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ESRD & Acute Kidney Injury Dialysis: CY 2025 Updates

Related CR Release Date: March 28, 2025	**MLN Matters Number:** MM13686 Revised
Effective Date: January 1, 2025	**Related Change Request (CR) Numbers:** CR 13686 and CR 13865
Implementation Date: January 6, 2025	**Related CR Transmittal Numbers:** R12957CP, R12979CP, R12999BP, and R13121BP
Related CR Title: Implementation of System Changes for the End Stage Renal Disease (ESRD) Prospective Payment System (PPS) and Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury (AKI) for Calendar Year (CY) 2025	

What's Changed? We made no substantive changes to the Article other than to update the CR release date, transmittal number, and transmittal link.

Affected Providers

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

Action Needed

Make sure your billing staff knows about these changes effective January 1, 2025:

- Finalized policies for the ESRD Prospective Payment System (PPS)
- Payment for renal dialysis services you provide to patients with AKI in ESRD facilities

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Background

CR 13686 and CR 13865 implement policies CMS finalized in the CY 2025 ESRD PPS final rule effective January 1, 2025. The CRs also implement system changes required for proposed policies discussed in the CY 2025 ESRD PPS proposed rule.

CY 2025 ESRD PPS and AKI Dialysis Payment Updates

ESRD PPS Base Rate

- A budget-neutrality adjustment factor of 0.988600 for the wage index and related policies
- A productivity-adjusted market basket increase of 2.2%
- The CY 2025 ESRD PPS base rate is $273.82 (($271.02 x. 0.988600) x 1.022 = $273.82)

Labor-Related Share

The labor-related share is 55.2%.

Wage Index

Starting in CY 2025, the ESRD PPS will use a new ESRD PPS wage index methodology, which uses Bureau of Labor Statistics wage data by geographic area weighted by occupational mix based on freestanding ESRD facility cost report full-time equivalent data.

We updated the CY 2025 ESRD PPS wage index to show the most recent wage data and the most recent full year of freestanding ESRD facility cost report data.

- We apply a 5% cap to the reduction in the wage index for ESRD facilities
- The wage index floor is 0.6000

We'll base the ESRD PPS wage index for an ESRD facility on the most recent core-based statistical area (CBSA) delineations according to OMB Bulletin 23-01.

Starting in CY 2025, we'll determine the ESRD PPS rural adjustment based on the most recent CBSA delineations according to OMB 23-01. ESRD facilities that received a 0.8% rural adjustment in CY 2024, but were redesignated into an urban CBSA under the most recent delineations, would receive a transitional phase-out of the rural adjustment:

- 0.53% of the adjustment for CY 2025
- 0.27% of the adjustment for CY 2026
- No rural adjustment for CY 2027

For CY 2025, the payment adjustment factor is 0.0053. To calculate the imputed Medicare allowed payment under the outlier payment, we apply two-thirds of the current 2.2% reduction factor to the average Medicare allowed payment, with the resulting multiplicative factor being 0.9853.

Outlier Policy

We made the following updates to the adjusted average outlier service Medicare allowed payment amount per treatment:

- $31.02 for adult patients
- $59.60 for pediatric patients

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

- $45.41 for adult patients
- $234.26 for pediatric patients

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

- Starting January 1, 2025, all renal dialysis drugs and biologicals, except those currently paid for using the Transitional Drug Add-on Payment Adjustment (TDAPA), are eligible for the outlier payment.
- 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.

Effective for CY 2025, we made the following methodological changes to the outlier calculation:

- We increased the imputed Medicare allowed payment for a claim by the case-mix adjusted post-TDAPA add-on payment amount applied to that claim
- We calculate the price proxy for drugs and biological products used in calculating the adult and pediatric FDL amounts using actual spending data
- The price proxy for laboratory tests and supplies used in calculating the adult and pediatric FDL amounts is the growth of these items in the ESRD market basket

Time on Machine

Starting January 1, 2025, we're implementing Value Code D6 (the total number of minutes of dialysis provided during the billing period). The designation is NM (non-monetary).

Definition: The number of minutes (rounded to the nearest whole minute) between the beginning of dialysis treatment time (for example, when you push the start button on the blood pump) and the end of dialysis treatment time (for example, when you push the stop button on the blood pump).

ESRD facilities don't have to reduce the total count of minutes for disruptions due to machine failures, bathroom breaks, or other stoppages.

- The number of minutes you report shouldn't include time outside the start and end of the dialysis session (for example, time when the patient is in-center waiting to sit 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 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

Report Value Code D6 on ESRD PPS claims for in-facility maintenance hemodialysis treatments as well as any training or retraining treatments you provide in-facility. We use time on machine data to help evaluate and monitor the accuracy of our payments for patient-level adjustment factors.

We also evaluate whether the data could be used to inform future refinements to the existing patient-level adjustment factors set forth at 42 CFR 413.235(a), which include:

- Patient age
- Body mass index
- Body surface area
- Co-morbidities, such as sickle cell anemia

We review the data for its potential 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. We haven't proposed any changes to ESRD PPS patient-level adjusters in relation to this new reporting requirement.

Consolidated Billing Requirements

We added 9 HCPCS codes to the consolidated billing (CB) list for CY 2025. See Attachment B of CR 13865.

Discarded Drug Reporting

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.

You must show there's no discarded amount by reporting the JZ modifier on the claim line along with the amount of drug or biological product you administered when you report a renal dialysis drug or biological product from a single-dose container or single-use packaging on an ESRD claim.

If there's no discarded amount, use the best information you have in determining the amount you expect to discard in each month when filling in information from the pharmacy and the patient's plan of care.

The TDAPA and outlier payment adjustments include payment for units of renal dialysis drugs and biological products billed with the JW modifier but don't allow payment for overfill units (88 FR 76382). This current ESRD PPS payment policy is consistent with the broader Part B policy to pay for the unused and discarded amount, as well as the dose administered, up to the amount of the drug indicated on the vial or package labeling.

The following clarifies billing guidelines for ESRD facilities and provides examples of proper billing for renal dialysis drugs and biological products from single-dose containers or single-use packaging:

- Make sure you accurately report amounts of drugs administered to patients in terms of the dosage specified by the HCPCS code descriptor.
- Report units of service in multiples of the dosage included in the HCPCS code descriptor. If the dosage given isn't a multiple of the number provided in the HCPCS code description, the ESRD facility will round up to the nearest whole number to express the number as a multiple.
- Follow these steps when billing for any discarded amount of a renal dialysis drug or biological product from a single-dose container or single-use package after administering the prescribed dosage of any given drug:
  - The drug must be from a single-dose container or single-use package. Multi-dose containers and multi-use packaging aren't subject to discarded amounts of the drug.
  - The units billed should correspond with the labeled amount of the product purchased to prepare the dose. Where possible, use the smallest dose (vial) available for purchase from the manufacturer that could provide the appropriate dose for the patient while minimizing any discarded amounts.

CR 13686 has detailed examples showing the correct use of the JW and JZ modifiers.

CR 13608, which we released on May 9, 2024:

- Established the TDAPA for DefenCath (taurolidine and heparin sodium) and using the JW and JZ modifiers as applicable
- Instructs facilities to use the JW modifier to report the amount of taurolidine and heparin sodium that's discarded and eligible for payment under the ESRD PPS
- Use the JZ modifier (zero drug amount discarded or not administered to any patient) on the 72x claim to report when there's no discarded amount of taurolidine and heparin sodium

Single-Dose Container and Single-Use Package Billing

Use the best information you have in determining the amount expected to be discarded in a given month when billing for any renal dialysis drug or biological product from a single-dose container or single-use package you provide to patients for use while receiving home dialysis services per 42 CFR 413.217 or oral forms of renal dialysis drugs and biological products.

The HCPCS codes that identify single-dose container and single-use packaging renal dialysis drugs and biological products for which you must report the JW or JZ modifier are in Attachment 1 of CR 13686. This isn't an exhaustive list of the drugs and biological products subject to the JW and JZ reporting requirement under the ESRD PPS. Refer to the label information to decide if it's a single-dose container or single-use packaging when billing for a renal dialysis drug or biological product.

For public awareness, Attachment 2 of CR 13686 provides a list of HCPCS codes that include National Drug Codes for multi-dose containers as well as single-dose containers or single-use packaging. These HCPCS codes may represent a drug or biological product subject to the ESRD PPS reporting requirement for the JW and JZ modifiers.

The Medicare Part B JW modifier policy in effect since 2017 generally doesn't apply to drugs that aren't separately payable. The ESRD PPS statute requires a single bundled payment for renal dialysis services.

We don't consider renal dialysis drugs and biological products separately payable under the ESRD PPS. We do allow ESRD facilities to bill and receive separate payment using the AY modifier for drugs and biological products not related to ESRD treatment. Any separately payable drugs or biological products that ESRD facilities bill for using the AY modifier would be subject to the Part B drug refund program and reporting requirements for the JW and JZ modifiers.

TDAPA

TDAPA is a payment adjustment under the ESRD PPS for certain new renal dialysis drugs and biologicals. TDAPA eligibility requirements are in the ESRD PPS regulations at 42 CFR 413.234.

When new renal dialysis drugs and biologicals fall into an existing ESRD PPS functional category, the TDAPA helps ESRD facilities:

- Incorporate and make appropriate business changes to adopt new drugs and biologicals
- Provide additional payment for associated costs
- Promote product competition within the ESRD PPS functional categories while focusing Medicare resources on innovative products

When new renal dialysis drugs and biologicals don't fall within an existing PPS functional category, the TDAPA is a pathway toward a potential base rate modification.

- We base the TDAPA on 100% of the average sales price (ASP)
- If the ASP isn't available, we base the TDAPA on 100% of the wholesale acquisition cost (WAC)
- If the WAC isn't available, we base the payment on the drug manufacturer's invoice

Under the conditional ASP reporting policy at 42 CFR 413.234(c), if we determine the latest full calendar quarter of the ASP data isn't available for any drug paid for using the TDAPA, we stop applying the TDAPA for the new renal dialysis drug or biological within the next 2 calendar quarters.

We pay the TDAPA for 2-year periods for a new renal dialysis drug or biological that's used to treat or manage a condition that has an existing ESRD PPS functional category. Following TDAPA payment, we won't modify the ESRD PPS base rate. We don't consider the drug or biological that the TDAPA applies to as an ESRD outlier service.

We review and issue TDAPA payment determinations on a quarterly basis for new renal dialysis drugs and biologicals that fit within an existing ESRD PPS functional category.

Post-TDAPA Add-On Payment Adjustment

As of January 1, 2024, the ESRD PPS provides additional payment for certain new renal dialysis drugs and biologicals after the end of the TDAPA period. We apply the post-TDAPA add-on payment adjustment to all ESRD PPS payment, and it's:

- Calculated annually using use of the drug or biological during the most recent 12-month period for which data is available
- Applied for 12 calendar quarters following the end of the TDAPA period for a drug or biological, conditional on receiving ASP data

Then, we multiply the post-TDAPA add-on payment adjustment amount by the patient-level case-mix adjustment factors for the patient, which we add on to the ESRD PPS payment.

For CY 2025, we'll include 2 drugs—Korsuva and Jesduvroq—in calculating the post-TDAPA add-on payment adjustment.

- We'll include Korsuva for all 4 calendar quarters at $0.4601
- We'll include Jesduvroq for only the fourth quarter at $0.0096 (estimated); we'll publish the final post-TDAPA add-on payment adjustment amount for Jesduvroq once a full year's worth of usage data is available

The estimated post-TDAPA add-on payment adjustment amounts for each quarter of CY 2025 are:

- Q1 (January–March): $0.4601 (Korsuva only)
- Q2 (April–June): $0.4601 (Korsuva only)
- Q3 (July–September): $0.4601 (Korsuva only)
- Q4 (October–December): $0.4697 (Korsuva and Jesduvroq)

TDAPA Updates

Starting January 1, 2025, vadadustat, an oral hypoxia-inducible factor prolyl hydroxylase inhibitor indicated for treating anemia due to chronic kidney disease in adults who have been receiving dialysis for at least 3 months, qualifies for the TDAPA as a drug or biological used for anemia management, an existing ESRD PPS functional category. Vadadustat is eligible for the TDAPA but doesn't qualify for outlier payments. You should only use the AX modifier for a drug or biological that qualifies for payment using the TDAPA. Use HCPCS code J0901, Vadadustat, oral, 1 mg (for esrd on dialysis).

We always consider vadadustat a drug used for treating ESRD. ESRD facilities won't receive a separate payment for J0901 with or without the AY modifier, and claims will process the line item as covered with no separate payment under the ESRD PPS.

Starting January 1, 2025, we'll update the ESRD PPS CB requirements to include J0901. We use the payer-only Value Code Q8 (total TDAPA amount) to capture the add-on payment.

Two additional drugs will continue for CY 2025: daprodustat and taurolidine and heparin sodium.

For daprodustat and taurolidine and heparin sodium:

- We pay ESRD facilities the TDAPA for daprodustat starting October 1, 2023 – September 30, 2025
- We calculate the TDAPA for daprodustat as described in CR 13275
- We pay ESRD facilities the TDAPA for tauroldinie and heparin sodium starting July 1, 2024 – June 30, 2026
- We calculate the TDAPA for taurolidine and heparin sodium as described in CR 13608
- Use HCPCS code J0889, Daprodustat, oral, 1 mg, (for esrd on dialysis)
- Use HCPCS code J0911, Instillation, taurolidine 1.35 mg and heparin sodium 100 units (central venous catheter lock for adult patients receiving chronic hemodialysis)

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 for outlier payments. Use the JW modifier to report discarded portions 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.

Payment for Oral-Only Drugs

We established a drug designation process for:

- Determining when a product is no longer an oral-only drug
- Including new injectable and intravenous products into the ESRD PPS

We provide additional payment under this process using the TDAPA for qualifying new injectable or intravenous drugs and biological products.

Starting January 1, 2025, we include payment for renal dialysis drugs and biologicals in oral-only form provided to ESRD patients with the PPS rates established in 42 CFR 413.230.

Also starting January 1, 2025, oral-only phosphate binders qualify for the TDAPA. ESRD facilities should report the AX modifier (item furnished in conjunction with dialysis services) with the drug and biological HCPCS codes to receive payment using the TDAPA. While these drugs are eligible for the TDAPA, they don't qualify toward outlier payment calculation. Report phosphate binders on ESRD PPS claims using the following HCPCS codes:

- J0601 Sevelamer carbonate (renvela or therapeutically equivalent), oral, 20 mg (for esrd on dialysis)
- J0602 Sevelamer carbonate (renvela or therapeutically equivalent), oral, powder, 20 mg (for esrd on dialysis)
- J0603 Sevelamer hydrochloride (renagel or therapeutically equivalent), oral, 20 mg (for esrd on dialysis)
- J0605 Sucroferric oxyhydroxide, oral, 5 mg (for esrd on dialysis)
- J0607 Lanthanum carbonate, oral, 5 mg (for esrd on dialysis)
- J0608 Lanthanum carbonate, oral, powder, 5 mg, not therapeutically equivalent to j0607 (for esrd on dialysis)
- J0609 Ferric citrate, oral, 3 mg ferric iron (for esrd on dialysis)
- J0615 Calcium acetate, oral, 23 mg (for esrd on dialysis)

Phosphate binders are drugs used for maintaining bone and mineral metabolism. Bone and mineral metabolism are an ESRD functional category where we always consider drugs and biologicals that fall in this category as treatment for ESRD. ESRD facilities won't receive separate payment for phosphate binders with or without the AY modifier, and the line item will process as covered with no separate payment under the ESRD PPS. We've updated the ESRD PPS CB requirements for CY 2025 to include the above HCPCS codes for phosphate binders.

Additionally for CY 2025, we'll add a fixed amount of $36.41 to the TDAPA calculation for each monthly claim that includes phosphate binders. The Fiscal Intermediary Standard System will add this amount when calculating the payer only Value Code Q8 (total TDAPA amount) on the monthly ESRD claim.

Transitional Pediatric ESRD Add-on Payment Adjustment

As of January 1, 2024, the ESRD PPS provides the Transitional Pediatric ESRD Add-on Payment Adjustment (TPEAPA) for all claims for services the ESRD facility provides to pediatric patients. The TPEAPA is equal to 30% of the per-treatment payment amount for the pediatric ESRD patient, and we'll apply it for CYs 2024, 2025, and 2026.

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

No renal dialysis equipment or supplies are eligible for the Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) for CY 2025.

Capital Related Assets Adjustment for the TPNIES

No TPNIES for Capital Related Assets (CRA) Adjustments are continuing for CY 2025 that are home dialysis machines for hemodialysis. The CY 2025 average per treatment TPNIES for CRA offset amount is $10.22.

AKI Dialysis Payment Rate Updates

- The AKI dialysis payment rate for CY 2025 is $273.82, which is the base rate under the ESRD PPS for CY 2025 reduced by a budget neutrality factor of $0 per treatment for the home and self-dialysis add-on payment adjustment
- The labor-related share is 55.2%
- We adjust the AKI dialysis payment rate for wages using the same wage index used under the ESRD PPS
- We don't reduce the AKI dialysis payment rate for the ESRD Quality Initiative Program
- The TDAPA, TPNIES, and TPEAPA don't apply to AKI claims
- The post-TDAPA payment adjustment doesn't apply to AKI claims
- Patients with AKI will still be able to get phosphate binders through Part D during the TDAPA period for phosphate binders under the ESRD PPS

Payment for AKI Home Dialysis

Starting January 1, 2025, we'll pay under the AKI PPS for AKI dialysis treatments at home. We'll pay for AKI home dialysis at the same rate as in-center AKI dialysis treatments. ESRD facilities billing for AKI dialysis treatments must include both condition codes 74 and 84 on home AKI dialysis claims.

For patients with AKI, ESRD facilities should bill for the home and self-dialysis training add-on payment adjustment when appropriate. ESRD facilities billing for training or re-training for AKI home and self-dialysis must include condition code 84 as well as either 73 or 87, as appropriate.

We'll pay at the daily rate based on hemo-equivalent treatments when you bill for continuous ambulatory peritoneal dialysis or continuous cycling peritoneal dialysis in the home setting for AKI patients.

- The home dialysis payment rate for AKI patients will be the same as in-center patients: $273.82.
- AKI patients will be eligible for the home dialysis add-on payment adjustment, which is $95.60, adjusted by the providing ESRD facility's wage index. We extended this benefit budget neutrality with a corresponding decrease to the base AKI payment rate that rounds to $0 per treatment based on projected use.

Changes to the Low Volume Payment Adjustment Policy

Starting in CY 2025, there are 2 tiers for low volume payment adjustment (LVPA) payment based on treatment volume with different payment adjustments for each tier.

- An ESRD facility that meets all the existing LVPA criteria at 42 CFR 413.232(b) will get a 28.9% adjustment if it provides fewer than 3,000 treatments per year
- An ESRD facility will get an 18.3% adjustment if it provides between 3,000 and 3,999 treatments per year

We base a facility's annual treatment count on the median treatment volume over its 3 most recent cost reporting years.

Changes to the Scope of Drugs and Biological Products Considered ESRD Outlier Services

Effective January 1, 2025, we revised the definition of ESRD outlier services to include drugs and biological products that are composite rate services per 42 CFR 413.171. That regulation defines these as "Items and services used in the provision of outpatient maintenance dialysis for the treatment of ESRD and included in the composite payment system established under Section 1881(b)(7) and the basic case-mix adjusted composite payment system established under Section 1881(b)(12) of the Act."

This includes all drugs and biological products that you included or would have included in the composite rate prior to establishing the ESRD PPS.

Expanding the definition of ESRD outlier services is in response to concerns from interested parties that excluding drugs and biological products that are substitutes for, or are used to achieve the same effect as, composite rate drugs and biological products from the definition of ESRD outlier services could limit the ability of the ESRD PPS outlier adjustment to appropriately recognize the drivers of cost for renal dialysis services.

Starting January 1, 2025, we consider all renal dialysis drugs and biological products reported on ESRD facility claims for the ESRD PPS outlier adjustment with the following exceptions:

- Drugs and biological products reported with the AY modifier, indicating you didn't provide them for treating ESRD
- Drugs and biological products reported with the AX modifier for which we pay under the TDAPA

More Information

We issued these transmittals to your MAC as the official instructions for the changes:

- R12957CP
- R12979CP
- R12999BP
- R13121BP

For more information, find your MAC's website.

Document History

Date of Change	Description
March 31, 2025	We made no substantive changes to the Article other than to update the CR release date, transmittal number, and transmittal link.
December 16, 2024	We made no substantive changes to the Article other than to update the CR release date, transmittal number, and transmittal link.
November 22, 2024	Initial article released.