

PASS-THROUGH PAYMENT

A Billing and Coding Guide

The reimbursement information provided by CorMedix is intended to provide general information relevant to coding and reimbursement of CorMedix products only. CorMedix does not guarantee coverage or payment of its products.

WHAT ARE PASS-THROUGH PAYMENTS?

Pass-through payments provide additional payment for new devices, drugs, and biologicals that meet eligibility criteria for a period of at least 2 years but not more than 3 years while CMS gathers additional data on the cost of those items.

The intent of pass-through payments is to help facilitate patient access to technologies that are too new to be well represented in the data that CMS use to set Outpatient Prospective Payment System (OPPS) payment rates.¹

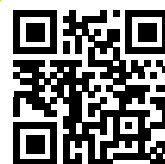
TRANSITIONAL PASS-THROUGH PAYMENTS: DRUGS AND BIOLOGICALS¹

CMS provides for temporary additional payments or “transitional pass-through payments” for certain drugs and biologicals that are not being paid for as a hospital outpatient department (HOPD) service and whose cost is “not insignificant” in relation to the OPPS payments for the procedures or services associated with the new drug or biological.

CMS considers the average cost of a new drug or biological to be “not insignificant” if it meets the following conditions:

- The estimated average reasonable cost of the drug or biological in the category exceeds 10% of the applicable APC payment amount for the service related to the drug or biological.
- The estimated average reasonable cost of the drug or biological exceeds the cost of the drug or biological portion of the APC payment amount for the related service by at least 25%.
- The difference between the estimated reasonable cost of the drug or biological and the estimated portion of the APC payment amount for the drug or biological exceeds 10% of the APC payment amount for the related service.

For more information on pass-through payments,
scan the QR code or visit www.cms.gov



INDICATIONS AND USAGE

LIMITED POPULATION: DEFENCATH® is indicated to reduce the incidence of catheter-related bloodstream infections (CRBSI) in adult patients with kidney failure receiving chronic hemodialysis (HD) through a central venous catheter (CVC). This drug is indicated for use in a limited and specific population of patients.

Limitations of Use

The safety and effectiveness of DEFENCATH have not been established for use in populations other than adult patients with kidney failure receiving chronic HD through a CVC.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

DEFENCATH is contraindicated in patients with:

- Known heparin-induced thrombocytopenia (HIT).
- Known hypersensitivity to taurolidine, heparin or the citrate excipient (components of DEFENCATH), or pork products.

WARNINGS AND PRECAUTIONS

DEFENCATH is contraindicated in patients with:

- **Heparin-Induced Thrombocytopenia (HIT):** HIT was reported in patients using heparin, a component of DEFENCATH, as a catheter lock solution. If HIT occurs, discontinue DEFENCATH and institute appropriate supportive measures.

Please see additional Important Safety Information throughout and the full Prescribing Information.

BILLING AND CODING INFORMATION

The reimbursement information provided by CorMedix is intended to provide general information relevant to coding and reimbursement of CorMedix products only. CorMedix does not guarantee coverage or payment of its products.

SETTINGS OF CARE²

- ☒ Hospital outpatient facilities
- ☒ Freestanding vascular access centers and/or ambulatory surgery centers
- ☒ Centers where interventional nephrologists and vascular access surgeons perform vascular access procedures

The following codes may be used to bill for the use of DefenCath:		
HCPCS Code	J0911	
HCPCS Description	Instillation, taurolidine 1.35 mg and heparin sodium 100 units (central venous catheter lock for adult patients receiving chronic hemodialysis)	
National Drug Code (NDC)	3 mL single dose vial	10 digit: 72990-103-03
		11 digit: 72990-0103-03
	Carton - 10 vial pack	10 digit: 72990-103-10
		11 digit: 72990-0103-10
HCPCS Code Dosage	0.1 mL	
Reimbursement	ASP + 6%	

APC=ambulatory payment classification; ASP=average sales price; CMS=Centers for Medicare & Medicaid Services; HCPCS=Healthcare Common Procedure Coding System; OBL=office-based laboratory; OPPS=Outpatient Prospective Payment System; POS=Place of Service.

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS (CONT'D)

- Drug Hypersensitivity:** Drug hypersensitivity reactions have been reported in patients using heparin, a component of DEFENCATH, as a catheter lock solution. If a hypersensitivity reaction occurs, discontinue DEFENCATH and institute appropriate supportive measures.

ADVERSE REACTIONS

The most frequently reported adverse reactions occurring in ≥2% of patients using DEFENCATH as a CLS were hemodialysis catheter malfunction, hemorrhage/bleeding, nausea, vomiting, dizziness, musculoskeletal chest pain, and thrombocytopenia.

To report SUSPECTED ADVERSE REACTIONS, contact CorMedix Inc at 1-844-424-6345 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see additional Important Safety Information throughout and the full [Prescribing Information](#).

REFERENCES: 1. Centers for Medicare & Medicaid Services. Hospital Outpatient Prospective Payment System (OPPS). <https://www.cms.gov/cms-guide-medical-technology-companies-and-other-interested-parties/payment/opps> 2. Centers for Medicare & Medicaid Services. Medicare program: hospital outpatient prospective payment and ambulatory surgical center payment systems; quality reporting programs; payment for intensive outpatient services in hospital outpatient departments, community mental health centers, rural health clinics, federally qualified health centers, and opioid treatment programs; hospital price transparency; changes to community mental health centers conditions of participation, changes to the inpatient prospective payment system Medicare code editor; rural emergency hospital conditions of participation technical correction. *Federal Register*. 2023;88(224):81540-82185.



DEFENCATH, CORMEDIX, the CORMEDIX logo and CORMEDIX INC. are registered trademarks of CorMedix Inc.
© 2024 CorMedix Inc. All rights reserved. US-DC-0095 (V2.0) 09/24



Limited Population