

Effective October 1, 2023

CMS APPROVES NEW TECHNOLOGY ADD-ON PAYMENT (NTAP) FOR INPATIENT USE OF XACDURO® (SULBACTAM FOR INJECTION; DURLOBACTAM FOR INJECTION), CO-PACKAGED FOR INTRAVENOUS USE¹

As of October 1, 2023, CMS will provide an additional payment for XACDURO of up to \$13,680 per qualifying case to acute care hospitals through the Hospital Inpatient Prospective Payment System (IPPS).^{*1}

What is an NTAP?^{2,3}

- NTAPs are temporary payments additional to the Medicare Severity Diagnosis Related Groups (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}

INDICATION & USAGE

Indication

XACDURO® (sulbactam for injection; durlobactam for injection), co-packaged for intravenous use is indicated in adults for the treatment of hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP) caused by susceptible isolates of *Acinetobacter baumannii-calcoaceticus* complex.

Limitations of Use

XACDURO is not indicated for the treatment of HABP/VABP caused by pathogens other than susceptible isolates of *Acinetobacter baumannii-calcoaceticus* complex.

Usage

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

SELECTED IMPORTANT SAFETY INFORMATION

Contraindications: XACDURO is contraindicated in patients with a history of known severe hypersensitivity to the components of XACDURO or other beta-lactam antibacterial drugs.

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

XACDURO[®]
(sulbactam for injection;
durlobactam for injection),
co-packaged for intravenous use

DETERMINING THE AMOUNT OF AN NTAP

XACDURO[®]
(sulbactam for injection;
durlobactam for injection),
co-packaged for intravenous use

75%

XACDURO has been designated as a Qualified Infectious Disease Product (QIDP) by the FDA. As a result, use of XACDURO will result in an **NTAP payment of 75% of the cost of the technology** (\$13,680).¹

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

Billing NTAPs for XACDURO

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

ICD-10-PCS CODES FOR USE OF XACDURO¹ (EFFECTIVE OCTOBER 1, 2023)

XW033K9	Introduction of sulbactam-durlobactam into peripheral vein, percutaneous approach, new technology group 9
XW043K9	Introduction of sulbactam-durlobactam into central vein, percutaneous approach, new technology group 9

USE THESE CODES IN COMBINATION WITH ONE OF THE FOLLOWING ICD-10-CM CODES

To identify hospital-acquired bacterial pneumonia due to <i>Acinetobacter baumannii-calcoaceticus</i> complex:	Y95	Nosocomial condition
	J15.61	Pneumonia due to <i>Acinetobacter baumannii</i>
To identify ventilator-associated bacterial pneumonia due to <i>Acinetobacter baumannii-calcoaceticus</i> complex:	J95.851	Ventilator-associated pneumonia
	B96.83	<i>Acinetobacter baumannii</i> 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:

- Hypersensitivity was observed in patients treated with XACDURO in clinical trials. Serious and occasionally fatal hypersensitivity (anaphylactic) reactions and serious skin reactions have been reported in patients receiving beta-lactam antibacterial drugs. Before initiating therapy with XACDURO, careful inquiry should be made concerning previous hypersensitivity reactions to carbapenems, penicillins, cephalosporins, other beta lactams, and other allergens. If an allergic reaction occurs, discontinue XACDURO.
- 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. If CDAD is suspected or confirmed, the risk/benefit of continuing treatment with XACDURO should be assessed.
- Prescribing XACDURO in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

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

Sample Claim Form UB-04 CMS-1450

Highlighted fields on this form must be filled in order to receive an NTAP for XACDURO.

42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES	49				
1											
2											
3											
4											
5											
6											
7											
8											
9											
10											
11											
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16											
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21											
22											
PAGE ____ OF ____		CREATION DATE		TOTALS							
50 PAYER NAME			51 HEALTH PLAN ID		52 REL INFO	53 ASGI BEN.	54 PRIOR PAYMENTS	55 EST. AMOUNT DUE	56 NPI		
A			B		C	D	E	F	G		
B			C		D	E	F	G	H		
C			D		E	F	G	H	I		
58 INSURED'S NAME			59 P.REL	60 INSURED'S UNIQUE ID		61 GROUP NAME		62 INSURANCE GROUP NO.			
A			B	C		D		E			
B			C	D		E		F			
C			D	E		F		G			
63 TREATMENT AUTHORIZATION CODES			64 DOCUMENT CONTROL NUMBER			65 EMPLOYER NAME					
A			B			C					
B			C			D					
C			D			E					
66 DX	67	A	B	C	D	E	F	G	H	68	
69 ADMIT DX	70 PATIENT REASON DX	71 PPS CODE	72 ECI	73	74 PRINCIPAL PROCEDURE CODE		75		76 ATTENDING NPI		
a.		b.		c.		d.		e.		f.	
77 OPERATING NPI		78 OTHER NPI		79 OTHER NPI		QUAL		FIRST		LAST	
A		B		C		D		E		F	
B		C		D		E		F		G	
C		D		E		F		G		H	
80 REMARKS			81 CC a		b		c		d		
A			B		C		D		E		
B			C		D		E		F		
C			D		E		F		G		

Enter NDC code(s) for XACDURO
 68547-111-10 – 1 kit in carton
 68547-211-20 – 5 mL in 1 vial (single dose)
 68547-311-30 – 2.5 mL in 1 vial (single-dose)

Enter appropriate diagnosis code(s)

Enter appropriate ICD-10-PCS code(s) for XACDURO

- Make sure to include all of the required information on the form to avoid delays in reimbursement
- Always check with your payer for complete instructions when billing for XACDURO

SELECTED IMPORTANT SAFETY INFORMATION

Adverse Reactions: The most common adverse reactions reported in >10% of patients treated with XACDURO were liver test abnormalities (19%), diarrhea (17%), anemia (13%), and hypokalemia (12%).

Please see additional Important Safety Information throughout. Before administering, please click here to see the Full Prescribing Information for XACDURO.



Scan this QR code to find [Medicare CMS-1450 UB-04 form completion and coding instructions in Chapter 25 of the Medicare Claims Processing Manual \(Pub. 100-04\)](#)

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To report SUSPECTED ADVERSE REACTIONS, contact 1-800-651-3861 or medinfo@istx.com or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Before administering, please click here to see the Full Prescribing Information for XACDURO.

References: **1.** Centers for Medicare & Medicaid Services. Medicare 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 2024 rates; quality programs and Medicare promoting interoperability program requirements for eligible hospitals and critical access hospitals; rural emergency hospital and physician-owned hospital requirements; and provider and supplier disclosure of ownership; and Medicare disproportionate share hospital (DSH) payments: counting certain days associated with section 1115 demonstrations in the Medicaid fraction. *Federal Register*. 2023;88:58640-59438. Accessed September 8, 2023. <https://www.govinfo.gov/content/pkg/FR-2023-08-28/pdf/2023-16252.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 December 4, 2024. <https://www.cms.gov/newsroom/fact-sheets/fy-2023-hospital-inpatient-prospective-payment-system-ipps-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>.

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