CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-02 Medicare Benefit Policy	Centers for Medicare & Medicaid Services (CMS)
Transmittal 12371	**Date: November 22, 2023**
	Change Request 13445

SUBJECT: 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

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to implement the CY 2024 rate updates and policies for the ESRD PPS and to implement the payment for renal dialysis services furnished to beneficiaries with AKI in ESRD facilities. This Recurring Update Notification applies to Publication 100-02, Medicare Benefit Policy Manual, Chapter 11, Section 50.

EFFECTIVE DATE: January 1, 2024
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: January 2, 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.*

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
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. 100-02	Transmittal: 12371	Date: November 22, 2023	Change Request: 13445

SUBJECT: 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

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I. GENERAL INFORMATION

A. Background: CY 2024 ESRD PPS and AKI Dialysis Payment Updates: Effective January 1, 2011, CMS implemented the ESRD PPS based on the requirements of section 1881(b)(14) of the Social Security Act (the Act). The ESRD PPS provides a single per treatment payment to ESRD facilities that covers all the resources used in furnishing an outpatient dialysis treatment. The ESRD PPS base rate is adjusted to reflect patient and facility characteristics that contribute to higher per treatment costs.

In accordance with section 1834(r) of the Act, as added by section 808(b) of the Trade Preferences Extension Act of 2015, CMS pays ESRD facilities for furnishing renal dialysis services to Medicare beneficiaries with AKI. CR 9598 implemented the payment for AKI renal dialysis services and provides detailed information regarding payment policies.

The ESRD PPS includes consolidated billing 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.

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 Code of Federal Regulations (CFR) section 413.234.

Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES): Beginning January 1, 2020, the ESRD PPS provides the TPNIES for new and innovative renal dialysis equipment and supplies that qualify under section 413.236. The TPNIES payment is based on 65 percent of the Medicare Administrative Contractor (MAC) determined price. The TPNIES is paid 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 is not considered an outlier service. CR 11869 created the system changes necessary to implement the TPNIES.

Capital Related Assets (CRA) Eligible for the TPNIES: Beginning January 1, 2021, the TPNIES policy was expanded to include CRA that are home dialysis machines when used in the home for a single patient. The TPNIES for CRA is based on 65 percent of the MAC determined price. The MACs, on behalf of CMS, establish prices for 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 the following sources, if available: (1) the invoice amount, facility charges for the item, discounts, allowances, and rebates; (2) the price established for the item by other MACs and the sources of information used to establish that price; (3) payment amounts determined by other payers and the information used to establish those payment amounts; and (4) charges and payment amounts required for other equipment and supplies that may be comparable or otherwise relevant. The CRA for TPNIES is paid for 2 calendar years, beginning on January 1 and ending on December 31. Following payment of the CRA for TPNIES, the ESRD PPS base rate will not be modified and the new CRA that is a home dialysis machine will not be an eligible outlier

service as provided in section 413.237. CR 12347 created the system changes necessary to implement the TPNIES for CRA under the ESRD PPS.

B. Policy: CY 2024 ESRD PPS and AKI Dialysis Payment Updates: Section 1881(b)(14)(F) of 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. That is, the ESRD bundled 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, discussed in further detail below), of 0.999534
- A productivity-adjusted market basket increase of 2.1 percent
- The CY 2024 ESRD PPS base rate is $271.02 (($265.57 × 0.999534) × 1.021 = $*271.02*).

Labor-related share:

- The labor-related share is 55.2 percent.

Wage index:

- The CY 2024 ESRD PPS wage index is updated to reflect the latest available hospital wage data.
- A cap will be applied to the reduction in the wage index for ESRD facilities.
- The wage index floor is 0.6000.

Outpatient Provider Specific File Changes

Effective CY 2023, a permanent five percent cap was adopted and 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 five percent cap policy, a new ESRD facility that opens during CY 2024 would be paid the wage index for the area in which it is geographically located for its first full or partial CY with no cap applied, because a new ESRD facility would not have a wage index in the prior CY. To implement this policy for CY 2024, MACs must update the following fields in the PSF for all ESRD facilities:

- **Supplemental Wage Index** - used for the prior CY wage index value
- **Supplemental Wage Index Indicator** - used to indicate the value in the "Supplemental Wage Index" field is the prior CY wage index.

MACs must update the "Supplemental Wage Index" and "Supplemental Wage Index Indicator" for all facilities that were active in CY 2023.

MACs must follow the steps below to ensure the appropriate values are applied in the Supplemental Wage Index and Supplemental Wage Indicator fields:

1. If the facility was not active for CY 2023, then skip all of the below steps and leave the "Supplemental Wage Index" and "Supplemental Wage Index Indicator" fields blank. If the facility was active for CY 2023, then follow the steps below.
2. Update the value of "Supplemental Wage Index Indicator" to be "1".
3. Validate the accuracy of the facility's Federal Information Processing Standard (FIPS) state and county codes.

4. Validate the accuracy of the facility's CY 2023 Core-Based Statistical Area (CBSA) based on the facility's FIPS state and county codes and the CBSA delineations defined in Office of Management and Budget Bulletin No. 18–04.
5. Identify the CY 2023 ESRD PPS wage index calculated by the pricer software and used to pay claims for each ESRD facility in CY 2023, and add this wage index value to "Supplemental Wage Index" field.

Outlier Policy:

- CMS made the following updates to the adjusted average outlier service Medicare Allowable Payment (MAP) amount per treatment:
    - The adjusted average outlier service MAP amount per treatment is $36.28 for adult patients.
    - The adjusted average outlier service MAP amount per treatment is $23.36 for pediatric patients.

- CMS made the following updates to the fixed dollar loss (FDL) amount that is added to the predicted MAP to determine the outlier threshold:
    - The FDL amount is $71.76 for adult patients.
    - The FDL amount is $11.32 for pediatric patients.

- CMS 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, are updated to reflect the most recent mean unit cost. In addition, CMS will add or remove any renal dialysis items and services as necessary. See Attachment A.
    - 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. See Attachment A.

Transitional Pediatric ESRD Add-On Payment Adjustment (TPEAPA):

- Effective January 1, 2024, an add-on payment adjustment of 30 percent of the per-treatment payment amount will be applied to renal dialysis payments for Pediatric ESRD Patients, as defined at 42 CFR 413.171. This add-on payment adjustment will apply for CY 2024, 2025 and 2026.

Post-TDAPA Add-On Payment Adjustment:

- Effective January 1, 2024, an add-on payment adjustment will be applied to all renal dialysis payments for ESRD patients for three years following the end of the TDAPA period for a drug or biological product which is in an existing functional category. The amount of this add-on payment adjustment will be based on the utilization of the drug or biological product during the most recent twelve-month period for which data is available.
    - For CY 2024 there is one 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 the post-TDAPA add-on payment adjustment will be applied for all ESRD PPS claims begining 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 are impacted by a disaster or other emergency.
    - For ESRD facilities that exceed the 4,000 treatment volume threshold due to temporary patient shifting (that is, providing renal dialysis services to one or more patient(s) whose original ESRD facility experiences a disaster or other emergency at any time through the end of the CY following the 12-month period beginning when the receiving ESRD facility first begins providing renal dialysis services to the displaced patient(s)) , they can receive an exception to the requirement at 42 CFR 413.232(b)(1). The deadline for requesting this exception is either the annual attestation deadline of November 1 or 30 days after the end of the ESRD facility's cost reporting year for which it is attesting, whichever is later.
    - For ESRD facilities that close temporarily due to a disaster or other emergency, they can receive 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 as specified above.
- Should the exception be approved, CMS will notify the MAC by issuing a technical direction letter.

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

Beginning January 1, 2025, ESRD facilities are required to 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 a renal dialysis drug or biological product from a single-dose container or single-use packaging is reported on an ESRD PPS claim and there is no discarded amount, ESRD facilities are required to attest that there is 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 that is provided to beneficiaries for use while receiving home dialysis services as defined in § 413.217, or oral forms of renal dialysis drugs and biological products, ESRD facilities should use the best information they 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 outlines the current list of Healthcare Common Procedure Coding System (HCPCS) codes identified as single-dose container and single-use packaging renal dialysis drugs and biological products for which the JW or JZ modifier must be reported. Further information about system edits to enforce these reporting requirements will be forthcoming in a future CR. The list in Attachment C is not 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. For public awareness, Attachment D provides a list of HCPCS codes that include NDCs for multi-dose containers as well as single-dose containers or single-use packaging. This reporting requirement is discussed in further detail in the following paragraphs.

As we discussed in the CY 2024 ESRD PPS final rule (88 FR 76380), the Medicare Part B JW modifier policy, in effect since 2017, generally does not apply to drugs that are not separately payable. The ESRD PPS statute generally requires a single bundled payment for renal dialysis services. Specifically, section 1881(b)(14)(A)(i) of the Act requires the Secretary to implement a payment system under which a single

payment is made to a provider of services or a renal dialysis facility for renal dialysis services in lieu of any other payment. The only exception is for oral-only drugs, as defined at 42 C.F.R. § 413.234(a), which are currently paid separately under Medicare Part D. Section 204 of the Stephen Beck, Jr., Achieving a Better Life Experience Act of 2014 (ABLE) (Pub. L. 113–295) amended section 632(b)(1) of the American Taxpayer Relief Act of 2012 (ATRA) (Pub. L. 112– 240), as amended by section 217(a)(1) of the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93), to provide that payment for oral-only renal dialysis drugs and biological products cannot be made under the ESRD PPS bundled payment prior to January 1, 2025. However, ESRD facilities are instructed to report the JW modifier in certain circumstances. Current guidance in Chapter 17, section 40.1 of the Medicare Claims Processing Manual states that the ESRD facility must bill the program using the JW modifier for the amount of erythropoiesis stimulating agents (ESAs) appropriately discarded if a home dialysis patient must discard a portion of the ESA supply due to expiration of a vial, because of interruption in the patient's plan of care, or unused ESAs on hand after a patient's death. Most recently, the March 15, 2022 CR that established the TDAPA for KorsuvaTM (difelikefalin), instructs facilities to use the JW modifier to report the amount of difelikefalin that is discarded and eligible for payment under the ESRD PPS.

Additionally, although renal dialysis drugs and biological products paid under the ESRD PPS are not considered separately payable, we note that ESRD facilities are permitted to bill and receive separate payment using the AY modifier for drugs and biological products that are not related to the treatment of ESRD. Any separately payable drugs or biological products that ESRD facilities bill for using the AY modifier would generally be subject to the Medicare Part B drug refund program and reporting requirements for the JW and JZ modifiers.

As we further discussed in the CY 2024 ESRD PPS final rule, our longstanding policy for payment under the ESRD PPS, including the calculation of the TDAPA and outlier payment adjustments, includes payment for units of renal dialysis drugs and biological products billed with the JW modifier, but does not allow payment for overfill units. That is, the current ESRD PPS payment policy is consistent with the broader Medicare 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.

Lastly, as discussed in the CY 2024 ESRD PPS final rule, ESRD facilities should not report discarded amounts of renal dialysis drugs or biological products from multi-use vials. Discarded amounts of renal dialysis drugs and biological products from multi-use vials should not be billed on ESRD PPS claims.

The following serves to clarify billing guidelines and provide examples of proper billing for renal dialysis drugs and biological products from single-dose containers or single-use packaging:

- ESRD facilities are reminded to ensure amounts of drugs administered to patients are accurately reported in terms of the dosage specified by the HCPCS code descriptor.
- When submitting Medicare claims, units of service should be reported in multiples of the dosage included in the HCPCS code descriptor. If the dosage given is not a multiple of the number provided in the HCPCS code description, the ESRD facility shall round up to the nearest whole number to express the number as a multiple.
- The ESRD facility must 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.

1. The drug must be from a single-dose container or single-use package. Multi-dose containers and multi-use packaging are not expected to result in discarded amounts of the drug.

2. The units billed should correspond with the labeled amount of the product that is actually purchased to prepare the dose. Where possible, ESRD facilities should use the smallest dose (vial) available for purchase from the manufacturer(s) that could provide the appropriate dose for the patient, while minimizing any

discarded amounts.

a. For example, metoclopramide (administered for Diabetic Gastric Stasis not nausea and vomiting associated with the dialysis treatment) is supplied as 10 mg in a 2 mL single-use vial. If ESRD dialysis facility staff administers 5 mg of metoclopramide to a patient, the most efficient way to administer this dose is with half of one 10 mg vial.

3. Any discarded amount of a renal dialysis drug or biological product from a single-dose container or single-use package for which an ESRD facility bills under the ESRD PPS must be discarded and may not be used for another patient regardless of whether the other patient has Medicare.

The following examples illustrate appropriate usage of the JW and JZ modifiers for any renal dialysis drug or biological product from a single-dose container or single-use package that is paid for under the ESRD PPS.

- Example #1 Billing for a renal dialysis drug or biological product with a discarded amount:

Medicare requires discarded drugs be reported with the JW modifier on a separate line.

Claim line #1:

a. HCPCS code for drug administered

b. No modifier

c. Number of billing units administered to the patient

d. Calculated submitted price for ONLY the amount of drug administered

Claim line #2:

a. HCPCS code for drug discarded

b. JW modifier to indicate discard

c. Number of billing units discarded

d. Calculated submitted price for ONLY the amount of drug discarded

Using the example given above, metoclopramide 5 mg would be identified on one line as being given to the patient. On the next line, metoclopramide 5 mg would be identified with the JW modifier to indicate 5 mg of metoclopramide was discarded.

- Example #2 Billing for a renal dialysis drug or biological product with no discarded amount:

Effective January 1, 2025, Medicare requires the JZ modifier on all claim for single-dose containers where there are no discarded amounts.

Claim line #1:

a. HCPCS code for drug administered

b. JZ modifier to indicate no discarded amount

c. Number of billing units administered to the patient

d. Calculate submitted price for the amount administered

For example, if ESRD facility staff administers 10 mg of metoclopramide to a patient, the most efficient way to administer this dose is with one 10 mg vial, and this would be identified on one line as being given to the patient with the identifier JZ because there is no discarded amount.

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

As discussed in the CY 2024 ESRD PPS final rule (88 FR 76397), CMS contracted with a data contractor to conduct research and analysis to refine the case-mix adjustment model. A Technical Expert Panel (TEP) was held on December 6, 2018 to discuss options for improving data collection to refine the ESRD PPS case-mix adjustment model.

The composite rate comprises payment for the basic dialysis treatment received by all ESRD PPS beneficiaries. In order to more precisely estimate the average cost of a dialysis treatment, it is critical to know the variation in treatment-level costs for each component of the composite rate. Under current reporting practices, there are no data on the patient- and treatment-level variation in the cost of composite rate items and services included under the ESRD PPS. The data contractor presented the participants in the TEP with options for optimizing data collection on composite rate items and services, and each option was specifically formulated to minimize reporting burden for ESRD facilities where possible. An option presented and preferred by TEP participants was reporting duration of dialysis on Medicare ESRD PPS claims.

Beginning with dates of service on or after January 1, 2025, CMS is implementing Value Code D6:

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 (i.e. , when the start button on the blood pump is pushed) and the end of dialysis treatment time (i.e., when the stop button on the blood bump is pushed). ESRD facilities are not 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 should not 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.

The ESRD facility counts only the minutes spent dialyzing. It reports 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 provided during the month.

ESRD facilities are required to report Value Code D6 on ESRD PPS claims for in-facility maintenance hemodialysis treatments, as well as any training or retraining treatments that are provided in-facility. As explained in the CY 2024 ESRD PPS final rule (88 FR 76397), CMS will use time on machine data to help us evaluate and monitor the accuracy of our payments for patient-level adjustment factors. CMS will also evaluate whether the data could be used to inform future refinements to the existing patient-level adjustment factors set forth at § 413.235(a), which include patient age, body mass index, body surface area, and co-

morbidities such as sickle cell anemia. Finally, CMS will 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. CMS has not proposed any changes to ESRD PPS patient-level adjusters in relation to this new reporting requirement. Any potential new case-mix adjusters or changes to the case-mix adjusters would be the subject of separate notice and comment rulemaking in the future.

Consolidated Billing Requirements:

- There are no updates to the consolidated billing list for CY 2024. See Attachment B.

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 percent.
- The AKI dialysis payment rate is adjusted for wages using the same wage index that is used under the ESRD PPS.
- The AKI dialysis payment rate is not reduced for the ESRD Quality Incentive Program (QIP).
- The TDAPA does not apply to AKI claims.
- The TPNIES does not apply to AKI claims.
- The TPEAPA does not apply to AKI claims.
- The post-TDAPA payment adjustment does not apply to AKI claims.

<u>TDAPA:</u> There are two eligible drugs for which ESRD facilities will continue to receive payment using the TDAPA under the ESRD PPS for CY 2024; difelikefalin and daprodustat.

- ESRD facilities will be paid the TDAPA for difelikefalin beginning April 1, 2022, through March 31, 2024.
- The TDAPA for difelikefalin will be calculated as described in CR 12583.
- ESRD facilities will be paid the TDAPA for daprodustat beginning October 1, 2023, through September 30, 2025.
- The TDAPA for daprodustat will be calculated as described in CR 13275.
- Under CMS's conditional Average Sales Price (ASP) reporting policy at § 413.234(c), as finalized in the CY 2020 ESRD PPS final rule (84 FR 60679) and clarified in the CY 2024 ESRD PPS final rule (88 FR 76409), if CMS determines that the latest full calendar quarter of ASP is not available for any drug paid for using the TDAPA, we would stop applying the TDAPA for the new renal dialysis drug or biological product within the next 2-calendar quarters.

The following HCPCS codes should be used:

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

ESRD facilities should report the AX modifier (item furnished in conjunction with dialysis services) with the HCPCS code for these drugs to receive payment for the drugs using the TDAPA. While these drugs are eligible for the TDAPA, they do not qualify toward outlier calculation. We note that difelikefalin and daprodustat are the only drugs that qualify for payment using the TDAPA and ESRD facilities should not use the AX modifier for any other drug until notified by CMS. Furthermore, the JW modifier should be used by facilities on the 72x claim to report the amount of difelikefalin that is discarded and eligible for

payment under the ESRD PPS. The AX modifier should be reported 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 CRA for TPNIES offset amount is $10.00.

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	
13445.1	The ESRD PPS Pricer shall include all CY 2024 ESRD PPS updates.									ESRD Pricer
13445.2	Medicare contractors shall pay claims (type of bill 72X) with the CY 2024 ESRD PPS Pricer for renal dialysis services furnished on or after January 1, 2024.					X				
13445.3	Medicare contractors shall update the provider file for ESRD facilities as necessary to reflect: 1. Attested low volume facilities if applicable; 2. Revised CBSA codes if applicable; 3. Quality indicator for any applicable QIP adjustments.	X								
13445.3.1	Medicare contractors shall update the Supplemental Wage Index fields and the Supplemental Wage flags for CY 2024 for all ESRD facilities, in accordance with the instructions provided under Section I.B of this CR.	X								

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
13445.4	Medicare contractors shall update the NDC dispensing fee for ESRD outlier services to $0.35 for claims with dates of service on or after January 1, 2024.					X				
13445.5	Medicare contractors shall update the list of items and services that qualify as outlier services according to the updated list in Attachment A, effective January 1, 2024.					X				
13445.6	Effective for claims dates of service on and after 1/1/2024, Medicare contractors shall update the TPNIES CRA codes list to remove the following HCPCS: • E1629 Tablo hemodialysis system for the billable dialysis service NOTE: There are no changes to the following code lists for CY 2024: TPNIES – no approved codes ESRD PPS Consolidated Billing- current list of codes is available in Attachment B and remains unchanged for CY 2024.					X				
13445.6.1	Effective for claims dates of service on and after 1/1/2024, Medicare contractors shall discontinue manually pricing HCPCS E1629 for TPNIES CRA.	X								
13445.6.2	FISS shall ensure that HCPCS E1629 with dates of service on or after 1/1/2024 is processed as a covered line item, bundled into the PPS without separate payment.					X				

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
13445.7	Medicare contractors shall continue to apply the TDAPA for HCPCS J0879 through March 31, 2024.					X				
13445.8	Medicare contractors shall continue to apply the TDAPA for HCPCS J0889 for CY 2024.					X				
13445.9	When Medicare contractors are evaluating an ESRD facility's attestation for eligibility for the LVPA, they shall not disqualify the ESRD facility from receiving the LVPA if they do not fulfill the requirement for which the ESRD facility has received an approved exception from CMS.	X								

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
13445.10	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.

X-Ref Requirement Number	Recommendations or other supporting information:

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):
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.

ATTACHMENTS: 4

CY 2024 Outlier Services (Effective January 1, 2024 - March 31, 2024)

Oral and Other Equivalent Forms of Injectable Drugs [1,2]

NDC	Reference NDC RxNorm Description	Mean Unit Cost
00054000713	CALCITRIOL 0.00025 MG ORAL CAPSULE	$0.34
00054000725	CALCITRIOL 0.00025 MG ORAL CAPSULE	$0.34
00093735201	CALCITRIOL 0.00025 MG ORAL CAPSULE	$0.34
23155011801	CALCITRIOL 0.00025 MG ORAL CAPSULE	$0.34
23155011803	CALCITRIOL 0.00025 MG ORAL CAPSULE	$0.34
23155066201	CALCITRIOL 0.00025 MG ORAL CAPSULE	$0.34
23155066203	CALCITRIOL 0.00025 MG ORAL CAPSULE	$0.34
43353003409	CALCITRIOL 0.00025 MG ORAL CAPSULE	$0.34
43353003430	CALCITRIOL 0.00025 MG ORAL CAPSULE	$0.34
43353003481	CALCITRIOL 0.00025 MG ORAL CAPSULE	$0.34
43353013809	CALCITRIOL 0.00025 MG ORAL CAPSULE	$0.34
43353013830	CALCITRIOL 0.00025 MG ORAL CAPSULE	$0.34
43353063309	CALCITRIOL 0.00025 MG ORAL CAPSULE	$0.34
43353063330	CALCITRIOL 0.00025 MG ORAL CAPSULE	$0.34
43353063381	CALCITRIOL 0.00025 MG ORAL CAPSULE	$0.34
43353099809	CALCITRIOL 0.00025 MG ORAL CAPSULE	$0.34
51407016901	CALCITRIOL 0.00025 MG ORAL CAPSULE	$0.34
51407016930	CALCITRIOL 0.00025 MG ORAL CAPSULE	$0.34
60687034501	CALCITRIOL 0.00025 MG ORAL CAPSULE	$0.34
60687034511	CALCITRIOL 0.00025 MG ORAL CAPSULE	$0.34
62135061090	CALCITRIOL 0.00025 MG ORAL CAPSULE	$0.34
62756096783	CALCITRIOL 0.00025 MG ORAL CAPSULE	$0.34
62756096788	CALCITRIOL 0.00025 MG ORAL CAPSULE	$0.34
63304023901	CALCITRIOL 0.00025 MG ORAL CAPSULE	$0.34
63304023930	CALCITRIOL 0.00025 MG ORAL CAPSULE	$0.34
63629244501	CALCITRIOL 0.00025 MG ORAL CAPSULE	$0.34
63629874101	CALCITRIOL 0.00025 MG ORAL CAPSULE	$0.34
64380072304	CALCITRIOL 0.00025 MG ORAL CAPSULE	$0.34
64380072306	CALCITRIOL 0.00025 MG ORAL CAPSULE	$0.34
69452020713	CALCITRIOL 0.00025 MG ORAL CAPSULE	$0.34
69452020720	CALCITRIOL 0.00025 MG ORAL CAPSULE	$0.34
71610046809	CALCITRIOL 0.00025 MG ORAL CAPSULE	$0.34
71610046830	CALCITRIOL 0.00025 MG ORAL CAPSULE	$0.34
71610052109	CALCITRIOL 0.00025 MG ORAL CAPSULE	$0.34
72789005801	CALCITRIOL 0.00025 MG ORAL CAPSULE	$0.34
72789005830	CALCITRIOL 0.00025 MG ORAL CAPSULE	$0.34
30698014301	CALCITRIOL 0.00025 MG ORAL CAPSULE [ROCALTROL]	$1.73
30698014323	CALCITRIOL 0.00025 MG ORAL CAPSULE [ROCALTROL]	$1.73
00093735301	CALCITRIOL 0.0005 MG ORAL CAPSULE	$0.47
23155011901	CALCITRIOL 0.0005 MG ORAL CAPSULE	$0.47
23155066301	CALCITRIOL 0.0005 MG ORAL CAPSULE	$0.47

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Oral and Other Equivalent Forms of Injectable Drugs [1,2]

NDC	Reference NDC RxNorm Description	Mean Unit Cost
51407017001	CALCITRIOL 0.0005 MG ORAL CAPSULE	$0.47
62135061190	CALCITRIOL 0.0005 MG ORAL CAPSULE	$0.47
62756096888	CALCITRIOL 0.0005 MG ORAL CAPSULE	$0.47
63304024001	CALCITRIOL 0.0005 MG ORAL CAPSULE	$0.47
63629874201	CALCITRIOL 0.0005 MG ORAL CAPSULE	$0.47
64380072406	CALCITRIOL 0.0005 MG ORAL CAPSULE	$0.47
69452020820	CALCITRIOL 0.0005 MG ORAL CAPSULE	$0.47
30698014401	CALCITRIOL 0.0005 MG ORAL CAPSULE [ROCALTROL]	$2.76
00054312041	CALCITRIOL 0.001 MG/ML ORAL SOLUTION	$5.75
63304024159	CALCITRIOL 0.001 MG/ML ORAL SOLUTION	$5.75
64980044715	CALCITRIOL 0.001 MG/ML ORAL SOLUTION	$5.75
30698091115	CALCITRIOL 0.001 MG/ML ORAL SOLUTION [ROCALTROL]	$14.85
00955172050	DOXERCALCIFEROL 0.0005 MG ORAL CAPSULE	$5.22
23155053825	DOXERCALCIFEROL 0.0005 MG ORAL CAPSULE	$5.22
62135045030	DOXERCALCIFEROL 0.0005 MG ORAL CAPSULE	$5.22
68084087225	DOXERCALCIFEROL 0.0005 MG ORAL CAPSULE	$5.22
68084087295	DOXERCALCIFEROL 0.0005 MG ORAL CAPSULE	$5.22
00955172150	DOXERCALCIFEROL 0.001 MG ORAL CAPSULE	$9.86
23155053925	DOXERCALCIFEROL 0.001 MG ORAL CAPSULE	$9.86
62135045130	DOXERCALCIFEROL 0.001 MG ORAL CAPSULE	$9.86
00955172250	DOXERCALCIFEROL 0.0025 MG ORAL CAPSULE	$11.87
23155054025	DOXERCALCIFEROL 0.0025 MG ORAL CAPSULE	$11.87
62135045230	DOXERCALCIFEROL 0.0025 MG ORAL CAPSULE	$11.87
10888500102	PARICALCITOL 0.001 MG ORAL CAPSULE	$2.77
49483068703	PARICALCITOL 0.001 MG ORAL CAPSULE	$2.77
55111066330	PARICALCITOL 0.001 MG ORAL CAPSULE	$2.77
60429048130	PARICALCITOL 0.001 MG ORAL CAPSULE	$2.77
60429083630	PARICALCITOL 0.001 MG ORAL CAPSULE	$2.77
63629245201	PARICALCITOL 0.001 MG ORAL CAPSULE	$2.77
64980022503	PARICALCITOL 0.001 MG ORAL CAPSULE	$2.77
65862093630	PARICALCITOL 0.001 MG ORAL CAPSULE	$2.77
68382033006	PARICALCITOL 0.001 MG ORAL CAPSULE	$2.77
69387010330	PARICALCITOL 0.001 MG ORAL CAPSULE	$2.77
69452014513	PARICALCITOL 0.001 MG ORAL CAPSULE	$2.77
00074903630	PARICALCITOL 0.001 MG ORAL CAPSULE [ZEMPLAR]	$13.45
10888500202	PARICALCITOL 0.002 MG ORAL CAPSULE	$9.03
49483068803	PARICALCITOL 0.002 MG ORAL CAPSULE	$9.03
55111066430	PARICALCITOL 0.002 MG ORAL CAPSULE	$9.03
60429048230	PARICALCITOL 0.002 MG ORAL CAPSULE	$9.03
60429083730	PARICALCITOL 0.002 MG ORAL CAPSULE	$9.03
63629245301	PARICALCITOL 0.002 MG ORAL CAPSULE	$9.03

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Oral and Other Equivalent Forms of Injectable Drugs [1,2]

NDC	Reference NDC RxNorm Description	Mean Unit Cost
64980022603	PARICALCITOL 0.002 MG ORAL CAPSULE	$9.03
65862093730	PARICALCITOL 0.002 MG ORAL CAPSULE	$9.03
68382033106	PARICALCITOL 0.002 MG ORAL CAPSULE	$9.03
69387010430	PARICALCITOL 0.002 MG ORAL CAPSULE	$9.03
69452014613	PARICALCITOL 0.002 MG ORAL CAPSULE	$9.03
00074903730	PARICALCITOL 0.002 MG ORAL CAPSULE [ZEMPLAR]	$26.97
10888500302	PARICALCITOL 0.004 MG ORAL CAPSULE	$10.64
49483068903	PARICALCITOL 0.004 MG ORAL CAPSULE	$10.64
55111066530	PARICALCITOL 0.004 MG ORAL CAPSULE	$10.64
60429048330	PARICALCITOL 0.004 MG ORAL CAPSULE	$10.64
60429083830	PARICALCITOL 0.004 MG ORAL CAPSULE	$10.64
65862093830	PARICALCITOL 0.004 MG ORAL CAPSULE	$10.64
69452014713	PARICALCITOL 0.004 MG ORAL CAPSULE	$10.64
00378619793	CINACALCET 30 MG ORAL TABLET	$7.79
00904706704	CINACALCET 30 MG ORAL TABLET	$7.79
16714007801	CINACALCET 30 MG ORAL TABLET	$7.79
16729044010	CINACALCET 30 MG ORAL TABLET	$7.79
16729044015	CINACALCET 30 MG ORAL TABLET	$7.79
31722010330	CINACALCET 30 MG ORAL TABLET	$7.79
42291045930	CINACALCET 30 MG ORAL TABLET	$7.79
42543096104	CINACALCET 30 MG ORAL TABLET	$7.79
43598036730	CINACALCET 30 MG ORAL TABLET	$7.79
47335037983	CINACALCET 30 MG ORAL TABLET	$7.79
50268015311	CINACALCET 30 MG ORAL TABLET	$7.79
50268015312	CINACALCET 30 MG ORAL TABLET	$7.79
51407029530	CINACALCET 30 MG ORAL TABLET	$7.79
60687052511	CINACALCET 30 MG ORAL TABLET	$7.79
60687052521	CINACALCET 30 MG ORAL TABLET	$7.79
63629876301	CINACALCET 30 MG ORAL TABLET	$7.79
63629960801	CINACALCET 30 MG ORAL TABLET	$7.79
64380088304	CINACALCET 30 MG ORAL TABLET	$7.79
65862083105	CINACALCET 30 MG ORAL TABLET	$7.79
65862083130	CINACALCET 30 MG ORAL TABLET	$7.79
67877050330	CINACALCET 30 MG ORAL TABLET	$7.79
69097041002	CINACALCET 30 MG ORAL TABLET	$7.79
70436000704	CINACALCET 30 MG ORAL TABLET	$7.79
71093015201	CINACALCET 30 MG ORAL TABLET	$7.79
72865015030	CINACALCET 30 MG ORAL TABLET	$7.79
76282067430	CINACALCET 30 MG ORAL TABLET	$7.79
55513007330	CINACALCET 30 MG ORAL TABLET [SENSIPAR]	$26.26
00378619693	CINACALCET 60 MG ORAL TABLET	$15.71

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Oral and Other Equivalent Forms of Injectable Drugs [1,2]

NDC	Reference NDC RxNorm Description	Mean Unit Cost
16714007901	CINACALCET 60 MG ORAL TABLET	$15.71
16729044110	CINACALCET 60 MG ORAL TABLET	$15.71
16729044115	CINACALCET 60 MG ORAL TABLET	$15.71
31722010430	CINACALCET 60 MG ORAL TABLET	$15.71
42291046030	CINACALCET 60 MG ORAL TABLET	$15.71
42543096204	CINACALCET 60 MG ORAL TABLET	$15.71
43598036830	CINACALCET 60 MG ORAL TABLET	$15.71
47335038083	CINACALCET 60 MG ORAL TABLET	$15.71
51407029630	CINACALCET 60 MG ORAL TABLET	$15.71
63629876401	CINACALCET 60 MG ORAL TABLET	$15.71
63629960701	CINACALCET 60 MG ORAL TABLET	$15.71
64380088404	CINACALCET 60 MG ORAL TABLET	$15.71
65862083205	CINACALCET 60 MG ORAL TABLET	$15.71
65862083230	CINACALCET 60 MG ORAL TABLET	$15.71
67877050430	CINACALCET 60 MG ORAL TABLET	$15.71
69097041102	CINACALCET 60 MG ORAL TABLET	$15.71
70436000804	CINACALCET 60 MG ORAL TABLET	$15.71
71093015301	CINACALCET 60 MG ORAL TABLET	$15.71
72865015130	CINACALCET 60 MG ORAL TABLET	$15.71
76282067530	CINACALCET 60 MG ORAL TABLET	$15.71
55513007430	CINACALCET 60 MG ORAL TABLET [SENSIPAR]	$53.30
00378619593	CINACALCET 90 MG ORAL TABLET	$21.98
16714008001	CINACALCET 90 MG ORAL TABLET	$21.98
16729044210	CINACALCET 90 MG ORAL TABLET	$21.98
16729044215	CINACALCET 90 MG ORAL TABLET	$21.98
31722010530	CINACALCET 90 MG ORAL TABLET	$21.98
42291046130	CINACALCET 90 MG ORAL TABLET	$21.98
42543096304	CINACALCET 90 MG ORAL TABLET	$21.98
43598036930	CINACALCET 90 MG ORAL TABLET	$21.98
47335060083	CINACALCET 90 MG ORAL TABLET	$21.98
51407029730	CINACALCET 90 MG ORAL TABLET	$21.98
63629876501	CINACALCET 90 MG ORAL TABLET	$21.98
63629960601	CINACALCET 90 MG ORAL TABLET	$21.98
64380088504	CINACALCET 90 MG ORAL TABLET	$21.98
65862083305	CINACALCET 90 MG ORAL TABLET	$21.98
65862083330	CINACALCET 90 MG ORAL TABLET	$21.98
67877050530	CINACALCET 90 MG ORAL TABLET	$21.98
69097041202	CINACALCET 90 MG ORAL TABLET	$21.98
70436000904	CINACALCET 90 MG ORAL TABLET	$21.98
71093015401	CINACALCET 90 MG ORAL TABLET	$21.98
72865015230	CINACALCET 90 MG ORAL TABLET	$21.98

CY 2024 Outlier Services (Effective January 1, 2024 - March 31, 2024)

Oral and Other Equivalent Forms of Injectable Drugs [1,2]

NDC	Reference NDC RxNorm Description	Mean Unit Cost
76282067630	CINACALCET 90 MG ORAL TABLET	$21.98
55513007530	CINACALCET 90 MG ORAL TABLET [SENSIPAR]	$81.22

[1] Outlier services imputed payment amounts. Oral or other equivalent forms of Part B injectable drugs included in the ESRD PPS bundle (notwithstanding the delayed implementation of ESRD-related oral-only drugs effective 1/1/2025).

[2] The mean dispensing fee of the NDCs listed above is $0.35. This amount will be applied to each NDC included fee on the monthly claim. We will limit 1 dispensing per NDC per month. Providers should report the quantity in the smallest available unit. This is necessary because Medicare is using the mean per unit cost in calculating the outlier. For example, if the provider reports NDC 00054312041 Calcitriol 1 mcg/ml oral solution (15/ml/bottle) reported and uses the full 15 ml bottle, the quantity is as 15, not 1. This allows for the most accurate calculation for the outlier.

ATTACHMENT B

CY 2024 ESRD PPS CONSOLIDATED BILLING LIST

This is not an all-inclusive list. All injectable drugs and biologicals and their oral or other form of administration, laboratory tests, supplies, and services provided for the treatment of ESRD are included in the ESRD PPS.

DME ESRD SUPPLY HCPCS FOR ESRD PPS CONSOLIDATED BILLING EDITS

HCPCS Code	Long Description
A4216	STERILE WATER, SALINE AND/OR DEXTROSE, DILUENT/FLUSH, 10 ML
A4217	STERILE WATER/SALINE, 500 ML
A4218	STERILE SALINE OR WATER, METERED DOSE DISPENSER, 10 ML
A4450	TAPE, NON-WATERPROOF, PER 18 SQUARE INCHES
A4452	TAPE, WATERPROOF, PER 18 SQUARE INCHES
A6215	FOAM DRESSING, WOUND FILLER, STERILE, PER GRAM
A6216	GAUZE, NON-IMPREGNATED, NON-STERILE, PAD SIZE 16 SQ. IN. OR LESS, WITHOUT ADHESIVE BORDER, EACH DRESSING
A6402	GAUZE, NON-IMPREGNATED, STERILE, PAD SIZE 16 SQ. IN. OR LESS, WITHOUT ADHESIVE BORDER, EACH DRESSING
E0210	ELECTRIC HEAT PAD, STANDARD

DME ESRD SUPPLY HCPCS NOT PAYABLE TO DME SUPPLIERS

HCPCS Code	Long Description
A4215	NEEDLE, STERILE, ANY SIZE, EACH
A4244	ALCOHOL OR PEROXIDE, PER PINT
A4245	ALCOHOL WIPES, PER BOX
A4246	BETADINE OR PHISOHEX SOLUTION, PER PINT
A4247	BETADINE OR IODINE SWABS/WIPES, PER BOX
A4248	CHLORHEXIDINE CONTAINING ANTISEPTIC, 1 ML
A4651	CALIBRATED MICROCAPILLARY TUBE, EACH
A4652	MICROCAPILLARY TUBE SEALANT
A4653	PERITONEAL DIALYSIS CATHETER ANCHORING DEVICE, BELT, EACH
A4657	SYRINGE, WITH OR WITHOUT NEEDLE, EACH
A4660	SPHYGMOMANOMETER/BLOOD PRESSURE APPARATUS WITH CUFF AND STETHOSCOPE

HCPCS Code	Long Description
A4663	BLOOD PRESSURE CUFF ONLY
A4670	AUTOMATIC BLOOD PRESSURE MONITOR
A4671	DISPOSABLE CYCLER SET USED WITH CYCLER DIALYSIS MACHINE, EACH
A4672	DRAINAGE EXTENSION LINE, STERILE, FOR DIALYSIS, EACH
A4673	EXTENSION LINE WITH EASY LOCK CONNECTORS, USED WITH DIALYSIS
A4674	CHEMICALS/ANTISEPTICS SOLUTION USED TO CLEAN/STERILIZE DIALYSIS EQUIPMENT, PER 8 OZ
A4680	ACTIVATED CARBON FILTER FOR HEMODIALYSIS, EACH
A4690	DIALYZER (ARTIFICIAL KIDNEYS), ALL TYPES, ALL SIZES, FOR HEMODIALYSIS, EACH
A4706	BICARBONATE CONCENTRATE, SOLUTION, FOR HEMODIALYSIS, PER GALLON
A4707	BICARBONATE CONCENTRATE, POWDER, FOR HEMODIALYSIS, PER PACKET
A4708	ACETATE CONCENTRATE SOLUTION, FOR HEMODIALYSIS, PER GALLON
A4709	ACID CONCENTRATE, SOLUTION, FOR HEMODIALYSIS, PER GALLON
A4714	TREATED WATER (DEIONIZED, DISTILLED, OR REVERSE OSMOSIS) FOR PERITONEAL DIALYSIS, PER GALLON
A4719	"Y SET" TUBING FOR PERITONEAL DIALYSIS
A4720	DIALYSATE SOLUTION, ANY CONCENTRATION OF DEXTROSE, FLUID VOLUME GREATER THAN 249CC, BUT LESS THAN OR EQUAL TO 999CC, FOR PERITONEAL DIALYSIS
A4721	DIALYSATE SOLUTION, ANY CONCENTRATION OF DEXTROSE, FLUID VOLUME GREATER THAN 999CC BUT LESS THAN OR EQUAL TO 1999CC, FOR PERITONEAL DIALYSIS
A4722	DIALYSATE SOLUTION, ANY CONCENTRATION OF DEXTROSE, FLUID VOLUME GREATER THAN 1999CC BUT LESS THAN OR EQUAL TO 2999CC, FOR PERITONEAL DIALYSIS
A4723	DIALYSATE SOLUTION, ANY CONCENTRATION OF DEXTROSE, FLUID VOLUME GREATER THAN 2999CC BUT LESS THAN OR EQUAL TO 3999CC, FOR PERITONEAL DIALYSIS
A4724	DIALYSATE SOLUTION, ANY CONCENTRATION OF DEXTROSE, FLUID VOLUME GREATER THAN 3999CC BUT LESS THAN OR EQUAL TO 4999CC, FOR PERITONEAL DIALYSIS

HCPCS Code	Long Description
A4725	DIALYSATE SOLUTION, ANY CONCENTRATION OF DEXTROSE, FLUID VOLUME GREATER THAN 4999CC BUT LESS THAN OR EQUAL TO 5999CC, FOR PERITONEAL DIALYSIS
A4726	DIALYSATE SOLUTION, ANY CONCENTRATION OF DEXTROSE, FLUID VOLUME GREATER THAN 5999CC, FOR PERITONEAL DIALYSIS
A4728	DIALYSATE SOLUTION, NON-DEXTROSE CONTAINING, 500 ML
A4730	FISTULA CANNULATION SET FOR HEMODIALYSIS, EACH
A4736	TOPICAL ANESTHETIC, FOR DIALYSIS, PER GRAM
A4737	INJECTABLE ANESTHETIC, FOR DIALYSIS, PER 10 ML
A4740	SHUNT ACCESSORY, FOR HEMODIALYSIS, ANY TYPE, EACH
A4750	BLOOD TUBING, ARTERIAL OR VENOUS, FOR HEMODIALYSIS, EACH
A4755	BLOOD TUBING, ARTERIAL AND VENOUS COMBINED, FOR HEMODIALYSIS, EACH
A4760	DIALYSATE SOLUTION TEST KIT, FOR PERITONEAL DIALYSIS, ANY TYPE, EACH
A4765	DIALYSATE CONCENTRATE, POWDER, ADDITIVE FOR PERITONEAL DIALYSIS, PER PACKET
A4766	DIALYSATE CONCENTRATE, SOLUTION, ADDITIVE FOR PERITONEAL DIALYSIS, PER 10 ML
A4770	BLOOD COLLECTION TUBE, VACUUM, FOR DIALYSIS, PER 50
A4771	SERUM CLOTTING TIME TUBE, FOR DIALYSIS, PER 50
A4772	BLOOD GLUCOSE TEST STRIPS, FOR DIALYSIS, PER 50
A4773	OCCULT BLOOD TEST STRIPS, FOR DIALYSIS, PER 50
A4774	AMMONIA TEST STRIPS, FOR DIALYSIS, PER 50
A4802	PROTAMINE SULFATE, FOR HEMODIALYSIS, PER 50 MG
A4860	DISPOSABLE CATHETER TIPS FOR PERITONEAL DIALYSIS, PER 10
A4870	PLUMBING AND/OR ELECTRICAL WORK FOR HOME HEMODIALYSIS EQUIPMENT
A4890	CONTRACTS, REPAIR, AND MAINTENANCE, FOR HEMODIALYSIS EQUIPMENT
A4911	DRAIN BAG/BOTTLE, FOR DIALYSIS, EACH
A4913	MISCELLANEOUS DIALYSIS SUPPLIES, NOT OTHERWISE SPECIFIED
A4918	VENOUS PRESSURE CLAMP, FOR HEMODIALYSIS, EACH
A4927	GLOVES, NON-STERILE, PER 100
A4928	SURGICAL MASK, PER 20

HCPCS Code	Long Description
A4929	TOURNIQUET FOR DIALYSIS, EACH
A4930	GLOVES, STERILE, PER PAIR
A4931	ORAL THERMOMETER, REUSABLE, ANY TYPE, EACH
A6204	SURGICAL DRESSING
A6250	SKIN SEALANTS, PROTECTANTS, MOISTURIZERS, OINTMENTS, ANY TYPE, ANY SIZE
A6260	WOUND CLEANSERS, STERILE, ANY TYPE, ANY SIZE
E1500	CENTRIFUGE, FOR DIALYSIS
E1510	KIDNEY, DIALYSATE DELIVERY SYST. KIDNEY MACHINE, PUMP RECIRCULAT- ING, AIR REMOVAL SYST, FLOWRATE METER, POWER OFF, HEATER AND TEMPERATURE CONTROL WITH ALARM, I.V.POLES, PRESSURE GAUGE, CONCENTRATE CONTAINER
E1520	HEPARIN INFUSION PUMP FOR HEMODIALYSIS
E1530	AIR BUBBLE DETECTOR FOR HEMODIALYSIS, EACH, REPLACEMENT
E1540	PRESSURE ALARM FOR HEMODIALYSIS, EACH, REPLACEMENT
E1550	BATH CONDUCTIVITY METER FOR HEMODIALYSIS, EACH
E1560	BLOOD LEAK DETECTOR FOR HEMODIALYSIS, EACH, REPLACEMENT
E1570	ADJUSTABLE CHAIR, FOR ESRD PATIENTS
E1575	TRANSDUCER PROTECTORS/FLUID BARRIERS, FOR HEMODIALYSIS, ANY SIZE, PER 10
E1580	UNIPUNCTURE CONTROL SYSTEM FOR HEMODIALYSIS
E1590	HEMODIALYSIS MACHINE
E1592	AUTOMATIC INTERMITTENT PERITIONEAL DIALYSIS SYSTEM
E1594	CYCLER DIALYSIS MACHINE FOR PERITONEAL DIALYSIS
E1600	DELIVERY AND/OR INSTALLATION CHARGES FOR HEMODIALYSIS EQUIPMENT
E1610	REVERSE OSMOSIS WATER PURIFICATION SYSTEM, FOR HEMODIALYSIS
E1615	DEIONIZER WATER PURIFICATION SYSTEM, FOR HEMODIALYSIS
E1620	BLOOD PUMP FOR HEMODIALYSIS, REPLACEMENT
E1625	WATER SOFTENING SYSTEM, FOR HEMODIALYSIS
E1630	RECIPROCATING PERITONEAL DIALYSIS SYSTEM
E1632	WEARABLE ARTIFICIAL KIDNEY, EACH
E1634	PERITONEAL DIALYSIS CLAMPS, EACH
E1635	COMPACT (PORTABLE) TRAVEL HEMODIALYZER SYSTEM
E1636	SORBENT CARTRIDGES, FOR HEMODIALYSIS, PER 10

HCPCS Code	Long Description
E1637	HEMOSTATS, EACH
E1639	SCALE, EACH
E1699	DIALYSIS EQUIPMENT, NOT OTHERWISE SPECIFIED

LABS SUBJECT TO ESRD CONSOLIDATED BILLING

CPT/ HCPCS Code	Short Description
80047	Basic Metabolic Panel (Calcium, ionized)
80048	Basic Metabolic Panel (Calcium, total)
80051	Electrolyte Panel
80053	Comprehensive Metabolic Panel
80069	Renal Function Panel
80076	Hepatic Function Panel
82040	Assay of serum albumin
82108	Assay of aluminum
82306	Vitamin d, 25 hydroxy
82310	Assay of calcium
82330	Assay of calcium, Ionized
82374	Assay, blood carbon dioxide
82379	Assay of carnitine
82435	Assay of blood chloride
82565	Assay of creatinine
82570	Assay of urine creatinine
82575	Creatinine clearance test
82607	Vitamin B-12
82652	Vit d 1, 25-dihydroxy
82668	Assay of erythropoietin
82728	Assay of ferritin
82746	Blood folic acid serum
83540	Assay of iron
83550	Iron binding test
83735	Assay of magnesium
83970	Assay of parathormone
84075	Assay alkaline phosphatase
84100	Assay of phosphorus
84132	Assay of serum potassium
84134	Assay of prealbumin

CPT/ HCPCS Code	Short Description
84155	Assay of protein, serum
84157	Assay of protein by other source
84295	Assay of serum sodium
84466	Assay of transferrin
84520	Assay of urea nitrogen
84540	Assay of urine/urea-n
84545	Urea-N clearance test
85014	Hematocrit
85018	Hemoglobin
85025	Complete (cbc), automated (HgB, Hct, RBC, WBC, and Platelet count) and automated differential WBC count.
85027	Complete (cbc), automated (HgB, Hct, RBC, WBC, and Platelet count)
85041	Automated rbc count
85044	Manual reticulocyte count
85045	Automated reticulocyte count
85046	Reticyte/hgb concentrate
85048	Automated leukocyte count
86704	Hep b core antibody, total
86705	Hep b core antibody, igm
86706	Hep b surface antibody
87040	Blood culture for bacteria
87070	Culture, bacteria, other
87071	Culture bacteri aerobic othr
87073	Culture bacteria anaerobic
87075	Cultr bacteria, except blood
87076	Culture anaerobe ident, each
87077	Culture aerobic identify
87081	Culture screen only
87340	Hepatitis b surface ag, eia
87341	Hepatitis b surface ag eia
G0499	Hepb screen high risk indiv
G0306	CBC/diff wbc w/o platelet
G0307	CBC without platelet

DRUGS SUBJECT TO ESRD CONSOLIDATED BILLING

Category	HCPCS	Title
Access Management	J1642	INJ HEPARIN SODIUM PER 10 U
	J1644	INJ HEPARIN SODIUM PER 1000U
	J1945	LEPIRIDUN
	J2993	RETEPLASE INJECTION
	J2997	ALTEPLASE RECOMBINANT
	J3364	UROKINA SE 5000 IU INJECTION
	J3365	UROKINA SE 250,000 IU INJ
	J0884	INJ ARGATROBAN
	J0899[1]	ARGATROBAN DIALYSIS, AUROMED
Anemia Management	J0882	DARBEPOETIN
	J0887	INJ. EPOETIN BETA (FOR ESRD ON DIALYSIS), 1 MCG
	J0889[2]	DAPRODUSTAT, ORAL, 1MG, (FOR ESRD ON DIALYSIS)
	J1439	INJ FERRIC CARBOXY MALTOSE, 1MG
	J1444[3]	FE PYRO CIT POW 0.1 MG IRON
	J1750	IRON DEXTRAN
	J1443	INJ. FERRIC PYRO PHOSPHATE CIT
	J1756	IRON SUCROSE INJECTION
	J2916	NA FERRIC GLUCONATE COMPLEX
	J3420	VITAMIN B12 INJECTION
	Q0139	FERUMOXYTOL
	Q4081	EPO
Bone and Mineral Metabolism	Q5105	INJECTION, EPOETIN ALFA , BIOSIMILAR
	J0604[4]	CINACALCET, ORAL, 1 MG, (FOR ESRD ON DIALYSIS)
	J0606	INJECTION, ETELCALCETIDE, 0.1 MG
	J0612[5]	CALCIUM GLUCONATE INJECTION
	J0620	CALCIUM GLYCER & LA CT/10 ML
	J0630	CALCITONIN SALMON INJECTION
	J0636	INJ CALCITRIOL PER 0.1 MCG
	J0895	DEFEROXAMINE MESYLATE INJ
	J1270	INJECTION, DOXERCALCIFEROL
	J1740	IBANDRONATE SODIUM
	J2430	PAMIDRONATE DISODIUM /30 MG
	J2501	PARICALCITOL
	J3489	ZOLEDRONIC ACID
Cellular Management	J1955	INJ LEVOCARNITINE PER 1 GM

Anti-Infectives	J0878	DAPTOMYCIN
	J3370	VANCOMYCIN HCL INJECTION
Composite Rate Drugs and Biologicals	A4802	INJ PROTAMINE SULFATE
	J0670	INJ MEPIVACAINE HYDROCHLORIDE
	J0879[6]	INJECTION, DIFELIKEFALIN, 0.1 MICROGRAM, (FOR ESRD ON DIALYSIS)
	J0945	BROMPHE NIRAMINE MALEATE
	J1200	INJ DIPHEN HYDRAMINE HCL
	J1205	INJ CHLOROTHIAZIDE SODIUM
	J1240	INJ DIMENHYDRINATE
	J1940	INJ FUROSEMIDE
	J2001	INJ LIDOCAINE HCL FOR INTRAVENOUS INFUSION, 10 MG
	J2150	INJ MANNITOL
	J2360	INJECTION, ORPHENADRINE CITRATE, UP TO 60 MG
	J2720	INJ PROTAMINE SULFATE
	J2795	INJ ROPIVACAINE HYDROCHLORIDE
	J3265	INJ TORSEMIDE
	J3410	INJ HYDROXYZINE HCL
	J3480	INJ. POTASSIUM CHLORIDE, PER 2 MEQ.
	J7030	INFUSION, NORMAL SALINE SOLUTION , 1000 CC
	J7040	INFUSION, NORMAL SALINE SOLUTION, STERILE (500 ML = 1 UNIT)
	J7042	5% DEXTROSE/NORMAL SALINE (500 ML = 1 UNIT)
	J7050	INFUSION, NORMAL SALINE SOLUTION, 250 CC
	J7060	5% DEXTROSE/WATER (500 ML = 1 UNIT)
	J7070	INFUSION, D5W, 1000 CC
	J7120	RINGERS LACTATE INFUSION, UP TO 1000 CC
	J7131	HYPERTONIC SALINE SOL

	Q0163	DIPHENHYDRAMINE HYDROCHLORIDE

[1] Effective January 1, 2022.

[2] Effective October 1, 2023.

[3] Effective July 1, 2019.

[4] For outlier consideration, the NDC should be reported. For more information, please see the MLN Connects Article published on September 23, 2021.

[5] Effective April 1, 2023 J0612 replaced J0610.

[6] Effective April 1, 2022.

Attachment C - HCPCS Codes for Drugs and Biological Products from Single-Dose Containers or Single-Use Packaging

HCPCS	Description
J0278	Injection, amikacin sulfate, 100 mg
J0290	INJECTION, AMPICILLIN SODIUM, 500 MG
J0606	Injection, etelcalcetide, 0.1 mg
J0636	INJECTION, CALCITRIOL, 0.1 MCG
J0692	INJECTION, CEFEPIME HYDROCHLORIDE, 500 MG
J0696	INJECTION, CEFTRIAXONE SODIUM, PER 250 MG
J0713	INJECTION, CEFTAZIDIME, PER 500 MG
J0878	Injection, daptomycin, 1 mg
J0879	Injection, difelikefalin, 0.1 microgram, (for esrd on dialysis)
J0882	Injection, darbepoetin alfa, 1 microgram (for esrd on dialysis)
J0887	Injection, epoetin beta, 1 microgram, (for esrd on dialysis)
J1580	INJECTION, GARAMYCIN, GENTAMICIN, UP TO 80 MG
J1642	INJECTION, HEPARIN SODIUM, (HEPARIN LOCK FLUSH), PER 10 UNITS
J1756	Injection, iron sucrose, 1 mg
J1956	INJECTION, LEVOFLOXACIN, 250 MG
J2185	Injection, meropenem, 100 mg
J2310	INJECTION, NALOXONE HYDROCHLORIDE, PER 1 MG
J2357	Injection, omalizumab, 5 mg
J2405	INJECTION, ONDANSETRON HYDROCHLORIDE, PER 1 MG
J2550	INJECTION, PROMETHAZINE HCL, UP TO 50 MG
J2704	Injection, propofol, 10 mg
J2916	INJECTION, SODIUM FERRIC GLUCONATE COMPLEX IN SUCROSE INJECTION, 12.5 MG
J2997	INJECTION, ALTEPLASE RECOMBINANT, 1 MG
J7050	INFUSION, NORMAL SALINE SOLUTION , 250 CC
Q0139	Injection, ferumoxytol, for treatment of iron deficiency anemia, 1 mg (for esrd on dialysis)

Attachment D – HCPCS with a mix of single-dose and multi-dose NDCs in ESRD claims

HCPCS	Description
J0690	INJECTION, CEFAZOLIN SODIUM, 500 MG
J1200	INJECTION, DIPHENHYDRAMINE HCL, UP TO 50 MG
J1270	INJECTION, DOXERCALCIFEROL, 1 MCG
J1644	INJECTION, HEPARIN SODIUM, PER 1000 UNITS
J2501	Injection, paricalcitol, 1 mcg
J3370	INJECTION, VANCOMYCIN HCL, 500 MG
Q4081	Injection, epoetin alfa, 100 units (for esrd on dialysis)
Q5105	Injection, epoetin alfa-epbx, biosimilar, (retacrit) (for esrd on dialysis), 100 units