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

MLN Matters Number: MM12583
Related Change Request (CR) Number: 12583
Related CR Release Date: March 15, 2022
Effective Date: April 1, 2022
Related CR Transmittal Number: R11295CP
Implementation Date: April 4, 2022

Provider Types Affected

This MLN Matters Article is for ESRD facilities billing Medicare Administrative Contractors (MACs) for services they provide to Medicare patients.

Provider Action Needed

Make sure your billing staff knows about:

- How to code for difelikefalin injection
- Modifier use for code J0879

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.

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
- Promotes competition among the products within the ESRD PPS functional categories
- Focuses Medicare resources on products that are innovative[1]

The TDAPA payment for these products is applicable for a period of 2 years. Following payment of the TDAPA, the ESRD PPS base rate won't be modified. While the TDAPA applies to a new renal dialysis drug or biological product, the drug or biological product isn't considered an ESRD outlier service. The ESRD PPS includes Consolidated Billing (CB) requirements for limited Medicare Part B services included in the ESRD facility's bundled payment.

[1] 83 FR 56935 and 84 FR 60654

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For new renal dialysis drugs and biological products that don't fall within an existing ESRD PPS functional category, the TDAPA is a pathway toward a potential base rate modification.[2]

TDAPA requirements are set forth in the ESRD PPS regulations at 42 C.F.R. § 413.234.

Effective April 1, 2022, difelikefalin, administered by intravenous bolus injection into the venous line of the dialysis circuit at the end of each hemodialysis (HD) treatment, qualifies for the TDAPA as a drug or biological product used to treat or manage a condition for which there is an existing ESRD PPS functional category – specifically, the antipruritic category.

ESRD facilities should report the AX modifier (item furnished in conjunction with dialysis services) with the HCPCS code for this drug to get payment for the drug using the TDAPA. While this drug is eligible for the TDAPA, it doesn't qualify toward outlier calculation. Facilities should use the JW modifier on the 72x claim to report the amount of difelikefalin that's discarded and eligible for payment under the ESRD PPS. Report the AX modifier in the first modifier position and the JW modifier in the second modifier position.

Difelikefalin is the only drug that qualifies for payment using the TDAPA. ESRD facilities shouldn't use the AX modifier for any other drug until we notify you.

The HCPCS code for difelikefalin is J0879 (Injection, difelikefalin, 0.1 microgram (for ESRD on dialysis)). 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.

ESRD facilities won't receive separate payment for J0879 with or without the AY modifier and the claims will process the line item as covered with no separate payment under the ESRD PPS. We'll update the ESRD PPS CB requirements to include J0879. The payer only value code Q8 – Total TDAPA amount – is used to capture the add-on payment adjustment.

More Information

We issued CR 12583 to your MAC as the official instruction for this change.

Attachment A of CR 12583 contains the 2022 ESRD PPS Consolidated Billing List.

For more information, find your MAC's website.

[2] 83 FR 56935

Document History

Date of Change	Description
March 18, 2022	Initial article released.