

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 12957	Date: November 8, 2024
	Change Request 13686

Transmittal 12724 issued July 18, 2024, is being rescinded and replaced by Transmittal 12957, dated November 8, 2024, to revise the CR title, attachment 3 API Contract as well as the background and policy sections to reflect the final CY 2025 ESRD PPS policies. All other information remains the same.

NOTE: This Transmittal is no longer sensitive and is being re-communicated. This instruction may now be posted to the Internet.

SUBJECT: 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

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to implement policies finalized in the CY 2024 ESRD PPS final rule that are effective January 1, 2025. In addition, this CR implements system changes required for final policies discussed in the CY 2025 ESRD PPS final rule. Updates to Internet Only Manual (IOM), Pub. 100-04, Chapter 4 - Part B Hospital (Including Inpatient Hospital Part B and OPPS) and Chapter 8 - Outpatient ESRD Hospital, Independent Facility, and Physician/Supplier Claims are also included in this CR.

EFFECTIVE DATE: January 1, 2025

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

IMPLEMENTATION DATE: January 6, 2025

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
R	4/50.1/Outpatient Provider Specific File
R	8/20/End Stage Renal Disease Prospective Payment System (ESRD PPS) Per Treatment Payment Amount
R	8/20.1/Calculation of the Basic Case-Mix Adjusted Composite Rate and the ESRD Prospective Payment System Rate
R	8/40/Acute Kidney Injury (AKI) Claims
R	8/50.2/Drugs and Biologicals Included in the End Stage Renal Disease Prospective Payment System (ESRD PPS)
R	8/50.3/Required Information for In-Facility Claims Paid Under the End Stage Renal Disease Prospective Payment System ESRD PPS
R	8/50.8/Training and Retraining

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:

**Business Requirements
Manual Instruction**

Attachment - Business Requirements

Pub. 100-04	Transmittal: 12957	Date: November 8, 2024	Change Request: 13686
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II. GENERAL INFORMATION

A. Background: The purpose of this Change Request (CR) is to implement policies finalized in the CY 2024 ESRD PPS final rule that are effective January 1, 2025. In addition, this CR implements system changes required for final policies discussed in the CY 2025 ESRD PPS final rule. Updates to Internet Only Manual (IOM), Pub. 100-04, Chapter 4 - Part B Hospital (Including Inpatient Hospital Part B and OPSS) and Chapter 8 - Outpatient ESRD Hospital, Independent Facility, and Physician/Supplier Claims are also included in this CR.

B. Policy:

1. Reporting Time in Minutes that ESRD Beneficiaries Spend In Center Receiving a Hemodialysis Treatment "Time on Machine" Data

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

The ESRD PPS includes patient-level adjustments that adjust the ESRD PPS base rate for certain patient characteristics. The current ESRD PPS case-mix adjustments are derived from a case-mix adjustment model involving two equations. In the CY 2011 ESRD PPS final rule (75 FR 49083), we discussed the two-equation methodology used to develop the adjustment factors that would be applied to the ESRD PPS base rate to calculate each patient's case-mix adjusted payment per treatment. The two-equation approach used to

develop the ESRD PPS included a facility-based regression model for services historically paid for under the composite rate as indicated in ESRD facility cost reports, and a patient month-level regression model for services historically billed separately. One significant limitation, which in large part drove the development of the two-equation model, was that there was no way to reliably identify, using claims data, the costs for composite rate services—that is, items and services such as staff labor, dialysate, capital-related assets such as renal dialysis machines, and certain drugs and laboratory tests that are used in the provision of outpatient maintenance dialysis for the treatment of ESRD and that were included in the composite payment system established under section 1881(b)(7) of the Social Security Act and the basic case-mix adjusted composite payment system established under section 1881(b)(12) of the Act.

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 renal 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 improving 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. This option was adopted in the CY 2024 final rule (88 FR 76397 through 76409), effective January 1, 2025, and codified at 42 CFR 413.198(b)(5)(i). We provided additional guidance in MLN Matters article number: MM13445, published on November 22, 2023.

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 pump 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 stoppages, 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 based on 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 factors related to social determinants of health. 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.

2. Discarded Drug reporting

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 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 the 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.

The Fiscal Intermediary Shared System (FISS) will edit ESRD facility claims for the presence of certain Healthcare Common Procedure Coding System (HCPCS) codes for which either the JW or JZ modifier must be reported. The HCPCS codes that are 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, and which are subject to this edit, are outlined in Attachment 1.

The list in Attachment 1 is not an exhaustive list of the renal dialysis drugs and biological products subject to the JW and JZ reporting requirement under the ESRD Prospective Payment System (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 provided in a single-dose container or single-use packaging. For public awareness, Attachment 2 provides a list of HCPCS codes that include National Drug Codes (NDCs) for renal dialysis drugs and biological products distributed in multi-dose containers as well as single-dose containers or single-use packaging. These HCPCS codes are not subject to editing in FISS but may represent a renal dialysis drug or biological product subject to the ESRD PPS reporting requirement for the JW and JZ modifiers. This reporting requirement is discussed in further detail in the following paragraphs.

As we discussed in the CY2024 ESRD PPS final rule, 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 Social Security 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. 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 the 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. In addition, renal dialysis drugs and biological products that receive the Transitional Drug Add-on Payment Adjustment (TDAPA) that are distributed in single-dose containers or single use packaging must be billed using the JW and JZ modifiers as applicable. Most recently, the May 9, 2024, change request that established the TDAPA for DefenCath (taurolidine and heparin sodium), instructs facilities to use the JW modifier to report the amount of taurolidine and heparin sodium that is discarded and eligible for payment under the ESRD PPS, and to use the JZ modifier (zero drug amount discarded/not administered to any patient) on the 72x claim to report when there is no discarded amount of taurolidine and heparin sodium.

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 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 (88 FR 76382). 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, we finalized a new policy to require the use of the JW or JZ modifier on claims to track discarded amounts of single-dose container and single-use package renal dialysis drugs and biological products paid for under the ESRD PPS, effective January 1, 2025. 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 (88 FR 76385). 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 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.
 2. 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:

1. HCPCS code for drug administered
2. No modifier
3. Number of billing units administered to the patient
4. Calculated submitted price for ONLY the amount of drug administered

Claim line #2:

1. HCPCS code for drug discarded
2. JW modifier to indicate discarded amount

3. Number of billing units discarded
4. Calculated submitted price for ONLY the amount of drug discarded

For example, if ESRD facility staff administers 7mL of taurolidine and heparin sodium to a patient, the most efficient way to administer this dose is with one 5mL single-dose vial and two thirds of a 3mL single-dose vial. This would be reported on claim line #1 with 70 billing units for the amount of the drug administered. Neither the JW nor the JZ modifier is reported on claim line #1. Claim line #2 would report 10 billing units for the amount of the drug discarded and would include the JW modifier.

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 claims for renal dialysis drugs and biological products from single-dose containers or packages where there are no discarded amounts.

Claim line #1:

1. HCPCS code for drug administered
2. JZ modifier to indicate no discarded amount
3. Number of billing units administered to the patient
4. 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 JZ modifier because there is no discarded amount. Likewise, metoclopramide 5 milligrams (mg) would be identified on one line as being given to the patient. Because the billing unit is 10mg, 5mg is reported as 1 billing unit with the JZ modifier.

3. Payment for Acute Kidney Injury (AKI) home dialysis

As discussed in Section III.B of the CY 2025 ESRD PPS final rule, CMS has carefully reviewed the totality of the information and evidence presented to the agency regarding AKI dialysis at home, and now recognizes that current information regarding beneficiaries with AKI dialyzing in a home setting supports more frequent dialysis at a lower ultrafiltration rate. The ability to dialyze at a lower ultrafiltration rate supports a decrease in hemodynamic fluctuation and the complications associated with it, which in turn support recovery of kidney function.

CMS will make Medicare payment for AKI dialysis treatments furnished at home, beginning January 1, 2025. AKI home dialysis will be paid at the same rate as in-center AKI dialysis treatments. ESRD facilities billing for AKI dialysis treatments will be required to include both condition codes 74 and 84 on home AKI dialysis claims.

In addition, CMS will permit ESRD facilities to bill Medicare for the home and self-dialysis training add-on payment adjustment for beneficiaries with AKI. ESRD facilities billing for training or re-training for AKI home and self-dialysis will be required to include condition code 84 as well as either 73 or 87 as appropriate.

When billing for Continuous Ambulatory Peritoneal Dialysis (CAPD) or Continuous Cycling Peritoneal Dialysis (CCPD) in the home setting for AKI patients, payment will be made at the daily rate based on hemodialysis-equivalent treatments.

4. Changes to Low Volume Payment Adjustment (LVPA) Policy

Beginning in CY 2025, CMS will establish two (2) tiers for LVPA payment based on treatment volume with different payment adjustments for each tier. An ESRD facility that meets all the existing LVPA

criteria at § 413.232(b) will receive a 28.4 percent adjustment if it furnishes fewer than 3,000 treatments per year and will receive an 18.1 percent adjustment if it furnishes between 3,000 and 3,999 treatments per year. A facility's annual treatment count will be based on the median treatment volume over its most recent prior three (3) cost reporting years. Additional instructions for MACs to apply the appropriate tier to an ESRD facility will be provided in the ESRD PPS Annual Update CR.

Effective January 1, 2025, as a result of these policy changes to the LVPA, the outpatient provider specific file (OPSF) field that indicates an ESRD facility's low-volume status must change to alphanumeric and must accept a range of values that indicate whether the facility is low-volume and the tier to which it is assigned.

5. Changes to the Scope of Renal Dialysis Drugs and Biological Products Considered ESRD Outlier Services

Effective January 1, 2025, CMS is revising the definition of ESRD Outlier Services to include renal dialysis drugs and biological products that are Composite Rate Services as defined at § 413.171. Current regulations at § 413.171 define Composite Rate Services 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 were or would have been included in the composite rate prior to the establishment of the ESRD PPS. We note that this expands outlier eligibility to longstanding renal dialysis drugs and biological products that were historically included in the composite rate, as well as newer drugs and biological products that are currently included in the calculation of the post-TDAPA add-on payment adjustment. Additional information about changes to the calculation of the predicted Medicare Allowable Payment (MAP) amount, which will be performed in Pricer, will be provided in the ESRD PPS Annual Update CR.

As discussed in Section II.B.3 of the CY 2025 ESRD PPS final rule, this expansion of 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.

Beginning January 1, 2025, all renal dialysis drugs and biological products reported on ESRD facility claims shall be considered for the ESRD PPS outlier adjustment, with the following exceptions:

1. Drugs and biological products reported with the AY modifier, indicating that they were not provided for the treatment of ESRD, and
2. Drugs and biological products reported with the AX modifier, for which payment is made under the TDAPA.

CMS will provide contractors Average Sale Price (ASP) on a quarterly basis for HCPCS codes that describe injectable ESRD outlier service drugs and biological products, including any such drugs and biological products that are Composite Rate Services. CMS will provide pricing information for NDCs on a semi-annual basis for oral drugs that are ESRD Outlier Services.

III. 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	CFW	
13686.1	<p>The contractor shall revise reason code requiring time on machine (36205) as follows:</p> <ul style="list-style-type: none"> • Effective for ESRD in-facility hemodialysis claims with dates of service on or after January 1, 2025. • Applicable to TOB 72X when billing for revenue code 821 with one of the following condition codes 59, 71, 72, 73, 76, 87. <p>Note: This reason code does not apply to AKI claims with condition code 84, but AKI claims may report value code D6 for time on machine.</p>					X				
13686.2	<p>The contractor shall revise reason code requiring only one ESRD condition code (36104) to allow AKI claims with condition code 84 to also report for at home treatments (condition code 74) and training treatments with condition codes 73 or 87 to be on the same claim with dates of service on or after January 1, 2025.</p>					X				
13686.2.1	<p>The contractor shall process AKI claims with condition code 84 when one of the following condition codes are present 73, 74 or 87.</p> <p>Note: All AKI payment rules remain the same with the exception of allowing it in the home and to receive the training add-on payments when applicable. The Pricer will calculate the training add-on and daily per diem</p>					X				ESRD Pricer

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CFW	
	rate when applicable.									
13686.2.2	<p>When both condition code 84 and one of the following condition codes 73, 74, or 87 are present on the same claim, the contractor shall send both condition codes to the ESRD Pricer.</p> <p>See Attachment 3 for API Contract details.</p>					X			ESRD Pricer	
13686.3	<p>The contractor shall revise the OPSF field 57 (field must be alpha/numeric)</p> <p>File Position 57 X(1) Special Locality Indicator</p> <p>Indicates the type of special locality provision that applies.</p> <p>For End Stage Renal Disease (ESRD) facilities:</p> <p>Dates of service prior to Jan 1, 2025:</p> <p>Value “Y” equals low volume adjustment applicable</p> <p>Dates of service on or after Jan 1, 2025:</p> <p>Value blank = No LVPA</p> <p>Value 1, 2 = equals tier for low volume adjustment applicable</p> <p>Note: A/B MACs Part A will be provided additional instructions for applying the appropriate tier in the ESRD PPS Annual Update CR.</p>					X			ESRD Pricer	
13686.3.1	The contractor shall send the tier value in the OPSF field 57 when applicable to the					X			ESRD Pricer	

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CFW	
	ESRD Pricer.									
13686.3.2	The contractor shall remove the tier indicator when refreshing the OPSF for the start of the new calendar year.	X				X				
13686.4	The contractor shall apply all drugs on the ESRD claim to be applied to the value code 79 for outlier consideration except for drugs reporting the AY modifier or those receiving the TDAPA add-on. Note: Once the drug is removed from TDAPA, FISS shall apply it to outlier. AKI condition code 84 remains excluded from outlier.					X				
13686.4.1	The contractor shall apply the ASP rate for outlier with the exception of oral renal dialysis drugs.					X				
13686.4.2	The contractor shall apply the rate provided by CMS on future recurring updates for the oral renal dialysis drugs to the value code 79 for outlier.					X				
13686.5	The contractor shall create an overridable edit for ESRD PPS claims Type of Bill (TOB) 72X), received with dates of service on or after January 1, 2025, with the following criteria: The claim is reporting a line item with a HCPCS code for a drug shown on attachment 1 and the drug code line does not include the JZ modifier in any of the modifier fields and there is not another					X				

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CFW	
	<p>matching drug code line item with same HCPCS and date of service reporting the JW modifier in any of the modifier fields.</p> <p>This edit shall not apply to Acute Kidney Injury (AKI) claims (bypass 72X type of bill with condition code 84).</p> <p>Note: All ESRD claim lines submitted with a drug from attachment 1 without a JZ modifier appended, must have a subsequent claim line with a JW modifier present.</p>									
13686.5.1	The contractor shall return the claim to the provider (RTP) when the edit associated with requirement 5 above is applicable to the claim.	X								
13686.6	The contractor shall revise as necessary, the documentation to perform the following tasks with recurring change requests Rxxx05A and Rxxx59Q to make necessary updates to the list of drugs and the edit associated with requirement 5 above and add them in the estimates attachment section of eChimp.					X				
13686.7	The contractor shall be aware of the revisions to IOM Pub. 100-04, Chapter 4 - Part B Hospital (Including Inpatient Hospital Part B and OPPS) and Chapter 8 - Outpatient ESRD Hospital, Independent Facility, and Physician/Supplier Claims contained in this CR.	X								
13686.8	The contractors shall be aware that attachment 2 is	X				X				

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	informational only for provider awareness.									

IV. PROVIDER EDUCATION

Medicare Learning Network® (MLN): CMS will develop and release national provider education content and market it through the MLN Connects® newsletter shortly after we issue the CR. MACs shall link to relevant information on your website and follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1 for distributing the newsletter to providers. When you follow this manual section, you don't need to separately track and report MLN content releases. You may supplement with your local educational content after we release the newsletter.

Impacted Contractors: A/B MAC Part A

V. 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

VI. CONTACTS

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

VII. 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: 3

Attachment 1 - 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, CEFTRIAZONE 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)
J0911	Instillation, taurididine 1.35 mg and heparin sodium 100 units (central venous catheter lock for adult patients receiving chronic hemodialysis)
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 2- 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

Attachment 3: API Contract

```
@ArraySchema(  
    arraySchema =  
        @Schema(  
            description = "The condition codes related to the claim.",  
            example = "[\"84\" + \"73\" + \"n\"]",  
            uniqueItems = true)  
        @Size(max = 2, min = 1)  
    private List<@Pattern(regexp = "\\d{2}", message = "must be two digits") String> conditionCodes;
```


Medicare Claims Processing Manual
Chapter 4 - Part B Hospital
(Including Inpatient Hospital Part B and OPPS)

Table of Contents
(Rev. 12957; Issued: 11-08-24)

50.1 - Outpatient Provider Specific File

(Rev. 12957; Issued: 11-08-24; Effective:01-01-25; Implementation: 01-06-25)

The Outpatient Provider Specific File (OPSF) contains the required information about each provider to enable the pricing software to calculate the payment amount. Data elements and formats are shown below. Contractors must maintain the accuracy of the data, and update the file as changes occur in data element values, e.g., changes in metropolitan statistical area (MSA), bed size, cost to charge ratio. An update is accomplished by preparing and adding an additional complete record showing new current values and the effective date of the change. The old record is retained without change.

Contractors must also furnish CMS a quarterly file in the same format.

NOTE: All data elements, whether required or optional, must have a default value of “0” (zero) if numerical, or blank if alphanumeric.

File Position	Format	Title	Description
1-10	X(10)	National Provider Identifier (NPI)	Alpha-numeric 10 character provider number.
11-16	X(6)	Provider Oscar Number	Alpha-numeric 6 character provider number.
17-24	9(8)	Effective Date	Must be numeric, CCYYMMDD. This is the effective date of the provider's first OPSP period. For subsequent OPSP periods, the effective date is the date of a change to the PROV file. If a termination date is present for this record, the effective date must be equal to or less than the termination date.
25-32	9(8)	Fiscal Year Beginning Date	Must be numeric, CCYYMMDD. Month: 01-12 Day: 01-31 The date must be greater than 19990630.
33-40	9(8)	Report Date	Must be numeric, CCYYMMDD. Month: 01-12 Day: 01-31 The created/run date of the PROV report for submittal to CO.
41-48	9(8)	Termination Date	Must be numeric, CCYYMMDD. Must be zeroes or contain a termination date. (Once the official “tie-out” notice from CMS is received). Must be equal to or greater than the effective date. (Termination date is the date on which the reporting contractor ceased servicing the provider in question).

49	X(1)	Waiver Indicator	<p>Enter a "Y" or "N."</p> <p>Y = waived (provider is not under OPPS) For End Stage Renal Disease (ESRD) facilities provider waived blended payment, pay full PPS.</p> <p>N = not waived (provider is under OPPS) For ESRD facilities provider did not waive blended payment. Pay according to transitional payment method for ESRD PPS through 2013.</p>
50-54	9(5)	Intermediary Number	Enter the Contractor #.
55-56	X(2)	Provider Type	<p>This identifies providers that require special handling. Enter one of the following codes as appropriate.</p> <p>00 or blanks = Short Term Facility 02 Long Term 03 Psychiatric 04 Rehabilitation Facility 05 Pediatric 06 Reserved 07 Rural Referral Center 08 Indian Health Service 13 Cancer Facility 14 Medicare Dependent Hospital (during cost reporting periods that began on or after April 1, 1990. 15 Medicare Dependent Hospital/Referral Center (during cost reporting periods that began on or after April 1, 1990. Invalid October 1, 1994 through September 30, 1997). 16 Re-based Sole Community Hospital 17 Re-based Sole Community Hospital /Referral Center 18 Medical Assistance Facility 21 Essential Access Community Hospital 22 Essential Access Community Hospital/Referral Center 23 Rural Primary Care Hospital 24 Rural Emergency Hospitals 32 Nursing Home Case Mix Quality Demonstration Project – Phase II 33 Nursing Home Case Mix Quality Demonstration Project – Phase III – Step 1 34 Free-standing Opioid Treatment Program 35 Hospice 36 Home Health Agency 37 Critical Access Hospital</p>

			<p>38 Skilled Nursing Facility (SNF) – For non-demo PPS SNFs – effective for cost reporting periods beginning on or after July 1, 1998</p> <p>40 Hospital Based ESRD Facility</p> <p>41 Independent ESRD Facility</p> <p>42 Federally Qualified Health Centers</p> <p>43 Religious Non-Medical Health Care Institutions</p> <p>44 Rural Health Clinics-Free Standing</p> <p>45 Rural Health Clinics-Provider Based</p> <p>46 Comprehensive Outpatient Rehab Facilities</p> <p>47 Community Mental Health Centers</p> <p>48 Outpatient Physical Therapy Services</p> <p>49 Psychiatric Distinct Part</p> <p>50 Rehabilitation Distinct Part</p> <p>51 Short-Term Hospital – Swing Bed</p> <p>52 Long-Term Care Hospital – Swing Bed</p> <p>53 Rehabilitation Facility – Swing Bed</p> <p>54 Critical Access Hospital – Swing Bed</p>
57	X(1)	Special Locality Indicator	<p>Indicates the type of special locality provision that applies.</p> <p>For End Stage Renal Disease (ESRD) facilities: Dates of service prior to Jan 1, 2025: value “Y” equals low volume adjustment applicable. Dates of service on or after Jan 1, 2025: <i>Value blank = No low volume adjustment applicable</i> <i>Value 1 or 2 = tier number applicable for low volume adjustment</i></p>
58	X(1)	Change Code For Wage Index Reclassification	<p>Enter “Y” if the hospital’s wage index location has been reclassified for the year. Enter “N” if it has not been reclassified for the year. Adjust annually. Does not apply to ESRD Facilities.</p>
59-62	X(4)	Actual Geographic Location—MSA	<p>Enter the appropriate code for MSA, 0040–9965, or the rural area, <u>(blank)(blank)</u> 2-digit numeric State code, such as <u> 36</u> for Ohio, where the facility is physically located.</p>
63-66	X(4)	Wage Index Location—MSA	<p>The appropriate code for the MSA, 0040–9965, or the rural area, <u>(blank)(blank)</u> (2 digit numeric State code) such as <u> 36</u> for Ohio, to which a hospital has been reclassified for wage index. Leave blank or enter the actual location MSA if not reclassified. Does not apply to ESRD Facilities.</p>
67-70	9V9(3)	Payment-to-Cost Ratio	<p>Enter the provider’s payment-to-cost ratio. Does not apply to ESRD Facilities.</p>

71-72	9(2)	State Code	<p>Enter the 2-digit state where the provider is located. Enter only the first (lowest) code for a given state. For example, effective October 1, 2005, Florida has the following State Codes: 10, 68 and 69. Contractors shall enter a "10" for Florida's State Code.</p> <p>List of valid State Codes is located in Pub. 10007, Chapter 2, Section 2779A1.</p>
73	X(1)	TOPs Indicator	<p>Enter the code to indicate whether TOPs applies or not.</p> <p>Y = qualifies for TOPs N = does not qualify for TOPs</p>
74	X(1)	Quality Indicator Field	<p>Hospital: Enter the code to indicate whether the hospital meets data submission criteria per HOP QDRP requirements.</p> <p>1 = Hospital quality reporting standards have been met or hospital is not required to submit quality data (e.g., hospitals that are specifically excluded from the IPPS or which are not paid under the OPPS, including psychiatric, rehabilitation, long-term care and children's and cancer hospitals, Maryland hospitals, Indian Health Service hospitals, or hospital units; or hospitals that are located in Puerto Rico or the U.S. territories). The reduction does not apply to hospices, CORFs, HHAs, CMHCs, critical access hospitals or to any other provider type that is not a hospital.</p> <p>Blank = Hospital does not meet criteria.</p> <p>Independent and Hospital-based End Stage Renal Disease (ESRD)Facilities: Enter the code applicable to the ESRD Quality Incentive Program (QIP):</p> <p>Blank = no reduction 1 = ½ percent payment reduction 2 = 1 percent payment reduction 3 = 1 ½ percent payment reduction 4 = 2 percent payment reduction</p> <p>* Please refer to file position 101 for ESRD Children's Hospitals Quality Indicator.</p>
75	X(1)	Filler	Blank.

76-79	9V9(3)	Outpatient Cost-to-Charge Ratio	<p>Derived from the latest available cost report data. See §10.11 of this chapter for instructions on how to calculate and report the Cost-to-Charge Ratio.</p> <p>Does not apply to ESRD Facilities.</p>
80-84	X(5)	Actual Geographic Location CBSA	00001-89999, or the rural area, (blank) (blank) (blank) 2 digit numeric State code such as ___ <u>3</u> <u>6</u> for Ohio, where the facility is physically located.
85-89	X(5)	Wage Index Location CBSA	Enter the appropriate code for the CBSA, 0000189999, or the rural area, (blank)(blank)(blank) (2 digit numeric State code) such as ___ <u>3</u> <u>6</u> for Ohio, to which a hospital has been reclassified due to its prevailing wage rates. Leave blank or enter the Actual Geographic Location CBSA, if not reclassified. Pricer will automatically default to the actual location CBSA if this field is left blank. Does not apply to ESRD Facilities.
90-95	9(2) V9(4)	Special Wage Index	Enter the special wage index that certain providers may be assigned. Enter zeroes unless the Special Payment Indicator equals a "1" or "2."
96	X(1)	Special Payment Indicator	<p>The following codes indicate the type of special payment provision that applies.</p> <p>Blank = not applicable Y = reclassified 1 = special wage index indicator 2 = both special wage index indicator and reclassified D = Dual Reclassified</p>
97-100	9(4)	Reduced Coinsurance Trailer Count	Enter the number of APCs the provider has elected to reduce coinsurance for. The number cannot be greater than 999.
101	X(1)	Quality Indicator ESRD Children's Hospitals	<p>Children's Hospitals for End Stage Renal Disease (ESRD) Facilities: Enter the code applicable to the ESRD Quality Incentive Program (QIP):</p> <p>Blank = no reduction 1 = ½ percent payment reduction 2 = 1 percent payment reduction 3 = 1 ½ percent payment reduction 4 = 2 percent payment reduction</p>

102-105	9V9(3)	Device department's Cost-to-Charge Ratio	Derived from the latest available cost report data. Does not apply to ESRD Facilities.
106-112	X(7)	Carrier/Locality code	The carrier/locality code for the provider service facility. The first five positions represent the carrier code and the last two positions represent the locality code.
113-117	9(5)	County Code	Enter the County Code. Must be 5 numbers.
118-122	X(5)	Payment CBSA	Enter the appropriate code for the CBSA, 0000189999, or the rural area, (blank)(blank)(blank) (2 digit numeric State code) such as __ _ <u>3</u> 6 for Ohio, to which a hospital has been reclassified due to its prevailing wage rates. Leave blank or enter the Actual Geographic Location CBSA, if not reclassified. Pricer will automatically default to the actual location CBSA if this field is left blank. Does not apply to ESRD Facilities.
123-128	9V9(5)	Payment Model Adjustment (PMA)	Derived from payment model Technical Direction Letter.
129-133	9V9999	Medicare Performance Adjustment (MPA)	Enter the MPA percentage calculated and published by the Centers for Medicare & Medicaid Services (CMS).
134-139	9(2) V9(4)	Supplemental Wage Index	Enter the supplemental wage index that certain providers may be assigned. Enter zeroes if it does not apply.
140-140	X(1)	Supplemental Wage Index Flag	Enter the supplemental wage index flag: 1=Prior Year Wage Index 2=Future use 3=Future use Enter blank if it does not apply.
141-162	X(22)	FILLER	

The contractor enters the number of APCs for which the provider has elected to reduce coinsurance. Cannot be greater than 999. Reduced Coinsurance Trailer Record - Occurs 0-999 times depending on the reduced Coinsurance Trailer Count in positions 97-100. Due to system's capacity limitations the maximum number of reduced coinsurance trailers allowable is 999 at this time.

Medicare Claims Processing Manual

Chapter 8 - Outpatient ESRD Hospital, Independent Facility, and Physician/Supplier Claims

(Rev. 12957; Issued: 11-08-24)

20 - End Stage Renal Disease Prospective Payment System (ESRD PPS) Per Treatment Payment Amount

(Rev. 12957; Issued: 11-08-24; Effective:01-01-25; Implementation: 01-06-25)

A case mix methodology adjusts the Prospective Payment System (PPS) base rate based on a limited number of patient characteristics. Variables for which adjustments will be applied to the PPS base rate include age, body surface area (BSA), and low body mass index (BMI). These variables are determined in the ESRD PRICER to calculate the End Stage Renal Disease Prospective Payment System (ESRD PPS per treatment payment amount (including all other adjustments).

The following table contains claim data required to calculate the ESRD PPS per treatment payment amount.

Form CMS-1450	ASC X12 837 institutional claim
Through Date	2300 DTP segment 434 qualifier
Date of Birth	2010BA DMG02
Condition Codes (73, 74, 87)	2300 HI segment BG qualifier
Value Codes (A8 and A9) / Amounts	2300 HI segment BE qualifier
Revenue Code (0821, 0831, 0841, 0851, 0880, or 0881)	2400 SV201

For claims with dates of service on or after January 1, 2011, Medicare systems must pass the line item date of service dialysis revenue code lines when the onset of dialysis adjustment is applicable to one or more of the dialysis sessions reported on the claim.

Form CMS-1450	ASC X12 837 institutional claim
Line Item Date of Service for Revenue Code (0821, 0831, 0841, 0851)	2400 DTP Segment D8 qualifier

In addition to the above claim data, the following payer only codes are required on claims with dates of service on or after January 1, 2011 to calculate the ESRD PPS per treatment payment amount:

Form CMS-1450	Payer Only Format
Payer Only Condition Codes (MA, MB, MC, MD, ME, MF) (Identifies comorbid conditions for adjustments)	X(2)
Payer Only Value Code (79) (Identifies dollar amount for services applicable for the calculation for determining outlier)	<ul style="list-style-type: none"> X(2) V(9)
Payer Only Value Code (Q8) (Identifies dollar amount for services applicable for the calculation of the transitional drug add-on payment)	<ul style="list-style-type: none"> X(2) V(9)

Form CMS-1450	Payer Only Format
Payer Only Value Code (QG) (Identifies dollar amount for services applicable for the calculation of the transitional payment for new innovative equipment and supplies)	<ul style="list-style-type: none"> • X(2) V(9)
<i>Payer Only Value Code (QH) (Identifies dollar amount for services applicable for the calculation of the transitional payment for capital related assets for new innovative equipment)</i>	<ul style="list-style-type: none"> • X(2) V(9) •

Note: The payer only codes above are assigned by the Medicare standard systems and are not submitted on the claim by the provider.

The following provider data must also be passed to the ESRD PRICER to make provider-specific calculations that determine the ESRD PPS per treatment payment amount:

Field	Format
Actual Geographic Location MSA	X(4)
Actual Geographic Location CBSA	X(5)
Special Wage Index	9(2)V9(4)
Supplemental Wage Index	9(2)V9(4)
Provider Type	X(2)
Special Payment Indicator	X(1)

In addition to the above provider data, the following is required to calculate the final ESRD PPS rate effective January 1, 2011:

Field	Format
Blended Payment Indicator	X(1)
Low-Volume Indicator	X (1)

Effective January 1, 2012 the following is required to calculate the Quality Incentive Program adjustment for ESRD facilities:

Field	Format
Quality Indicator Field	X(1)

Based on the claim and provider data shown above, the ESRD PRICER makes adjustments to the PPS base rate to determine the ESRD PPS per treatment payment amount. The following factors are used to adjust and make calculations to the ESRD PPS per treatment payment amount.

- Provider Type
- Drug add-on
- Budget Neutrality Factor
- Patient Age
- Patient Height
- Patient Weight
- Patient BSA
- Patient BMI
- BSA factor
- BMI factor
- Condition Code 73 adjustment (if applicable)
- Condition Code 74 adjustment (if applicable)
- Condition Code 84 for AKI patients (if applicable)
- Condition Code 87 adjustment (if applicable)

In addition to the above adjustments, the following adjustments may be applicable to the ESRD PPS base rate for **adult** patient claims with dates of service on or after January 1, 2011:

- Onset of Dialysis
- Patient Comorbidities
- Low-Volume ESRD Facility

Onset of Dialysis:

Providers will receive an adjustment to the ESRD PPS base rate for patients within the initial 120 calendar days from when an ESRD beneficiary began their maintenance dialysis. The provider does not report anything on the claim for this adjustment. The adjustment is determined by the start date of dialysis in the Common Working File as reported on the patient's 2728 form. When the onset of dialysis adjustment is provided, the claim is not entitled to a comorbidity adjustment or a training add-on adjustment.

Patient Comorbidities:

The ESRD PPS will provide adjustments for each category of chronic and acute comorbidity conditions, 3 categories of chronic conditions and 3 categories of acute conditions. **In the event that more than one of the comorbidity categories is present on the claim, the claim will be adjusted for the highest paying comorbidity category.**

Chronic Comorbidities

When chronic comorbidity codes are reported on the claim an adjustment may be made for as long as the chronic condition remains applicable to the patient care provided and is reported on the claim.

Acute Comorbidities

Acute comorbidity category adjustments will be eligible for a payment for the first month reported and then for the next three consecutive months, regardless of whether or not the diagnosis code is on the claim after the first month. This adjustment applies for no more than four consecutive months for any reported acute comorbidity category. Acute comorbidity conditions reported for more than four consecutive months will not receive additional payment.

In the event that the comorbidity condition was resolved and later reoccurred, the provider may submit a condition code to indicate the diagnosis is a recurrence. The adjustment will be applicable for an additional four months.

For a list of specific acute and chronic comorbid conditions eligible for adjustment, refer to the following website:

<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Patient-Level-Adjustments>

This list may be updated as often as quarterly in January, April, July and October of each year.

Low-Volume ESRD Facilities:

ESRD facilities will receive an adjustment to their ESRD PPS base rate when the facility furnished less than 4,000 treatments in each of the three cost report years preceding the payment year and has not open, closed, or received a new provider number due to a change in ownership during the 3 years preceding the payment year. The ESRD facility must notify their A/B MAC (A) if they believe they are eligible for the low-volume adjustment. The A/B MAC (A) must validate the eligibility and update the provider specific file *according to the ESRD facility's low-volume payment tier*. Pediatric patient claims are not eligible for the low-volume adjustment.

A/B MACs (A) are instructed to validate the facility's eligibility for the low volume adjustment. If an A/B MAC (A) determines that an ESRD facility has received the low volume adjustment in error, the A/B MAC (A) is required to adjust all of the ESRD facility's affected claims to remove the adjustment within 6 months of finding the error.

In addition to the above adjustments, the following adjustments may be applicable to the ESRD PPS base rate for **adult and pediatric** patient claims with dates of service on or after January 1, 2011:

Training Adjustment: The ESRD PPS provides a training add-on of \$33.44 adjusted by the *ESRD PPS* wage index that accounts for an hour of nursing time for training treatments. The add-on applies to both PD and HD training treatments.

ESRD PPS Outlier Payments:

The ESRD Prospective Payment System (PPS) includes a payment adjustment for high cost outliers when there are unusual variations in the type or amount of medically necessary care.

Outlier consideration is provided for the following:

- ESRD-related drugs and biologicals that were or would have been prior to January 1, 2011, *either included under the case-mix adjusted composite payment system or* separately billable under Medicare Part B;
- ESRD-related laboratory tests that were or would have been, prior to January 1, 2011 separately billable under Part B;
- Medical/surgical supplies, including syringes, used to administer ESRD-related drugs that were or would have been prior to January 1, 2011, separately billable under Medicare Part B; and
- Renal dialysis service drugs that were or would have been, prior to January 1, 2011 covered under Medicare Part D.
- For new injectable renal dialysis drugs and biologicals that are eligible outlier services, ESRD facilities should report J3591 with the National Drug Code (NDC) in the 11-digit format 5-4-2. The MAC will set the payment rate based on pricing methodologies under 1847A of the Act using the guidance in the Medicare Claims Processing Manual, Chapter 17 - Drugs and Biologicals, Section 20.1.3 - Exceptions to Average Sales Price (ASP) Payment Methodology.

Statute requires the delay of the implementation of the oral-only renal dialysis service policy until January 1, 2025. Services not included in the PPS that remain separately payable are not considered outlier services.

When the ESRD PRICER returns an outlier payment, the standard systems shall display the total applicable outlier payment on the claim with value code 17.

Information related to the outlier services eligible for adjustment can be found at the following website:

http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Outlier_Services.html

This list may be updated as often as quarterly in January, April, July and October of each year.

For claims submitted with dates of service on or after January 1, 2012, all drugs reported on the ESRD claim under revenue codes 0634, 0635 and 0636 with a rate available on the ASP file will be considered in the Medicare allowed payment (MAP) amount for outlier consideration with the exception of any drugs reported with the AY modifier and drugs included in the original composite rate payment system.

Transitional Drug Add-On Payment Adjustment (TDAPA)

Effective January 1, 2016 under the ESRD PPS drug designation process, CMS provides payment using a Transitional Drug Add-on Payment Adjustment (TDAPA) for new renal dialysis new injectable or intravenous drugs and biologicals that qualify under 42 CFR 413.234(c)(1).

CMS will pay for the drug or biological using a transitional drug add-on payment adjustment, if the new injectable or intravenous drug or biological is used to treat or manage a condition for which there is not an existing ESRD PPS functional category. CMS bases the TDAPA on payment methodologies under section 1847A of the Social Security Act which are discussed in Pub. 100-04, Chapter 17, Section 20. The MAC will set the payment rate based on pricing methodologies under 1847A of the Act using the guidance in the Medicare Claims Processing Manual, Chapter 17 - Drugs and Biologicals, Section 20.1.3 - Exceptions to Average Sales Price (ASP) Payment Methodology. This payment is applicable for a period of 2 years. While the TDAPA applies to a new injectable or intravenous drug or biological, the drug or biological is not considered an outlier service, is not separately payable with the AY modifier and does not apply to acute kidney injury claims (AKI).

Drugs eligible for the TDAPA must be billed with revenue code 0636 and modifier AX must be appended to the HCPCS.

- The TDAPA claim lines are shown as covered line items but no payment will be included on the line item. The TDAPA is included in the prospective payment amount on the dialysis revenue code lines.
- Q8 payer only value code captures the total allowable payment for the TDAPA. The ESRD pricer divides the Q8 amount by the total number of dialysis treatments and the per treatment amount is added to PPS rate and included in each dialysis line payment.

Additional information on the TDAPA is available on the CMS website located at:

<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/ESRD-Transitional-Drug>

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

Beginning January 1, 2020, the ESRD PPS provides the Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) for new and innovative renal dialysis equipment and supplies that qualify under § 413.236.

The TPNIES payment is based on 65 percent of the Medicare Administrative Contractor (MAC) determined price. The MACs, on behalf of CMS, establish prices for new and innovative renal dialysis equipment and supplies that meet the TPNIES eligibility criteria using verifiable information from the following sources of information, 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.

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.

Items eligible for the TPNIES must be billed with revenue code 027X and modifier AX must be appended to the HCPCS. Until TPNIES items receive a HCPCS the TPNIES supplies are reported with HCPCS A4913 for miscellaneous dialysis supply not otherwise specified and for TPNIES equipment HCPCS E1699 is reported for miscellaneous dialysis equipment not otherwise specified.

- The TPNIES claim lines are shown as covered line items but no payment will be included on the line item. The TPNIES is included in the prospective payment amount on the dialysis revenue code lines.
- QG payer only value code captures the total allowable price for the TPNIES. The ESRD pricer calculates the 65 percent of the MAC determined price and divides the amount by the total number of dialysis treatments and the per treatment amount is added to PPS rate and included in each dialysis line payment.

Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) for Capital Related Assets (CRA)

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. For CRA for TPNIES only, CMS includes an offset adjustment to offset the costs already paid for dialysis machines in the ESRD PPS bundle. Effective January 1, 2022, CMS annually updates the offset adjustment amount by the ESRD bundled market basket percentage increase factor minus the productivity adjustment factor. The payment for CRA for TPNIES is based on 65 percent of the MAC determined price (see below), reduced by the offset adjustment amount described in the prior sentences.

The MACs, on behalf of CMS, establish prices for new and innovative renal dialysis equipment and supplies, including certain CRA that are home dialysis machines, that meet the TPNIES eligibility criteria using verifiable information from the following sources of information, 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.*

The TPNIES for CRA is paid for 2 calendar years, beginning on January 1 of the approval year and ending on December 31 the following year. Following payment of the TPNIES for CRA, 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 § 413.237.

Beginning January 1, 2021, ESRD facilities report the AX modifier (item furnished in conjunction with dialysis services) with the HCPCS code for the CRA that is eligible to receive TPNIES payment for CRA.

The TPNIES for CRA pricing instructions apply when a HCPCS code on the TPNIES CRA list is reported with the AX modifier and one of the following revenue codes:

- 0823, Hemodialysis Home Equipment*
- 0833, Peritoneal Home Equipment*
- 0843, Continuous Ambulatory Peritoneal Dialysis (CAPD) Home Equipment*
- 0853, Continuous Cycling Peritoneal Dialysis (CCPD) Home Equipment*
- 0889, Other Miscellaneous Dialysis (to be used for ultrafiltration home equipment).*

For CRAs that are home dialysis machines used in the home for a single patient, the MACs shall divide the annual allowance by the expected number of treatments to calculate the annual allowance and the per treatment amount. The expected number of treatments is always 156 per year. MACs shall assign an amount to value code QH (Total TPNIES CRA amount) which totals the CRA for TPNIES per treatment amount multiplied by the number of treatments on that claim.

The number of dialysis treatments for the month used in the CRA for TPNIES calculation, is limited to the 13 to 14 allowable monthly treatments that are deemed medically necessary. Dialysis treatments exceeding 13 to 14 per month (3 treatments per week) that are determined reasonable and necessary by the Medicare contractors are payable; however, treatments that exceed 13 to 14 per month shall not be considered for separate pricing for CRA for TPNIES. ESRD facilities should not bill separate line items for CRA for TPNIES in excess of 13 to 14 treatments per month. Regardless of the number of treatments given per month, the adjusted CRA for TPNIES per treatment amount will equal the adjusted CRA for TPNIES per treatment amount that is calculated for 13 treatments per month. MACs shall not allow CRA for TPNIES in excess of 156 treatments per calendar year.

Pricer puts a payment at the dialysis line so that it is a per treatment payment. Therefore, Pricer calculates the adjusted per treatment amount that is added to each dialysis line by: 1) dividing QH by the total number of administered dialysis treatments, 2) subtracting the applicable offset amount, and 3) multiplying by 65 percent.

CRA for TPNIES is not applicable to the per treatment payment amount that is paid to ESRD facilities for furnishing dialysis to individuals with Acute Kidney Injury (AKI).

20.1 – Calculation of the Basic Case-Mix Adjusted Composite Rate and the ESRD Prospective Payment System Rate

(Rev. 12957; Issued: 11-08-24; Effective:01-01-25; Implementation: 01-06-25)

A case mix methodology adjusts the composite payment rate based on a limited number of patient characteristics. Variables for which adjustments will be applied to each facility's composite rate include age, body surface area (BSA), and low body mass index (BMI). These variables are determined in the ESRD PRICER to calculate the final composite rate (including all other adjustments).

Effective January 1, 2011 the ESRD PPS replaced the basic case-mix adjusted composite rate payment system. See section 20 for information on the calculation of the ESRD PPS per treatment payment amount.

40 - Acute Kidney Injury (AKI) Claims

(Rev. 12957; Issued: 11-08-24; Effective:01-01-25; Implementation: 01-06-25)

Effective January 1, 2017, ESRD facilities, both hospital based and freestanding are able to furnish dialysis to AKI patients and receive payment under the ESRD PPS.

Medicare will pay ESRD facilities for the dialysis treatment using the ESRD PPS base rate adjusted by the applicable ESRD PPS wage index. In addition to the dialysis treatment, the ESRD PPS base rate pays ESRD facilities for other items and services considered to be renal dialysis services as defined in 42 CFR §413.171.

No separate payment is made for those services considered to be renal dialysis services as payment is included in the ESRD PPS base rate.

Other items and services that are furnished to beneficiaries with AKI that are not considered to be renal dialysis services but are related to their dialysis as a result of their AKI, would be separately payable, this includes drugs, biologicals, laboratory services, and supplies that ESRD facilities are certified to furnish and that would otherwise be furnished to a beneficiary with AKI in a hospital outpatient setting.

AKI claims are billed on the 072X type of bill with condition code 84. ESRD facilities are required to include revenue code 082X, 083x, or 088x for the modality of dialysis furnished with the Current Procedural Terminology (CPT) code G0491 (Dialysis procedure at a Medicare certified ESRD facility for Acute Kidney Injury without ESRD).

Note: AKI claims for dialysis in the home setting effective January 1, 2025 must also include condition code 74.

AKI claims do not receive payment adjustments for comorbidities, TDAPA, TPNIES or outlier. *When applicable, AKI claims receive the home dialysis training add-on payment adjustment (see section 50.8).* The ESRD network reduction is not applicable to AKI claims.

More information on dialysis provided for AKI patients including the required diagnosis codes for billing AKI is available on the CMS website at:

<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/AKI-and-ESRD-Facilities>.

50.2 - Drugs and Biologicals Included in the *End Stage Renal Disease Prospective Payment System* (ESRD PPS)

(Rev. 12957; Issued: 11-08-24; Effective:01-01-25; Implementation: 01-06-25)

With the implementation of the *End Stage Renal Disease Prospective Payment System* (ESRD PPS), effective for claims with dates of service on or after January 1, 2011, all ESRD-related injectable drugs and biologicals and oral equivalents of those injectable drugs and biologicals are included in the ESRD PPS.

If the renal dialysis facility needs to report a drug that was furnished to an ESRD beneficiary that was not related to the treatment of ESRD, they must include the modifier AY to indicate the item or service is not for the treatment of ESRD.

ESRD-related drugs and biologicals that were separately paid under the basic case-mix composite rate payment system, *and those that were included in the case-mix composite rate payment system*, are considered in the calculation of any applicable outlier payment under the ESRD PPS.

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 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.

A list of HCPCS codes that represent renal dialysis drugs and biological products subject to the JW and JZ reporting requirement can be found here: https://www.cms.gov/medicare/medicare-fee-for-service-payment/esrdpayment/consolidated_billing.

50.3 - Required Information for In-Facility Claims Paid Under the *End Stage Renal Disease Prospective Payment System* ESRD PPS

(Rev. 12957; Issued: 11-08-24; Effective:01-01-25; Implementation: 01-06-25)

The term Medicare beneficiary identifier (Mbi) is a general term describing a beneficiary's Medicare identification number. For purposes of this manual, Medicare beneficiary identifier references both the Health Insurance Claim Number (HICN) and the Medicare Beneficiary Identifier (MBI) during the new

Medicare card transition period and after for certain business areas that will continue to use the HICN as part of their processes.

The electronic form required for billing ESRD claims is the ASC X12 837 institutional claim transaction. The paper form, where permissible, is Form CMS-1450.

The coding and related descriptions for the following items are identical for the ASC X12 837 institutional claim format and Form CMS-1450. See the related X12 implementation guide or Chapter 25, respectively, for where the information is reported.

Type of Bill

Acceptable codes for Medicare are:

721 - Admit Through Discharge Claim - This code is used for a bill encompassing an entire course of outpatient treatment for which the provider expects payment from the payer.

722 - Interim - First Claim - This code is used for the first of an expected series of payment bills for the same course of treatment.

723 - Interim - Continuing Claim - This code is used when a payment bill for the same course of treatment is submitted and further bills are expected to be submitted later.

724 - Interim - Last Claim - This code is used for a payment bill which is the last of a series for this course of treatment. The "Through" date of this bill (FL 6) is the discharge date for this course of treatment.

727 - Replacement of Prior Claim - This code is used when the provider wants to correct (other than late charges) a previously submitted bill. The previously submitted bill needs to be resubmitted in its entirety, changing only the items that need correction. This is the code used for the corrected or "new" bill.

728 - Void/Cancel of a Prior Claim - This code indicates this bill is a cancel-only adjustment of an incorrect bill previously submitted. Cancel-only adjustments should be used only in cases of incorrect provider identification numbers, incorrect Medicare beneficiary identifier, duplicate payments and some OIG recoveries. For incorrect provider numbers or Medicare beneficiary identifier, a corrected bill is also submitted using a code 721.

Statement Covers Period (From-Through) - Hospital-based and independent renal dialysis facilities:

The beginning and ending service dates of the period included on this bill. Note: ESRD services are subject to the monthly billing requirements for repetitive services.

Condition Codes

Hospital-based and independent renal facilities complete these items. Note that one of the codes 71-76 is applicable for every bill. Special Program Indicator codes A0-A9 are not required.

Condition Code Structure (only codes affecting Medicare payment/processing are shown).

02 - Condition is Employment Related - Providers enter this code if the patient alleges that the medical condition causing this episode of care is due to environment/events resulting from employment.

04 - Information Only Bill - Providers enter this code to indicate the patient is a member of a Medicare Advantage plan.

59 – Non-Primary ESRD Facility – Providers enter this code to indicate that ESRD beneficiary received non-scheduled or emergency dialysis services at a facility other than his/her primary ESRD dialysis facility.

71 - Full Care in Unit - Providers enter this code to indicate the billing is for a patient who received staff-assisted dialysis services in a hospital or renal dialysis facility.

72 - Self-Care in Unit - Providers enter this code to indicate the billing is for a patient who managed his own dialysis in a hospital or renal dialysis facility.

73 - Self-Care in Training - Providers enter this code to indicate the billing is for special dialysis services where a patient and his/her helper (if necessary) were learning to perform dialysis.

74- Home-Providers enter this code to indicate the billing is for a patient who received dialysis services at home.

76 - Back-up In-facility Dialysis - Providers enter this code to indicate the billing is for a home dialysis patient who received back-up dialysis in a facility.

80- Home Dialysis-Nursing Facility – Home dialysis furnished in a SNF or Nursing Facility (report with condition code 74).

84 – Acute Kidney Injury- Provider enters this code to indicate the claim is for an AKI patient.

87 – Retraining – Provider enters this code to indicate the billing is for retraining of the patient and his/her helper (if necessary) to perform self-care dialysis.

H3 – Reoccurrence of GI Bleed comorbid category

H4 – Reoccurrence of Pneumonia comorbid category

H5 – Reoccurrence of Pericarditis comorbid Category

Occurrence Codes and Dates

Codes(s) and associated date(s) defining specific events(s) relating to this billing period are shown. Event codes are two alpha-numeric digits, and dates are shown as six numeric digits (MM-DD-YY). When occurrence codes 01-04 and 24 are entered, make sure the entry includes the appropriate value code, if there is another payer involved.

Occurrence and occurrence span codes are mutually exclusive. Occurrence codes have values from 01 through 69 and A0 through L9. Occurrence span codes have values from 70 through 99 and M0 through Z9.

24 - Date Insurance Denied - Code indicates the date of receipt of a denial of coverage by a higher priority payer.

33 - First Day of Medicare Coordination Period for ESRD Beneficiaries Covered by an EGHP - Code indicates the first day of the Medicare coordination period during which Medicare benefits are payable under an EGHP. This is required only for ESRD beneficiaries.

51 – Date of last Kt/V reading. For in-center hemodialysis patients, this is the date of the last reading taken during the billing period. For peritoneal dialysis patients and home hemodialysis patients, this date may be before the current billing period but should be within 4 months of the claim date of service.

Occurrence Span Code and Dates

Code(s) and associated beginning and ending dates(s) defining a specific event relating to this billing period are shown. Event codes are two alpha-numeric digits and dates are shown numerically as MM-DD-YY.

74 - Noncovered Level of Care - This code is used for repetitive Part B services to show a period of inpatient hospital care or of outpatient surgery during the billing period. Use of this code will not be necessary for ESRD claims with dates of service on or after April 1, 2007 due to the requirement of ESRD line item billing.

Document Control Number (DCN)

Required for all provider types on adjustment requests. (Bill Type/FL=XX7). All providers requesting an adjustment to a previous processed claim insert the DCN of the claims to be adjusted.

Value Codes and Amounts

Code(s) and related dollar amount(s) identify monetary data that are necessary for the processing of this claim. The codes are two alphanumeric digits and each value allows up to nine numeric digits (0000000.00). Negative amounts are not allowed. Whole numbers or non-dollar amounts are right justified to the left of the dollars and cents delimiter. Some values are reported as cents, so refer to specific codes for instructions. If more than one value code is shown for a billing period, show the codes in ascending alphanumeric sequence.

Value Code Structure (Only codes used to bill Medicare are shown.):

06 - Medicare Blood Deductible - Code indicates the amount the patient paid for un-replaced deductible blood.

13 - ESRD Beneficiary in the 30- Month Coordination Period with an EGHP - Code indicates that the amount shown is that portion of a higher priority EGHP payment on behalf of an ESRD beneficiary that applies to covered Medicare charges on this bill. If the provider enters six zeros (0000.00) in the amount field, it is claiming a conditional payment because the EGHP has denied coverage or there has been a substantial delay in its payment. Where the provider received no payment or a reduced payment because of failure to file a proper claim, this is the amount that would have been payable had it filed a proper claim.

17 – Not submitted by the provider. The Medicare shared system will display this payer only code on the claim when an outlier payment is being made. The value is the total claim outlier payment.

19 – Not submitted by the provider. The Medicare shared system will display this payer only code on the claim for low volume providers to identify the amount of the low volume adjustment being included in the provider's reimbursement.

37 - Pints of Blood Furnished - Code indicates the total number of pints of blood or units of packed red cells furnished, whether or not replaced. Blood is reported only in terms of complete pints rounded upwards, e.g., 1 1/4 pints is shown as 2 pints. This entry serves a basis for counting pints towards the blood deductible. Hospital-based and independent renal facilities must complete this item.

38 - Blood Deductible Pints - Code indicates the number of un-replaced deductible pints of blood supplied. If all deductible pints furnished have been replaced, no entry is made. Hospital-based and independent renal facilities must complete this item.

39 - Pints of Blood Replaced - Code indicates the total number of pints of blood donated on the patient's behalf. Where one pint is donated, one pint is replaced. If arrangements have been made for replacement, pints are shown as replaced. Where the provider charges only for the blood processing and administration, i.e., it does not charge a "replacement deposit fee" for un-replaced pints, the blood is considered replaced for

purposes of this item. In such cases, all blood charges are shown under the 039x revenue code series, Blood Administration. Hospital-based and independent renal facilities must complete this item.

44 - Amount Provider Agreed To Accept From Primary Payer When This Amount is Less Than Charges But Higher than Payment Received - Code indicates the amount shown is the amount the provider was obligated or required to accept from a primary payer as payment in full when that amount is less than the charges but higher than amount actually received. A Medicare secondary payment is due.

47 - Any Liability Insurance - Code indicates amount shown is that portion from a higher priority liability insurance made on behalf of a Medicare beneficiary that the provider is applying to Medicare covered services on this bill. If six zeros (0000.00) are entered in the amount field, the provider is claiming conditional payment because there has been substantial delay in the other payer's payment.

48 - Hemoglobin Reading - Code indicates the most recent hemoglobin reading taken before the start of this billing period. This is usually reported in three positions with a decimal. Use the right of the delimiter for the third digit. The blood sample for the hemoglobin reading must be obtained before the dialysis treatment. If a hemoglobin value is not available facilities must report the value 99.99.

49 - Hematocrit Reading - Code indicates the most recent hematocrit reading taken before the start of this billing period. This is usually reported in two positions (a percentage) to the left of the dollar/cents delimiter. If the reading is provided with a decimal, use the position to the right of the delimiter for the third digit. The blood sample for the hemoglobin reading must be obtained before the dialysis treatment. If a hematocrit value is not available facilities must report the value 99.99

71 - Funding of ESRD Networks - Code indicates the amount of Medicare payment reduction to help fund the ESRD networks. This amount is calculated by the A/B MAC (A) and forwarded to CWF. (See §120 for discussion of ESRD networks).

79 – Not submitted by the provider. The Medicare shared system will display this payer only code on the claim. The value represents the dollar amount for Medicare allowed payments applicable for the calculation in determining an outlier payment.

A8 – Weight of Patient – Code indicates the weight of the patient in kilograms. The weight of the patient should be measured after the last dialysis session of the month.

A9 – Height of Patient – Code indicates the height of the patient in centimeters. The height of the patient should be measured during the last dialysis session of the month. The measurement is required no less frequently than once per year but must be reported on every claim. This height is as the patient presents.

D5 – Result of last Kt/V reading. For in-center hemodialysis patients this is the last reading taken during the billing period. For peritoneal dialysis patients and home hemodialysis this may be before the current billing period but should be within 4 months of the claim date of service.

D6 – 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 pump 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.

Q8 – Not submitted by the provider. The Medicare shared system will display this payer only code on the claim. The value represents the dollar amount for the services applicable to the calculation of the transitional drug add-on adjustment (TDAPA).

QG – Not submitted by the provider. The Medicare shared system will display this payer only code on the claim. The value represents the dollar amount for the services applicable to the calculation of the new innovative equipment and supplies add-on adjustment (TPNIES).

QH – Not submitted by the provider. The Medicare shared system will display this payer only code on the claim. The value represents the dollar amount for the services applicable to the calculation of the new innovative equipment add-on for capital related assets.

Revenue Codes

The revenue code for the appropriate treatment modality is billed (e.g., 0821 for hemodialysis). Effective January 1, 2015, ESRD facilities are required to report on the claim the drugs identified on the consolidated billing list provided at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Consolidated_Billing.html

082X - Hemodialysis - Outpatient or Home Dialysis - A waste removal process performed in an outpatient or home setting, necessary when the body's own kidneys have failed. Waste is removed directly from the blood. Detailed revenue coding is required. Therefore, services may not be summed at the zero level.

0 - General Classification	HEMO/OP OR HOME
1 – Hemodialysis/Composite or other rate	HEMO/COMPOSITE
2 - Home Supplies	HEMO/HOME/SUPPL
3 - Home Equipment	HEMO/HOME/EQUIP
4 - Maintenance 100%	HEMO/HOME/100%
5 - Support Services	HEMO/HOME/SUPSERV
9 - Other Hemodialysis Outpatient	HEMO/HOME/OTHER

083X - Peritoneal Dialysis - Outpatient or Home - A waste removal process performed in an outpatient or home setting, necessary when the body's own kidneys have failed. Waste is removed indirectly by instilling a special solution into the abdomen using the peritoneal membrane as a filter.

0 - General Classification	PERITONEAL/OP OR HOME
1 - Peritoneal/Composite or other rate	PERTNL/COMPOSITE
2 - Home Supplies	PERTNL/HOME/SUPPL
3 - Home Equipment	PERTNL/HOME/EQUIP
4 - Maintenance 100%	PERTNL/HOME/100%
5 - Support Services	PERTNL/HOME/SUPSERV
9 -Other Peritoneal Dialysis	PERTNL/HOME/OTHER

084X - Continuous Ambulatory Peritoneal Dialysis (CAPD) - Outpatient - A continuous dialysis process performed in an outpatient or home setting, which uses the patient's peritoneal membrane as a dialyzer.

0 - General Classification	CAPD/OP OR HOME
1 - CAPD/Composite or other rate	CAPD/COMPOSITE
2 - Home Supplies	CAPD/HOME/SUPPL
3 - Home Equipment	CAPD/HOME/EQUIP
4 - Maintenance 100%	CAPD/HOME/100%
5 - Support Services	CAPD/HOME/SUPSERV
9 -Other CAPD Dialysis	CAPD/HOME/OTHER

085X - Continuous Cycling Peritoneal Dialysis (CCPD) - Outpatient. - A continuous dialysis process performed in an outpatient or home setting, which uses the patient's peritoneal membrane as a dialyzer.

0 - General Classification	CCPD/OP OR HOME
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1 - CCPD/Composite or other rate	CCPD/COMPOSITE
2 - Home Supplies	CCPD/HOME/SUPPL
3 - Home Equipment	CCPD/HOME/EQUIP
4 - Maintenance 100%	CCPD/HOME/100%
5 - Support Services	CCPD/HOME/SUPSERV
9 -Other CCPD Dialysis	CCPD/HOME/OTHER

088X - Miscellaneous Dialysis - Charges for Dialysis services not identified elsewhere.

0 - General Classification	DAILY/MISC
1 – Ultrafiltration	DAILY/ULTRAFILT
2 – Home dialysis aid visit	HOME DIALYSIS AID VISIT
9 -Other misc. Dialysis	DAILY/MISC/OTHER

HCPCS/Rates

All ESRD hemodialysis claims must include HCPCS 90999 on the line reporting revenue code 082x. All AKI claims must include HCPCS G0491.

Modifiers

Modifiers are required with ESRD Billing for reporting the adequacy of dialysis and the vascular access. For information on modifiers required for these quality measures see 50.9 of this chapter.

For information on reporting modifiers applicable to the Erythropoietin Stimulating Agents refer to section 60.4 of this chapter.

Route of administration modifiers required are JA, JB and JE.

For information on reporting the AY modifier for services not related to the treatment of ESRD, see sections 60.2.1.1 - Separately Billable ESRD Drugs and 60.1 - Lab Services.

For information on reporting the CG modifier for additional treatments provided without medical justification, see section 10.1 of this chapter.

For information on reporting the JW and JZ modifiers for drugs and biologicals see section 50.2.

Service Date

Report the line item date of service for each dialysis session and each separately payable item or service.

Service Units

Hospital-based and independent renal facilities must complete this item. The entries quantify services by revenue category, e.g., number of dialysis treatments. Units are defined as follows:

0634 - Erythropoietin (EPO) - Administrations, i.e., the number of times an injection of less than 10,000 units of EPO was administered. For claims with dates of service on or after January 1, 2008, facilities use the units field as a multiplier of the dosage description in the HCPCS to arrive at the dosage amount per administration.

0635 - Erythropoietin (EPO) - Administrations, i.e., the number of times an injection of 10,000 units or more of EPO was administered. For claims with dates of service on or after January 1, 2008, facilities use the units field as a multiplier of the dosage description in the HCPCS to arrive at the dosage amount per administration.

082X - (Hemodialysis) - Sessions

083X - (Peritoneal) - Sessions

084X - (CAPD) – Per Day

085X - (CCPD) – Per Day

Effective April 1, 2007, the implementation of ESRD line item billing requires that each dialysis session be billed on a separate line. As a result, claims with dates of service on or after April 1, 2007 should not report units greater than 1 for each dialysis revenue code line billed on the claim.

Total Charges

Hospital-based and independent renal facilities must complete this item. Hospital-based facilities must show their customary charges that correspond to the appropriate revenue code. They must not enter their composite or the EPO` rate as their charge. Independent facilities may enter their composite and/or EPO rates.

Neither revenue codes nor charges for services included in the composite rate may be billed separately, *but should be itemized on ESRD facility claims as appropriate*. Hospitals must maintain a log of these charges in their records for cost apportionment purposes.

Services which are provided but which are not included in the composite rate may be billed as described in sections that address those specific services.

The last revenue code entered in as 0001 represents the total of all charges billed.

Principal Diagnosis Code

Hospital-based and independent renal facilities must complete this item and it should include a diagnosis of end stage renal disease for patients with ESRD. For patients with AKI see section 40 of this chapter.

Other Diagnosis Code(s)

For claims with dates of service on or after January 1, 2011 renal dialysis facilities report the appropriate diagnosis code(s) for comorbidity conditions eligible for an adjustment.

50.8 - Training and Retraining

(Rev. 12957; Issued: 11-08-24; Effective:01-01-25; Implementation: 01-06-25)

See Pub. 100-02 Medicare Benefit Policy Manual, Chapter 11, for coverage rules for dialysis training.

Training services and supplies that are covered under the Prospective Payment System (PPS) base rate includes personnel services, dialysis supplies and parenteral items used in dialysis, written training manuals, material and laboratory tests.

End Stage Renal Disease Prospective Payment System (ESRD PPS) claims with dates of service on or after January 1, 2011, *and Acute Kidney Injury (AKI) claims with dates of service on or after January 1, 2025*, billing for dialysis training sessions will receive a home dialysis training add-on payment.

The home dialysis training add-on payment is adjusted by the *ESRD PPS* wage index and added to the PPS base rate. The home dialysis training add-on payment accounts for nursing time for training treatments. The home dialysis training add-on payment applies to both peritoneal dialysis (PD) and hemodialysis (HD)

training treatments. Updates to the home dialysis training add-on payment are published through rulemaking.

Hemodialysis (HD) Training (082X):

An ESRD facility may bill a maximum of 25 training sessions per patient for hemodialysis training.

Intermittent Peritoneal Dialysis (IPD) Training (083X):

An ESRD facility is not reimbursed for more than three IPD treatments in a single week, for a total duration longer than 3 months.

Continuous Ambulatory Peritoneal Dialysis (CAPD) Training (84X):

An ESRD facility may bill a maximum of 15 training sessions per patient for CAPD training. The A/B MAC (A) will make a determination whether or not to permit training sessions in excess of 15.

Continuous Cycling Peritoneal Dialysis (CCPD) Training (085X):

An ESRD facility may bill a maximum of 15 training sessions per patient for CCPD training. The A/B MAC (A) will determine whether or not training sessions over 15 are medically necessary.

Retraining

- A. General - Occasionally, it is necessary to furnish additional training to an ESRD self-dialysis beneficiary after the initial training course is completed. Retraining sessions are paid under the following conditions:
- The patient changes from one mode of dialysis to another, e.g., from hemodialysis to CAPD;
 - The patient's home dialysis equipment changes;
 - The patient's dialysis setting changes;
 - The patient's dialysis partner changes; or
 - The patient's medical condition changes e.g., temporary memory loss due to stroke, physical impairment.

The patient must continue to be an appropriate patient for self-dialysis.

B. Payment Rates - Retraining sessions are reimbursed at the same rate as the facility's training rate.

C. Duplicate Payments - No home dialysis training add-on payment is made for a home dialysis treatment furnished on the same day as a retraining session. In the case of a CAPD patient, the facility's equivalent CAPD daily rate is not paid on the day(s) of retraining.