

<b>CMS Manual System</b>	<b>Department of Health &amp; Human Services (DHHS)</b>
<b>Pub 100-04 Medicare Claims Processing</b>	<b>Centers for Medicare &amp; Medicaid Services (CMS)</b>
<b>Transmittal 12474</b>	<b>Date: January 25, 2024</b>
	<b>Change Request 13514</b>

**SUBJECT: Quarterly Update to the End-Stage Renal Disease Prospective Payment System (ESRD PPS)**

**I. SUMMARY OF CHANGES:** The purpose of this Change Request (CR) is to provide instructions for discontinuing the Transitional Drug Add-on Payment Adjustment (TDAPA) effective April 1, 2024, for Healthcare Common Procedure Coding System (HCPCS) code J0879 Injection, difelikefalin, 0.1 microgram, (for ESRD on dialysis).

**EFFECTIVE DATE: April 1, 2024**

*\*Unless otherwise specified, the effective date is the date of service.*

**IMPLEMENTATION DATE: April 1, 2024**

*Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.*

**II. CHANGES IN MANUAL INSTRUCTIONS:** (N/A if manual is not updated)

R=REVISED, N=NEW, D=DELETED-Only One Per Row.

<b>R/N/D</b>	<b>CHAPTER / SECTION / SUBSECTION / TITLE</b>
N/A	N/A

**III. FUNDING:**

**For Medicare Administrative Contractors (MACs):**

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

**IV. ATTACHMENTS:**

**Recurring Update Notification**

# Attachment - Recurring Update Notification

Pub. 100-04	Transmittal: 12474	Date: January 25, 2024	Change Request: 13514
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## I. GENERAL INFORMATION

**A. Background:** The Transitional Drug Add-on Payment Adjustment (TDAPA) is a payment adjustment under the ESRD PPS for certain new renal dialysis drugs and biological products. As discussed in the CY 2019 and CY 2020 ESRD PPS final rules, for new renal dialysis drugs and biological products that fall into an existing ESRD PPS functional category, the TDAPA helps ESRD facilities to incorporate new drugs and biological products and make appropriate changes in their businesses to adopt such products, provides additional payments for such associated costs, and promotes competition among the products within the ESRD PPS functional categories, while focusing Medicare resources on products that are innovative (83 FR 56935; 84 FR 60654). For new renal dialysis drugs and biological products that do not fall within an existing ESRD PPS functional category, the TDAPA is a pathway toward a potential base rate modification (83 FR 56935). The TDAPA requirements are set forth in the ESRD PPS regulations at 42 C.F.R. § 413.234. CMS bases the TDAPA on 100 percent of average sales price (ASP). If ASP is not available, the TDAPA is based on 100 percent of wholesale acquisition cost (WAC) and, when WAC is not available, the payment is based on the drug manufacturer's invoice.

The TDAPA for a new renal dialysis drug or biological product that is used to treat or manage a condition for which there is an existing ESRD PPS functional category is paid for a period of 2 years. Following payment of the TDAPA, the ESRD PPS base rate will not be modified. While the TDAPA applies to a new renal dialysis drug or biological product, the drug or biological product is not considered an ESRD outlier service. The ESRD PPS includes consolidated billing (CB) requirements for limited Part B services included in the ESRD facility's bundled payment. CMS periodically updates the lists of items and services that are subject to Part B consolidated billing and are therefore no longer separately payable when provided to ESRD beneficiaries by providers other than ESRD facilities.

CMS reviews and issues TDAPA payment determinations on a quarterly basis for new renal dialysis drugs or biological products that fit within an existing ESRD PPS functional category.

**B. Policy:** Difelikefalin (J0879 Injection, difelikefalin, 0.1 microgram, (for ESRD on dialysis)), is a drug used for the treatment of moderate-to-severe pruritus associated with chronic kidney disease (CKD-aP) in adults undergoing hemodialysis. Because difelikefalin falls within the existing ESRD PPS functional category of antipruritic and is only used for treating dialysis patients, it is considered to be always used for the treatment of ESRD. As discussed in CR 12583, the 2-year TDAPA payment period for difelikefalin is April 1, 2022, through March 31, 2024. Effective April 1, 2024, difelikefalin is no longer eligible for the TDAPA. As discussed in the CY 2024 ESRD PPS final rule (88 FR 76396 through 76397) and in CR 13445, the post-TDAPA add-on payment adjustment for difelikefalin will be calculated by the ESRD PPS pricer based on the methodology in 42 C.F.R. § 413.234(g) and applied for all ESRD PPS claims beginning April 1, 2024, through March 31, 2027, subject to the conditions described at § 413.234(c)(3).

## II. BUSINESS REQUIREMENTS TABLE

*"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.*

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
13514.1	Effective for ESRD PPS claims (type of bill 72X) with dates of service on and after 4/1/2024, Medicare contractors shall update the TDAPA codes list to remove HCPCS: J0879 Injection, difelikefalin, 0.1 microgram, (for ESRD on dialysis).					X				
13514.2	Effective for ESRD PPS claims (type of bill 72X) with dates of service on and after 4/1/2024, FISS shall ensure that HCPCS J0879 is processed as a covered line item, bundled into the PPS without separate payment.					X				

**III. PROVIDER EDUCATION TABLE**

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
13514.3	Medicare Learning Network® (MLN): CMS will market provider education content through the MLN Connects® newsletter shortly after CMS releases the CR. MACs shall follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1 instructions for distributing the MLN Connects newsletter information to providers and link to relevant information on your website. You may supplement MLN content with your local information after we release the MLN Connects newsletter. Subscribe to the “MLN Connects” listserv to get MLN content notifications. You don’t need to separately track and report MLN content releases when you distribute MLN Connects newsletter content per the manual section referenced above.	X				

**IV. SUPPORTING INFORMATION**

**Section A: Recommendations and supporting information associated with listed requirements: N/A**

*"Should" denotes a recommendation.*

<b>X-Ref Requirement Number</b>	<b>Recommendations or other supporting information:</b>
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**Section B: All other recommendations and supporting information:** N/A

## **V. CONTACTS**

**Post-Implementation Contact(s):** Contact your Contracting Officer's Representative (COR).

## **VI. FUNDING**

### **Section A: For Medicare Administrative Contractors (MACs):**

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**ATTACHMENTS: 0**