. Before administering, please see the Full Prescribing Information for ZEVTERA.

[CLICK HERE TO FIND THE MEDICARE CMS-1450-UB-04 FORM](#)

SELECTED IMPORTANT SAFETY INFORMATION

Adverse Reactions:

- SAB (adult patients): The most common adverse reactions occurring in $\geq 2\%$ of adult patients were anemia, nausea, hypokalemia, vomiting, hepatic enzyme and bilirubin increased, diarrhea, blood creatinine increased, hypertension, leukopenia, pyrexia, abdominal pain, fungal infection, headache, and dyspnea.
- ABSSSI (adult patients): The most common adverse reactions occurring in $\geq 2\%$ of adult patients were nausea, diarrhea, headache, injection site reaction, hepatic enzyme increase, rash, vomiting, and dysgeusia.
- CABP (adult and pediatric patients 3 months to less than 18 years of age):
 - ◊ Adult Patients: The most common adverse reactions occurring in $\geq 2\%$ of adult patients were nausea, hepatic enzyme increased, vomiting, diarrhea, headache, rash, insomnia, abdominal pain, phlebitis, hypertension, and dizziness.
 - ◊ Pediatric Patients: The most common adverse reactions occurring in $\geq 2\%$ of pediatric patients were vomiting, headache, hepatic enzyme increased, diarrhea, infusion site reaction, phlebitis, and pyrexia.

You are encouraged to report negative side effects of prescription drugs to the FDA. To report SUSPECTED ADVERSE REACTIONS, please contact:

Innoviva Specialty Therapeutics, Inc.™
1-800-651-3861
medinfo@istx.com

U.S. Food and Drug Administration
1-800-FDA-1088
www.fda.gov/medwatch

Please see additional Important Safety Information throughout. Before administering, please see the [Full Prescribing Information](#) for ZEVTERA.

References: 1. Centers for Medicare & Medicaid Services. Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals (IPPS) and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year (FY) 2026 Rates; Changes to the FY 2025 IPPS Rates Due to Court Decision; Requirements for Quality Programs; and Other Policy Changes; Health Data, Technology, and Interoperability: Electronic Prescribing, Real-Time Prescription Benefit and Electronic Prior Authorization. Federal Register. 2025; Accessed August 7, 2025. <https://www.govinfo.gov/content/pkg/FR-2025-08-04/pdf/2025-14681.pdf> 2. 42 C.F.R. Section 412.87. Additional payment for new medical services and technologies: general provisions. <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-412/subpart-F/subject-group-ECFR5703923263fedba/section-412.87> 3. Centers for Medicare & Medicaid Services. Fact sheet. FY 2023 hospital inpatient prospective payment system (IPPS) and long-term care hospital prospective payment system (LTCH PPS) final rule — CMS-1771-F. Published August 1, 2022. Accessed August 10, 2022. <https://www.cms.gov/newsroom/fact-sheets/fy-2023-hospital-inpatient-prospective-payment-systemipps-and-long-term-care-hospital-prospective>. 4. Centers for Medicare & Medicaid Services. Medicare program; payments for new medical services and new technologies under the acute care hospital inpatient prospective payment system. Federal Register. 2001;66:46901-46925. Accessed September 8, 2023. <https://www.govinfo.gov/content/pkg/FR-2001-09-07/pdf/01-22475.pdf> 5. Centers for Medicare & Medicaid Services. Affected hospitals. Last modified December 21, 2021. Accessed September 8, 2023. <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalAcqCond/AffectedHospitals>. 6. Centers for Medicare & Medicaid Services. *Medicare and Medicaid Programs and the Children's Health Insurance Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2025 Rates; Quality Programs Requirements; and Other Policy Changes*. Accessed August 7, 2025.

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 **ZEVTERA**®
(ceftobiprole medocaril
sodium for injection)