



ESRD & Acute Kidney Injury Dialysis: CY 2024 Updates

Related CR Release Date: November 22, 2023 MLN Matters Number: MM13445

Effective Date: January 1, 2024

Related Change Request (CR) Number: [CR 13445](#)

Implementation Date: January 2, 2024

Related CR Transmittal Number: R12371BP

Related CR Title: Implementation of Changes in the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) and Payment for Dialysis Furnished for Acute Kidney Injury (AKI) in ESRD Facilities for Calendar Year (CY) 2024

Affected Providers

- ESRD facilities
- Physicians
- Providers
- Suppliers
- Other providers billing Medicare Administrative Contractors (MACs) for ESRD and AKI services they provide to Medicare patients

Action Needed

Make sure your billing staff knows about:

- CY 2024 rate updates and policies for the ESRD Prospective Payment System (PPS)
- Updates to payment for renal dialysis services provided to patients with AKI in ESRD facilities

Background

The ESRD PPS includes consolidated billing (CB) requirements for limited Medicare Part B services included in the ESRD facility's bundled payment. CMS periodically updates the lists of items and services subject to Part B CB, which are no longer separately payable when provided to ESRD patients by providers other than ESRD facilities.

Transitional Drug Add-on Payment Adjustment (TDAPA)

Under the ESRD PPS drug designation process, the TDAPA is available for new renal dialysis drugs and biological products that qualify under [42 CFR 413.234](#).

Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES)

Starting January 1, 2020, the ESRD PPS provides the TPNIES for new and innovative renal dialysis equipment and supplies that qualify under [42 CFR 413.236](#). We base the TPNIES payment on 65% of your MAC-determined price. We pay the TPNIES for 2 calendar years, beginning on January 1 and ending on December 31. While the TPNIES applies to a new and innovative equipment or supply, the equipment or supply isn't considered an outlier service.

Capital Related Assets Adjustment (CRA) for the TPNIES

Starting January 1, 2021, we expanded the TPNIES policy to include certain CRAs that are home dialysis machines when used in the home for a single patient. The TPNIES for CRAs is based on 65% of the MAC-determined price. MACs price new and innovative renal dialysis equipment and supplies, including certain CRAs that are home dialysis machines, that meet the TPNIES eligibility criteria using verifiable information from these sources, if available:

- The invoice amount, facility charges for the item, discounts, allowances, and rebates
- The price established for the item by other MACs and the sources of information used to establish that price
- Payment amounts determined by other payers and the information used to establish those payment amounts
- Charges and payment amounts required for other equipment and supplies that may be comparable or otherwise relevant

Following payment of the TPNIES for CRAs, the ESRD PPS base rate won't be modified, and the new CRA that's a home dialysis machine won't qualify as an eligible outlier service as provided in [42 CFR 413.237](#).

CY 2024 ESRD PPS and AKI Dialysis Payment Updates

Section 1881(b)(14)(F) of the [Social Security Act](#) (the Act) requires an annual increase to the ESRD PPS base rate by an ESRD market basket increase factor, reduced by the productivity adjustment described in Section 1886(b)(3)(B)(xi)(II) of [the Act](#). In other words, the ESRD bundled (ESRDB) market basket increase factor minus the productivity adjustment will update the ESRD PPS base rate.

ESRD PPS Base Rate:

- A combined budget-neutrality adjustment factor for the wage index and the new transitional pediatric ESRD add-on payment adjustment (TPEAPA) of 0.999534
- A productivity-adjusted market basket increase of 2.1%
- The CY 2024 ESRD PPS base rate is \$ \$271.02 ($(\$265.57 \times 0.999534) \times 1.021 = \271.02)

Labor-related share

The labor-related share is 55.2%.

Wage Index

We updated the CY 2024 ESRD PPS wage index to show the latest available hospital wage data. We apply a cap to the reduction in the wage index for ESRD facilities. The wage index floor is 0.6000.

Effective CY 2024, we apply a permanent 5% cap to any decrease to an ESRD facility's CY 2024 final wage index from its final wage index in the prior year.

Effective CY 2023, we adopted a permanent 5% cap applied to all ESRD facilities on any decrease to an ESRD facility's CY 2023 final wage index from its final wage index in the prior year. Under the 5% cap policy, we'll pay a new ESRD facility that opens during CY 2024 the wage index for the area in which it's geographically located for its first full or partial CY with no cap applied, because a new ESRD facility wouldn't have a wage index in the prior CY.

Outlier Policy

We made the following updates to the adjusted average outlier service Medicare Allowable Payment (MAP) amount per treatment:

- \$36.28 for adult patients
- \$23.36 for pediatric patients

We made the following updates to the fixed dollar loss (FDL) amount that's added to the predicted MAP to determine the outlier threshold:

- \$71.76 for adult patients
- \$11.32 for pediatric patients

We made the following changes to the list of outlier services:

- Renal dialysis drugs that are oral equivalents to injectable drugs are based on the most recent prices obtained from the Medicare Prescription Drug Plan Finder, updated to show the most recent mean unit cost. Also, we'll add or remove any renal dialysis items and services as necessary. See [Attachment A of CR 13455](#).
- The mean dispensing fee of the National Drug Codes (NDCs) qualifying for outlier consideration is revised to \$0.35 per NDC per month for claims with dates of service on or after January 1, 2024.

Transitional Pediatric ESRD Add-On Payment Adjustment (TPEAPA)

Effective January 1, 2024, an add-on payment adjustment of 30% of the per-treatment payment amount will be applied to renal dialysis payments for Pediatric ESRD Patients. This add-on payment adjustment will apply for CYs 2024-2026.

Post-TDAPA Add-On Payment Adjustment

- Starting January 1, 2024, we'll apply an add-on payment adjustment to all renal dialysis payments for ESRD patients for 3 years following the end of the TDAPA period for a drug or biological product in an existing functional category. The amount of this add-on payment adjustment is based on the use of the drug or biological product during the most recent twelve-month period for which data is available.

- For CY 2024 there's 1 drug or biological product for which a post-TDAPA add-on payment adjustment will be applied: difelikefalin.
- The TDAPA period for difelikefalin ends on March 31, 2024, so we will apply the post-TDAPA add-on payment adjustment for all ESRD PPS claims starting April 1, 2024, through March 31, 2027.
- For CY 2024 the amount of the post-TDAPA add-on payment adjustment will be 0.2493.
- The amount of the post-TDAPA add-on payment adjustment paid for each claim will be adjusted by the patient-level ESRD PPS case-mix adjusters.

Exceptions to the eligibility requirements for the Low Volume Payment Adjustment (LVPA)

- Effective January 1, 2024, ESRD facilities can apply for exceptions to certain requirements to qualify for the LVPA if they're impacted by a disaster or other emergency.
 - For ESRD facilities that exceed the 4,000 treatment volume threshold due to temporary patient shifting (in other words, providing renal dialysis services to 1 or more patients whose original ESRD facility experiences a disaster or other emergency at any time through the end of the CY following the 12-month period starting when the receiving ESRD facility first begins providing renal dialysis services to the displaced patients), they can get an exception to the requirement at [42 CFR 413.232\(b\)\(1\)](#). The deadline for requesting this exception is either the annual deadline of November 1 or 30 days after the end of the ESRD facility's cost reporting year it's using, whichever is later.
 - For ESRD facilities that close temporarily due to a disaster or other emergency, they can get an exception to the requirement at 42 CFR 413.232(b)(2). The deadline for requesting this exception is 60 days from the ESRD facility's closure.
- These exceptions must be requested, in writing to CMS, by the deadline.
- We'll notify the MAC if we approve the exception.

Reporting Policy for Discarded Amounts of Renal Dialysis Drugs and Biological Products Paid for Under the ESRD PPS Beginning CY 2025

Starting January 1, 2025, ESRD facilities must report discarded billing units on a separate claim line containing a JW modifier for all renal dialysis drugs and biological products from single-dose containers or single-use packaging. When you report a renal dialysis drug or biological product from a single-dose container or single-use packaging on an ESRD PPS claim and there's no discarded amount, ESRD facilities must attest that there's no discarded amount by reporting a JZ modifier on the claim line along with the amount of drug or biological product administered.

When billing for any renal dialysis drug or biological product from a single-dose container or single use package you provided to patients for use while receiving home dialysis services, or oral forms of renal dialysis drugs and biological products, use the best information you have in determining the amount expected to be discarded in a given month, including fill information from the pharmacy and the patient's plan of care.

[Attachment C of CR 13445](#) is the current list of HCPCS codes identified as single-dose container and single-use packaging renal dialysis drugs and biological products for which you must report the JW or JZ modifier. The list in Attachment C isn't an exhaustive list of the drugs and biological products subject to the JW and JZ reporting requirement under the ESRD PPS. All ESRD facility claims for renal dialysis drugs and biological products from a single-dose container or single-use packaging must include either the JW or JZ modifier.

When billing for a renal dialysis drug or biological product, an ESRD facility should refer to the label information to determine whether it is a single-dose container or single-use packaging.

[CR 13445](#) and Chapter 17, Section 40.1 of the [Medicare Claims Processing Manual](#) have more background details on drug reporting and the Part B JW modifier policy. The CR includes some detailed examples.

ESRD facilities shouldn't report discarded amounts of renal dialysis drugs or biological products from multi-use vials.

Requirement of "Time on Machine" Hemodialysis Treatment Data as a Recordkeeping and Cost Reporting Requirement for Outpatient Maintenance Dialysis

We contracted with a data contractor to conduct research and analysis to refine the case-mix adjustment model. We held a Technical Expert Panel (TEP) on December 6, 2018, to discuss options for improving data collection to refine the ESRD PPS case-mix adjustment model. An option presented and preferred by TEP participants was reporting duration of dialysis on Medicare ESRD PPS claims. To support this, we're implementing Value Code D6 starting with dates of service on or after January 1, 2025.

Details of code D6 are:

- Title (short descriptor): The total number of minutes of dialysis provided during the billing period
- Designation: NM (Non-monetary)
- Definition: The number of minutes (rounded to the nearest whole minute) between the beginning of dialysis treatment time (for example, when the start button on the blood pump is pushed) and the end of dialysis treatment time (for example, when the stop button on the blood bump is pushed).

You aren't required to reduce the total count of minutes to account for disruptions due to machine failures, bathroom breaks, or other stoppage, but the number of minutes reported shouldn't include time outside the start and end of the dialysis session, for example, time when the patient is in-center waiting to be seated in a chair. The time on dialysis machine duration begins when the actual dialysis treatment starts and ends when the actual dialysis treatment is complete. The units reported must exceed 1.

Only count the minutes spent dialyzing. Report in whole minutes rounded to the nearest whole minute and reported left of the decimal. The value in the monthly claim line is the total number of minutes of dialysis you provided during the month.

You must report Value Code D6 on ESRD PPS claims for in-facility maintenance hemodialysis treatments, as well as any training or retraining treatments provided in-facility. We'll use time on machine data to help us evaluate and monitor the accuracy of our payments for patient-level adjustment factors.

We'll also evaluate whether the data could be used to inform future updates to existing patient-level adjustment factors, including patient age, Body Mass Index (BMI) and Body Surface Area (BSA), and co-morbidities such as sickle cell anemia.

We'll review the data to identify any disparities from a health equity perspective that may support proposing, in future rulemaking, new patient-level adjustment factors, including potential social determinants of health factors.

Consolidated Billing Requirements

There are no updates to the consolidated billing list for CY 2024. See [Attachment B of CR 13445](#).

AKI Dialysis Payment Rate Updates:

- The AKI dialysis payment rate for CY 2024 is \$271.02, which is the same as the base rate under the ESRD PPS for CY 2024
- The labor-related share is 55.2%
- We adjust the AKI dialysis payment rate for wages using the same wage index that's used under the ESRD PPS
- We don't reduce the AKI dialysis payment rate for the ESRD Quality Incentive Program (QIP)
- The TDAPA, TPNIES, and TPEAPA don't apply to AKI claims
- The post-TDAPA payment adjustment doesn't apply to AKI claims

TDAPA Updates

There's 2 eligible drugs continuing for CY 2024: difelikefalin and daprodustat

- We pay ESRD facilities the TDAPA for difelikefalin starting April 1, 2022-March 31, 2024.
- The TDAPA for difelikefalin will be calculated as described in [CR 12583](#).
- We pay ESRD facilities the TDAPA for daprodustat starting October 1, 2023-September 30, 2025.
- The TDAPA for daprodustat is calculated as described in [CR 13275](#).
- The conditional Average Sales Price (ASP) reporting policy is finalized in the [CY 2020 ESRD PPS final rule](#) and clarified in the [CY 2024 ESRD PPS final rule](#). If we determine that the latest full calendar quarter of ASP isn't available for any drug paid for using the TDAPA, we stop applying the TDAPA for the new renal dialysis drug or biological product within the next 2-calendar quarters.

For difelikefalin and daprodustat, use HCPCS codes:

- J0879 Injection, difelikefalin, 0.1 microgram, (for esrd on dialysis)
- J0889, daprodustat, oral, 1 mg, (for esrd on dialysis)

Report the AX modifier (item furnished in conjunction with dialysis services) with the HCPCS code for these drugs to get payment for the drug using the TDAPA. While these drugs are eligible for the TDAPA, they don't qualify toward outlier calculation. We note that difelikefalin and daprodustat are the only drugs that qualify for payment using the TDAPA, and ESRD facilities shouldn't use the AX modifier for any other drug until we notify you of a change. 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.

TPNIES

There are no renal dialysis equipment or supplies eligible for the TPNIES for CY 2024.

TPNIES for CRAs

There are no TPNIES for CRAs continuing for CY 2024 that are home dialysis machines for hemodialysis. The CY 2024 average per treatment TPNIES for CRA offset amount is \$10.00

More Information

We issued CR 13445 to your MAC as the official instruction for this change.

For more information, [find your MAC's website](#).

Document History

Date of Change	Description
November 22, 2023	Initial article released.

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