

TRANSITIONAL DRUG ADD-ON PAYMENT ADJUSTMENT (TDAPA)

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.

This guide provides **TDAPA** and Medicare coding information for billing outpatient use of DefenCath, the first and only FDA-approved catheter lock solution (CLS) proven to significantly 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.¹

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.

DEFENCATH TDAPA

In April 2024, the Centers for Medicare & Medicaid Services approved DefenCath for the TDAPA under the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS).

DEFENCATH HCPCS CODE

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)	
HCPCS Modifiers	1 st Position	AX (item furnished in conjunction with dialysis services)
	2 nd Position	JW (drug amount discarded/not administered to any patient) on the 72x claim to report the discarded amount of taurolidine and heparin sodium OR JZ (zero drug amount discarded/not administered to any patient) on the 72x claim to report when there is no discarded amount of taurolidine and heparin sodium
HCPCS Code Dosage	0.1 mL	
Payment	\$249 per 3 mL vial (based on WAC pricing)	

WHAT IS TDAPA?

- TDAPA is a payment adjustment for new certain renal dialysis drugs and biological products.²
- TDAPA helps ESRD facilities incorporate new drugs and biological products and make appropriate changes in their businesses to adopt such products.²
- The TDAPA provides additional payments for such associated costs and promotes competition among the products within the ESRD PPS functional categories, while also focusing Medicare resources on products that are innovative.²
- Under TDAPA, there will be **2 years of add-on payments based on average sales price (ASP)** (or wholesale acquisition cost [WAC] if ASP is not available) from July 1, 2024 to June 30, 2026.² In addition, **ESRD facilities that administer DefenCath will also receive additional payment under the ESRD PPS for 3 additional years after TDAPA ends.**³

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.

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

DEFENCATH BILLING CODES

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.

The following disease classification codes may be appropriate when billing for DefenCath and related services:

ICD-10-CM CODES

N18.5	Chronic kidney disease, stage 5	N18.6	End stage renal disease
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Apply the following additional billing codes as appropriate when billing for DefenCath and related services:

CPT CODE

90935	Hemodialysis procedure with single evaluation by a physician or other qualified healthcare professional
90937	Hemodialysis procedure requiring repeated evaluation(s) with or without substantial revision of dialysis prescription

NATIONAL DRUG CODE (NDC)

NDC 72990-103-99	3 mL single-dose vial
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REVENUE CODE

0636	Drugs requiring detailed coding
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ASP=average sales price; CPT=Current Procedural Terminology; ESRD=end-stage renal disease; FDA=US Food and Drug Administration; ICD-10-CM=International Classification of Diseases, 10th Revision, Clinical Modification; PPS=Prospective Payment System; TDAPA=Transitional Drug Add-on Payment Adjustment; WAC=wholesaler acquisition cost.

IMPORTANT SAFETY INFORMATION (CONT'D)

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.
- **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 $\geq 2\%$ 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. DefenCath (taurolidine and heparin) [prescribing information]. Berkeley Heights, NJ: CorMedix Inc; 2023. 2. Centers for Medicare & Medicaid Services. ESRD PPS Transitional Drug Add-on Payment Adjustment. Updated September 6, 2023. Accessed April 26, 2024. <https://www.cms.gov/medicare/payment/prospective-payment-systems/end-stage-renal-disease-esrd/esrd-pps-transitional-drug-add-payment-adjustment> 3. Centers for Medicare & Medicaid Services. Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choice Model. *Federal Register*. 2023;88(213)76344-76507.



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