

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 10640	Date: August 6, 2021
	Change Request 12079

SUBJECT: Update of Internet Only Manual (IOM), Pub. 100-04, Chapter 8 - Outpatient ESRD Hospital, Independent Facility, and Physician/Supplier Claims

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to update various chapters of IOM Pub.100-04, Chapter 8 - Outpatient ESRD Hospital, Independent Facility, and Physician/Supplier Claims.

EFFECTIVE DATE: September 7, 2021

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

IMPLEMENTATION DATE: September 7, 2021

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	8/Table of Contents
R	8/10/General Description of the End Stage Renal Disease Prospective Payment System (ESRD PPS)
R	8/10/10.1/ Billing for Additional Treatments
R	8/10/10.2 /Uncompleted Treatments
R	8/10/10.3/No-Shows
R	8/10/10.4/Deductible and Coinsurance
R	8/10/10.5/Hospital Services
R	8/10/10.6/ Amount of Payment
R	8/20/Calculation of the End Stage Renal Disease Prospective Payment System (ESRD PPS) Per Treatment Payment Amount
R	8/20/ 20.2 /Pediatric Payment Model for ESRD PPS
R	8/20/ 20.3 /End Stage Renal Disease Quality Incentive Program (QIP)
R	8/30/ Publication of the Prospective Payment System (PPS) Base Rate
D	8/30/30.1/Publication of Composite Rates

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
D	8/30/30.2/ Determining Individual Facility Composite Rate
D	8/30/30.3 /Transition Period
D	8/30/30.4 /Record-Keeping and Reporting Requirements Under Composite Rate System
D	8/30/30.5 /Facility Preparation and A/B MAC (A) Review of Cost Reports
D	8/30/30.6 / Issuance of Notice of Program Reimbursement
R	8/40/ Acute Kidney Injury (AKI) Claims
D	8/40/40.1/General Instructions for Processing Exceptions Under the Composite Rate Reimbursement System
D	8/40/40.2/ Criteria for Approval of ESRD Exception Requests
D	8/40/40.3/ Procedures for Requesting Exceptions to ESRD Payment Rates
D	8/40/40.4/Period of Approval: Payment Exception Requests
D	8/40/40.5/Criteria for Refiling a Denied Exception Request
D	8/40/40.6/Responsibility of A/B MACs (A)
D	8/40/40.7/Payment Exception: Pediatric Patient Mix
D	8/40/40.8 /Payment Exception: Self-Dialysis Training Costs in Pediatric Facilities
D	8/40/40.85/Pediatric Payment Model for ESRD PPS
R	8/50/50.1/Laboratory Services Included in the End Stage Renal Disease Prospective Payment System ESRD PPS
N	8/50/ 50.1.1 /Laboratory Services Performed During Emergency Room Service
D	8/50/50.1.5 /Lab Services Included in the Prospective Payment System
D	8/50/50.1.6 /Laboratory Services Performed During Emergency Room Service
R	8/50/50.2 / Drugs and Biologicals Included in the End Stage Renal Disease
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R	8/50/ 50.6.1/Payment for In-Facility Maintenance Dialysis Sessions Furnished to Continuous Ambulatory Peritoneal Dialysis (CAPD) Continuous Cycling Peritoneal Dialysis (CCPD) Home Dialysis Patients
R	8/50/50.6.2 /Payment for Hemodialysis Sessions
R	8/50/50.7/Ultrafiltration
R	8/50/50.8/Training and Retraining
R	8/50/50.9/Coding for Adequacy of Dialysis, Vascular Access and Infection
R	8/60/Separately Billable ESRD Items and Services
R	8/60/60.1/ Lab Services

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
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R	8/60/60.2.1.1/ Separately Billable ESRD Drugs
R	8/60/60.2.1.2/Facilities Billing for ESRD Drugs and Biologicals Equivalent to Injectable Drugs
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R	8/60/60.4.2/ Facility Billing Requirements for ESAs
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D	8/60/60.4.2.2/Completion of Subsequent Form CMS-1500 Claims for Epoetin Alfa (EPO)
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R	8/60/60.4.6.1/Reserved for Future Use
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D	8/60/60.8/Shared Systems Changes for Medicare Part B Drugs for ESRD Independent Dialysis Facilities

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D	8/70/70.2/Prevention of Double Billing Under Method I and II
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D	8/80/80.2.1/Required Billing Information for Method I Claims
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D	8/100/100.3/ Physician's Services Furnished to a Dialysis Patient Away From Home or Usual Facility
R	8/100/110/Reduction in Medicare Program Payment to Fund ESRD Networks
R	8/100/110/Reduction in Medicare Program Payment to Fund ESRD Networks

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:10640	Date: August 6, 2021	Change Request: 12079
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SUBJECT: Update of Internet Only Manual (IOM), Pub. 100-04, Chapter 8 - Outpatient ESRD Hospital, Independent Facility, and Physician/Supplier Claims

EFFECTIVE DATE: September 7, 2021

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IMPLEMENTATION DATE: September 7, 2021

I. GENERAL INFORMATION

A. Background: The purpose of this Change Request is to revise the Medicare Claims Processing Manual, Pub. 100-04, Chapter 8.

B. Policy: There are no policy changes.

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
12079.1	Contractors shall be in compliance with the update to CMS Internet Only Manual (IOM) Pub. 100-04, Chapter 8 Outpatient ESRD Hospital, Independent Facility, and Physician/Supplier Claims.	X								

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility					
		A/B MAC			DME MAC	CEDI	
		A	B	HHH			
12079.2	MLN Article: CMS will make available an MLN Matters provider education article that will be marketed through the MLN Connects weekly newsletter shortly after the CR is released. MACs shall follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1, instructions for distributing MLN Connects	X					

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
	information to providers, posting the article or a direct link to the article on your website, and including the article or a direct link to the article in your bulletin or newsletter. You may supplement MLN Matters articles with localized information benefiting your provider community in billing and administering the Medicare program correctly. Subscribe to the “MLN Matters” listserv to get article release notifications, or review them in the MLN Connects weekly newsletter.					

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:
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Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s): Teira Canty, teira.canty@cms.hhs.gov, Wendy Jones, wendy.jones@cms.hhs.gov

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

VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

ATTACHMENTS: 0

Medicare Claims Processing Manual

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

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10 - General Description of *the End Stage Renal Disease Prospective Payment System (ESRD PPS)*

(Rev. 10640, Issued:08-06-21, Effective:09-07-21, Implementation:09-07-21)

See the Medicare Benefit Policy Manual, Chapter 11, for a general description of coverage policies *and definitions* relating to the ESRD benefit.

Effective January 1, 2011 Section 153b of the Medicare Improvements for Patients and Providers (*MIPPA*) requires the implementation of *End Stage Renal Disease* Prospective Payment System (ESRD PPS). The ESRD PPS provides a single payment to ESRD facilities that will cover all of the resources used in furnishing an outpatient dialysis treatment, including supplies and equipment used to administer dialysis (in the ESRD facility or at a patient's home), drugs, biologicals, laboratory tests, training, and support services.

All ESRD related services and supplies are paid to the ESRD facility through the ESRD *PPS*. Other entities providing ESRD related services, including laboratories, suppliers and physicians billing for ESRD related drugs must look to the ESRD facility for payment. Consolidated Billing edits established with the implementation of the ESRD *PPS* will deny or reject claims to other providers and suppliers billing for ESRD related labs, drugs and supplies.

Information related to the lab tests, drugs and supplies subject to the ESRD consolidated billing requirement can be found at the following website:

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

The list of items and services subject to consolidated billing may be updated quarterly in January, April, July and October of each year.

10.1 – Billing for Additional Treatments

(Rev. 10640, Issued:08-06-21, Effective:09-07-21, Implementation:09-07-21)

- The End Stage Renal Disease (ESRD) Prospective Payment System (PPS) provides a per treatment unit of payment. The per treatment unit of payment is the same base rate that is paid for all dialysis treatment modalities furnished by an ESRD facility. The policy allows for 3 PPS payments per week. When a beneficiary's plan of care requires more than three weekly dialysis treatments, whether HD or daily PD, claim edits are applied to ensure that Medicare payment on the monthly claim is consistent with the 3-times weekly dialysis treatment payment limit. Thus, for a 30-day month, payment is limited to 13 treatments, and for a 31-day month, payment is limited to 14 treatments, with exceptions made for medical justification.*
- ESRD facilities billing for more than 13 or 14 treatments per month must provide medical justification as required by the Medicare Administrative Contractor in order to receive payment for the additional treatments. Additional treatments provided without meeting the medical justification required must include the modifier CG on the claim line. This modifier indicates that the facility attests the additional treatment does not meet medical justification requirements. Additional treatments billed without medical justification do not receive payment. Non-covered treatments are not considered in the outlier payment calculation.*
- This policy does not apply for training and retraining treatments billed within the allowable limits. See section 50.8 of this chapter for training and retraining treatments.*

10.2 - Uncompleted Treatments

(Rev. 10640, Issued:08-06-21, Effective:09-07-21, Implementation:09-07-21)

A dialysis treatment is started, *when* a patient is connected to the machine and a dialyzer and bloodlines are used. *However, if the* is not completed for some unforeseen, but valid reason *such as* a medical emergency when the patient must be rushed to an emergency room, the facility is paid based on the full *Prospective Payment System (PPS) base rate*. This is a rare occurrence and must be fully documented to the A/B MAC (A)'s satisfaction.

10.3 - No-Shows

(Rev. 10640, Issued:08-06-21, Effective:09-07-21, Implementation:09-07-21)

If a facility sets up in preparation for a dialysis treatment, but the treatment is never started *because* the patient never arrives, no payment is made. In this case, no service has been furnished to a Medicare beneficiary even though staff time and supplies may have been used. Furthermore, the facility may not bill the patient or the patient's private insurance for these services. This is because the program is already paying the cost of pre-dialysis services through the *PPS base rate*. In setting that rate, CMS has included the salaries of facility personnel and the cost of supplies used for furnishing pre-dialysis services.

Therefore, these costs (e.g., salaries for staff time, overhead, supply costs) are included in the facility's costs and reported on its cost report, and they are included in the allowable costs used to set future reimbursement rates under the *End Stage Renal Disease Prospective Payment System (ESRD PPS)* for ESRD facilities. However, these costs may not be used as the basis for a facility to be reimbursed as Medicare bad debts.

10.4 - Deductible and Coinsurance

(Rev. 10640, Issued:08-06-21, Effective:09-07-21, Implementation:09-07-21)

The beneficiary is responsible for any unmet deductible and for coinsurance.

Eighty percent of the total End Stage Renal Disease Prospective Payment System (ESRD PPS) payment amount for renal dialysis services furnished by ESRD facilities to ESRD beneficiaries is paid by Medicare. ESRD beneficiaries are responsible for the remaining twenty percent after the deductible. Therefore, the beneficiary coinsurance amount under the ESRD PPS is twenty percent of the total ESRD PPS payment, which includes the ESRD PPS base rate, all applicable adjustments, any applicable training add-on amounts and any applicable outlier payments.

10.5 - Hospital Services

(Rev. 10640, Issued:08-06-21, Effective:09-07-21, Implementation:09-07-21)

Outpatient dialysis services for a patient with acute kidney failure or chronic kidney failure but not eligible for Medicare under the ESRD provisions at the time services are rendered must be billed by the hospital and cannot be billed by a Medicare certified renal dialysis facility on bill type 72x.

Hospitals with a Medicare certified renal dialysis facility should have outpatient ESRD related services billed by the hospital-based renal dialysis facility on bill type 72x. Hospitals that do not have a Medicare certified renal dialysis facility may bill for outpatient emergency or unscheduled dialysis services. The *Prospective Payment System (PPS) base rate* is not paid. For more information regarding the outpatient hospital billing policy for ESRD related services, see chapter 4 section 210 of this manual.

When an individual is furnished outpatient hospital services and is thereafter admitted as an inpatient of the same hospital due to renal failure - within 24 hours for non PPS hospitals and within 72 hours for PPS hospitals - the outpatient hospital services furnished are treated as inpatient services unless the patient does not have Part A coverage. Charges are reported on the ASC X12 837 institutional claim format or on Form CMS-1450. The day on which the patient is formally admitted as an inpatient is counted as the first inpatient day. The *PPS base rate* is not paid.

10.6 - Amount of Payment

(Rev. 10640, Issued:08-06-21, Effective:09-07-21, Implementation:09-07-21)

Effective for dates of service beginning January 1, 2011, after the beneficiary's Part B deductible is met, the A/B MACs (A) pay 80 percent of the ESRD PPS base rate and all applicable adjustments (or the blended payment amount if the facility chooses to transition), for each outpatient maintenance dialysis treatment furnished to the ESRD beneficiary in the ESRD facility or at the beneficiary's home.

20 – Calculation of the *End Stage Renal Disease Prospective Payment System (ESRD PPS) Per Treatment Payment Amount*

(Rev. 10640, Issued:08-06-21, Effective:09-07-21, Implementation:09-07-21)

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	<i>Payer Only Format</i>
Payer Only Condition Codes (MA, MB, MC, MD, ME, MF) <i>(Identifies comorbid conditions for adjustments)</i>	<i>X(2)</i>
Payer Only Value Code (79) <i>(Identifies dollar amount for services applicable for the calculation for determining outlier)</i>	<ul style="list-style-type: none"><i>X(2) V(9)</i>

Form CMS-1450	<i>Payer Only Format</i>
<i>Payer Only Value Code (Q8) (Identifies dollar amount for services applicable for the calculation of the transitional drug add-on payment)</i>	<ul style="list-style-type: none"> <i>X(2) V(9)</i>
<i>Payer Only Value Code (QG) (Identifies dollar amount for services applicable for the calculation of the transitional payment for new innovative equipment and supplies)</i>	<ul style="list-style-type: none"> <i>X(2) V(9)</i>

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)
<i>Supplemental Wage Index</i>	<i>9(2)V9(4)</i>
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 reoccurrence. 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. 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 geographic area 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, 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.*

20.2 – Pediatric Payment Model for ESRD PPS

(Rev. 10640, Issued:08-06-21, Effective:09-07-21, Implementation:09-07-21)

The pediatric payment model applies to all dialysis patients that are under the age of 18. The model uses the ESRD PPS base rate applicable to adult dialysis patients which is then adjusted by separate adjusters based on two age groups (<13, 13-17), and dialysis modality (HD, PD).

20.3 -End Stage Renal Disease Quality Incentive Program (ESRD QIP)

(Rev. 10640, Issued:08-06-21, Effective:09-07-21, Implementation:09-07-21)

153c of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) required The Centers for Medicare & Medicaid Services (CMS) to implement a quality based payment program for dialysis services with payment consequences effective January 1, 2012. The measures are defined in the annual dialysis facility report (DFR) that each provider receives in addition to the final rule.

Contractors are notified annually through a Technical Direction Letter from CMS identifying ESRD facilities subject to QIP payment reduction. Medicare contractors shall update the outpatient provider specific file (OPSF) as indicated for the payment year specified.

See chapter 4 of this manual for appropriate OPSF fields to update.

Valid values for ESRD facilities:

Blank = no reduction

- 1 = ½ percent payment reduction
- 2 = 1 percent payment reduction
- 3 = 1 ½ percent payment reduction
- 4 = 2 percent payment reduction

30 - Publication of the Prospective Payment System (PPS) Base Rate *(Rev. 10640, Issued:08-06-21, Effective:09-07-21, Implementation:09-07-21)*

The *End Stage Renal Disease Prospective Payment System (ESRD PPS)* regulations require *Centers for Medicare & Medicaid Services (CMS)* to publish the *Prospective Payment System (PPS) base rate* in a “Federal Register” notice when CMS incorporates new cost data or wage index. When the *PPS base rate* is updated, a listing of the new payment rates *are* published *via Recurring Update Notifications*. These rates are updated and published as needed and are used when issuing a *PPS base rate* to a new or an existing facility.

40 – Acute Kidney Injury (AKI) Claims *(Rev. 10640, Issued:08-06-21, Effective:09-07-21, Implementation:09-07-21)*

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).

AKI claims do not receive payment adjustments for comorbidities, TDAPA, TPNIES or outlier. 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>.

50.1 - Laboratory Services Included in the End Stage Renal Disease Prospective Payment System ESRD PPS *(Rev. 10640, Issued:08-06-21, Effective:09-07-21, Implementation:09-07-21)*

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 laboratory services are included in the ESRD PPS base rate.

If the renal dialysis facility needs to report a lab service 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 lab services that were separately paid under the basic case-mix composite rate payment system are considered in the calculation of any applicable outlier payment under the ESRD PPS.

50.1.1 - Laboratory Services Performed During Emergency Room Service

(Rev. 10640, Issued:08-06-21, Effective:09-07-21, Implementation:09-07-21)

For claims with dates of service on or after January 1, 2012, the consolidated billing edit for laboratory services will be bypassed when billed in conjunction with an emergency room service on a hospital outpatient claim and the AY modifier will not be necessary. Allowing laboratory testing to bypass consolidated billing edits in the emergency room or department does not mean that *End Stage Renal Disease (ESRD)* facilities should send patients to the emergency room or department for routine laboratory testing or for the provision of renal dialysis services that should be provided by ESRD facilities. The intent of the bypass is to acknowledge that there are emergency circumstances where the reason for the patient's illness is unknown and the determination of a laboratory test as being ESRD-related is not known.

For hospital claims with dates of service on or after April 1, 2012, that include an emergency room service with revenue code 045x on a line item date that differs from the line item date of service for the related laboratory test(s) the hospital must include the modifier ET to attest that the laboratory test(s) were ordered in conjunction with the emergency services. This is necessary to recognize that emergency services often span two calendar days.

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

(Rev. 10640, Issued:08-06-21, Effective:09-07-21, Implementation:09-07-21)

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 are considered in the calculation of any applicable outlier payment under the ESRD PPS.

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

(Rev. 10640, Issued:08-06-21, Effective:09-07-21, Implementation:09-07-21)

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.

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.

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.

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).

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
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.

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 (see §90.3 for a description). 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.

50.5 - *Intermittent Peritoneal Dialysis (IPD)* in the Facility

(Rev. 10640, Issued:08-06-21, Effective:09-07-21, Implementation:09-07-21)

Payment for *Intermittent Peritoneal Dialysis (IPD)* in the facility is subject to the same payment rules as hemodialysis.

50.6 - In-Facility Back-Up Dialysis

(Rev. 10640, Issued:08-06-21, Effective:09-07-21, Implementation:09-07-21)

Back-up dialysis is an in-facility dialysis treatment furnished to a home dialysis patient. Condition code 76 must appear as one entry in *Form Locators (FLs)* 24-30. The facility must explain why any in-facility backup dialysis sessions (furnished on either an inpatient or outpatient basis) are furnished to home dialysis patients who are covered under the *Prospective Payment System (PPS) base rate*. If a backup session is furnished because of a failure to furnish any of the required items or services, then it will be covered only to the extent of a home dialysis session and reimbursed at the facility's *PPS base rate*. If the backup dialysis is furnished by an institution other than the home patient's *End Stage Renal Disease (ESRD)* facility, then the *ESRD* facility must assume financial liability for any cost or charge in excess of the *ESRD* facility's *PPS base rate* except where the patient is traveling away from home.

50.6.1 - Payment for In-Facility Maintenance Dialysis Sessions Furnished to *Continuous Ambulatory Peritoneal Dialysis (CAPD)* /*Continuous Cycling Peritoneal Dialysis (CCPD)* Home Dialysis Patients

(Rev. 10640, Issued:08-06-21, Effective:09-07-21, Implementation:09-07-21)

Although *Continuous Ambulatory Peritoneal Dialysis (CAPD)* and *Continuous Cycling Peritoneal Dialysis (CCPD)* patients are home dialysis patients, it may be necessary at times to dialyze them in-facility as a substitute. In this case, the total weekly reimbursement to the facility remains the same regardless of the type and frequency of in-facility dialysis involved.

In order to furnish covered CAPD services, a facility must be a Medicare approved ESRD facility and must meet additional standards established by CMS.

However, in rare instances an ESRD patient may require a combination of dialysis techniques, on the same day, in order to achieve satisfactory results. In these situations, Medicare pays for both types of dialysis services furnished on the same day. Medicare A/B MACs (A) determine the medical necessity. In each case the A/B MAC (A) obtains medical documentation from the facility that supports the use of back-up dialysis with another treatment modality. If a CAPD patient frequently requires back-up sessions, the A/B MAC (A)'s medical staff may request medical records to determine if this is the appropriate mode of treatment to meet medical necessity requirement for payment purposes and/or whether a different mode of treatment is more advantageous to the beneficiary.

50.6.2 - Payment for Hemodialysis Sessions

(Rev. 10640, Issued:08-06-21, Effective:09-07-21, Implementation:09-07-21)

Hemodialysis is typically furnished three times per week in sessions of three to five hours duration. Each hemodialysis session equals one *PPS base* rate payment. Therefore, three sessions per week is three *PPS base* rate payments. Dialysis furnished at this frequency is paid without the need for a secondary diagnosis to justify payment. The justification must support the medical necessity of the service(s) being rendered.

50.7 - Ultrafiltration

(Rev. 10640, Issued:08-06-21, Effective:09-07-21, Implementation:09-07-21)

Ultrafiltration (revenue code 0881) is a process for removing excess fluid from the blood through the dialysis membrane by means of pressure. It is not a substitute for dialysis. Ultrafiltration is used in cases where excess fluid cannot be removed easily during the regular course of hemodialysis. It is commonly done during the first hour or two of hemodialysis on patients who, for example, have refractory edema.

Pre-dialysis Ultrafiltration - While the need, if any, for pre-dialysis ultrafiltration varies from patient to patient, the facility's *PPS rate* covers the full range of complicated and uncomplicated outpatient dialysis treatments. Therefore, no additional charge is recognized for pre-dialysis ultrafiltration.

Separate Ultrafiltration - Occasionally, medical complications require that ultrafiltration be performed at a time other than when a dialysis treatment is given, and in these cases an additional payment may be made. However, the need for separate ultrafiltration must be documented in the medical record and a supporting other diagnosis must be included on the claim.

50.8 - Training and Retraining

(Rev. 10640, Issued:08-06-21, Effective:09-07-21, Implementation:09-07-21)

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, 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 geographic area wage index *and added to the PPS base rate*. *The home dialysis training add-on* payment ~~that~~ 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 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.

50.9 - Coding for Adequacy of Dialysis, Vascular Access and Infection

(Rev. 10640, Issued:08-06-21, Effective:09-07-21, Implementation:09-07-21)

A. Reporting the Urea Reduction Ratio (URR) for *End Stage Renal Disease(ESRD)* Hemodialysis Claims

All hemodialysis claims must indicate the most recent Urea Reduction Ratio (URR) for the dialysis patient. Code all claims using HCPCS code 90999 along with the appropriate G modifier listed in section B.

Claims for dialysis treatments must include the adequacy of hemodialysis data as measured by URR. Dialysis facilities must monitor the adequacy of dialysis treatments monthly for facility patients. Home hemodialysis and peritoneal dialysis patients may be monitored less frequently, but not less than quarterly. If a home hemodialysis patient is not monitored during a month, the last, most recent URR for the dialysis patient must be reported.

HCPCS code 90999 (unlisted dialysis procedure, inpatient or outpatient) must be reported in field location 44 for all bill types 72X. The appropriate G-modifier in field location 44 (HCPCS/RATES) is used, for patients that received seven or more dialysis treatments in a month. Continue to report revenue codes 0820, 0821, 0825, and 0829 in field location 43.

- G1 - Most recent URR of less than 60%
- G2 - Most recent URR of 60% to 64.9%
- G3 - Most recent URR of 65% to 69.9%
- G4 - Most recent URR of 70% to 74.9%
- G5 - Most recent URR of 75% or greater

For patients that have received dialysis 6 days or less in a month, facilities use the following modifier:

G6 - ESRD patient for whom less than seven dialysis sessions have been provided in a month.

For services beginning January 1, 2003, and after, if the modifier is not present, A/B/MACs (A) must return the claim to the provider for the appropriate modifier. Effective April, 2007 due to the requirement of line item billing, at least one revenue code line for hemodialysis on the claim must contain one of the URR modifiers shown above. The URR modifier is not required on every hemodialysis line on the claim.

The techniques to be used to draw the pre- and post-dialysis blood urea Nitrogen samples are listed in the National Kidney Foundation Dialysis Outcomes Quality Initiative Clinical Practice Guidelines for Hemodialysis Adequacy, Guideline 8, Acceptable Methods for BUN sampling, New York, National Kidney Foundation, 2000, pp.53-60.

B. Reporting the Vascular Access for *End Stage Renal Disease (ESRD)* Hemodialysis Claims

ESRD claims for hemodialysis with dates of service on or after July 1, 2010 must indicate the type of vascular access used for the delivery of the hemodialysis at the last hemodialysis session of the month. One of the following codes is required to be reported on the latest line item date of service billing for hemodialysis revenue code 0821. It may be reported on all revenue code 0821 lines at the discretion of the provider.

Note: Modifier V5 must be entered if a vascular catheter is present even if it is not being used for the delivery of the hemodialysis. In this instance 2 modifiers should be entered, V5 for the vascular catheter and either V6 or V7 for the access that is being used for the delivery of hemodialysis.

Modifier V5 - Any Vascular Catheter (alone or with any other vascular access),

Modifier V6 - Arteriovenous Graft (or other Vascular Access not including a vascular catheter in use with two needles)

Modifier V7 - Arteriovenous Fistula Only (in use with two needles)

C. Reporting the Kt/V for ALL *End Stage Renal Disease (ESRD)* Claims

All *End Stage Renal Disease (ESRD)* claims with dates of service on or after July 1, 2010 must indicate the applicable Kt/V reading for the dialysis patient. The reading result and the date of the reading must be reported on the claim using the following claim codes:

Value Code 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.

- **Hemodialysis:** For in-center and home-hemodialysis patients prescribed for three or fewer treatments per week, the last Kt/V obtained during the month must be reported. Facilities must report single pool Kt/V using the preferred National Quality Forum (NQF) endorsed methods for deriving the single pool Kt/V value: Daugirdas II or Urea Kinetic Modeling (UKM). The reported Kt/V should not include residual renal function.

A value of 8.88 shall be entered on the claim if the situation exists that a patient is prescribed and receiving greater than three hemodialysis treatments per week for a medically justified and documented clinical need. The 8.88 value is not to be used for patients who are receiving “extra” treatments for a temporary clinical need (e.g. fluid overload). A medical justification must be submitted for patients receiving greater than 13 treatments per month.

- **Peritoneal Dialysis:** When measured the delivered weekly total Kt/V (dialytic and residual) should be reported.

This code is effective and required on all ESRD claims with dates of service on or after July 1, 2010. In the event that no Kt/V reading was performed providers must report the D5 with a value of 9.99.

Occurrence Code 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. This code is effective for ESRD claims with dates of service on or after July 1, 2010. This code not required when reporting value code D5 with a value of 9.99 indicating no Kt/V reading is available for reporting or value 8.88 to indicate the patient is prescribed and receiving greater than 3 hemodialysis treatments per week for a medically justified and documented clinical need.

D. Reporting of Infection for *End Stage Renal Disease (ESRD)* Claims

Effective April 1, 2012, the infection modifiers V8 and V9 were terminated. All End Stage Renal Disease (ESRD) claims with dates of service on or after April 1, 2012, no longer require reporting of infection modifiers V8 and V9.

60 - Separately Billable ESRD Items and Services

(Rev. 10640, Issued:08-06-21, Effective:09-07-21, Implementation:09-07-21)

Payment for all items and services provided for the treatment of ESRD are included in the ESRD PPS. ESRD facilities are required to itemize the ESRD related services provided including drugs, laboratory tests and supplies that are eligible for outlier consideration.

60.1 - Lab Services

(Rev. 10640, Issued:08-06-21, Effective:09-07-21, Implementation:09-07-21)

See the Medicare Benefit Policy Manual, Chapter 11, for a description of lab services included in the *PPS rate*.

Renal dialysis facilities must bill all lab tests provided for the treatment of ESRD. This is true whether the tests were provided directly or under arrangements with an independent lab. When lab tests are billed by providers other than the ESRD facility and the lab test is provided for the treatment of ESRD, the claim will be rejected or denied. In the event that a lab test usually provided for the treatment of ESRD was furnished to an ESRD beneficiary for reasons other than for the treatment of ESRD, the provider may submit a claim for separate payment using modifier AY.

ESRD facilities should only bill for lab tests related to the treatment of ESRD or other lab tests performed by the dialysis facility (i.e. CLIA waived lab tests). Lab tests that are not for the treatment of ESRD and are not performed by the ESRD facility are not to be reported on the ESRD facility claim.

60.2 - Drugs Furnished in Dialysis Facilities

(Rev. 10640, Issued:08-06-21, Effective:09-07-21, Implementation:09-07-21)

Effective January 1, 2011, section 153b of the MIPPA requires that all drugs and biologicals *used in the treatment of ESRD are included in the ESRD PPS payment amount and must be billed by the ESRD facility*

60.2.1 - Billing Procedures for Drugs for ESRD Facilities

(Rev. 10640, Issued:08-06-21, Effective:09-07-21, Implementation:09-07-21)

The following billing procedures apply to independent and hospital based **ESRD** facilities.

Facilities identify and bill for drugs by HCPCS code, along with revenue code 0636, “Drugs Requiring Specific Information.” Example below includes the HCPCS code and indicates the dosage amount specified in the descriptor of that code. Facilities use the units field as a multiplier to arrive at the dosage amount.

EXAMPLE:

HCPCS	Drug	Dosage (lowest denominator)	Amount
J3360	Valium	5 mg	\$2.00

Actual dosage, 10 mg

On the bill, the facility shows J3360 and 2 in the units field (2 x 5 mg = 10 mg). For independent facilities, **A/B MACs (A)** compare the price of \$4.00 (2 x \$2.00) to the billed charge and pay the lower, subject to coinsurance and deductible. Effective January 1, 2006 payment is not subject to the lower of charges or fee. All separately payable drugs for both hospital-based and independent facilities are paid at ASP+6% except vaccines. For information on billing and payment for vaccines see section 60.6 of this chapter.

NOTE: When the dosage amount is greater than the amount indicated for the HCPCS code, the facility rounds up to determine units. When the dosage amount is less than the amount indicated for the HCPCS code, use one as the unit of measure. In the example above, if the dosage were 7 mg, the facility would show 2 in the unit field, if the dosage were 3 mg, the facility would show 1 in the unit field.

Facilities bill for supplies used to administer drugs with revenue code 0270, “Medical/Surgical Supplies.” The number of administrations is shown in the units field.

EXAMPLE:

Revenue Code	Units
0270	3

The number of units for supply codes billed should match the number of injections billed on the claim form.

Appropriate HCPCS codes for administration-supply of separately billable drugs would include:

A4657: Injection Administration-supply Charge: include the cost of alcohol swab, syringe, and gloves. Reimbursement for all ESRD facilities is based on a fee of \$0.50 per unit billed for A4657.

A4913: IV Administration-supply Charge: include the cost of IV solution administration set, alcohol swab, syringe, and gloves. This code should only be used when an IV solution set is required for a drug to be given. This rate will not be paid for drugs that only require a syringe for administration.

60.2.1.1 – Separately Billable ESRD Drugs

(Rev. 10640, Issued:08-06-21, Effective:09-07-21, Implementation:09-07-21)

Effective January 1, 2011, section 153b of the MIPPA requires that all drugs and biologicals that are used in the treatment of ESRD be provided and billed by the ESRD facility. When a drug or biological is billed by providers other than the ESRD facility and the drug or biological furnished is designated as a drug or biological that is included in the ESRD PPS (renal dialysis service), the claim will be rejected or denied. In the event that a drug or biological generally used in the treatment of ESRD was furnished to an ESRD beneficiary for reasons other than for the treatment of ESRD, the provider may report the drug on **the** claim **with** modifier AY and receive separate payment. For claims with dates of service on or after July 1, 2013, when these drugs are administered through the dialysate the provider must append the modifier JE (Administered via Dialysate).

All drugs reported on the renal dialysis facility claim are considered included in the ESRD PPS, unless they are covered by an exception as discussed below. The list of drugs and biologicals for consolidated billing are designated as always ESRD-related and therefore no separate payment *is* made to ESRD facilities. However, CMS has determined that some of these drugs warrant separate payment when they are used to treat conditions other than ESRD.

Exceptions to “Always ESRD Related” Drugs:

The following drugs have been approved for separate payment consideration when billed with the AY modifier attesting to the drug not being used for the treatment of ESRD. The ESRD facility is required to indicate (in accordance with ICD coding guidelines) the diagnosis code for which the drug is indicated.

- Vancomycin, effective January 1, 2012
- Daptomycin, effective January 1, 2013

Items and services subject to the consolidated billing requirements for the ESRD PPS can be found on the CMS website at:

http://www.cms.gov/ESRDPayment/50_Consolidated_Billing.asp#TopOfPage

Other drugs and biologicals are separately payable to the dialysis facility if the drug was not used for the treatment of ESRD. The facility must include the modifier AY to indicate it was not for the treatment of ESRD.

Drugs are assigned HCPCS codes. If no HCPCS code is listed for a drug (e.g., a new drug) the facility bills using HCPCS code J3490, “Unclassified Drugs,” and submits documentation identifying the drug. To establish a code for the drug, the A/B MAC (A) checks HCPCS to verify that there is no acceptable HCPCS code for billing and if a code is not found checks with the local A/B MAC (B), which may have a code and price that is appropriate. If no code is found the drug is processed under HCPCS code J3490. See Chapter 17 for a complete description of drug pricing.

60.2.1.2 – Facilities Billing for ESRD Drugs and Biologicals Equivalent to Injectable Drugs

(Rev. 10640, Issued:08-06-21, Effective:09-07-2021, Implementation:09-07-21)

The ESRD PPS includes some *injectable* drugs and biologicals *that have oral equivalent*. These drugs *should* be reported on the renal dialysis facility claim for consideration of outlier payments. For the drugs and biologicals *used in the treatment of ESRD* that do not have an assigned HCPCS, effective for dates of services on or after January 1, 2011, ESRD facilities should bill using revenue code 0250 and report the national drug code (NDC). The NDC is reported on the 837i claim transaction in loop 2410 line 03.

CMS will price these *oral* drugs based on a plan comparison for consideration in the outlier payment. CMS will maintain a list of these drug categories by NDC *and will post the list on the CMS.gov website*. Payment includes a mean dispensing fee and this amount is updated via Recurring Update Notifications. This amount *is* applied to each NDC included on the monthly claim. CMS limits 1 dispensing fee per NDC per month. Providers should report the quantity in the smallest available unit. This is necessary because Medicare is using the mean per unit cost in calculating the outlier. For example, if the provider reports NDC 00054312041 Calcitriol 1 mcg/ml oral solution (15/ml/bottle) and uses the full 15 ml bottle, the quantity is reported as 15, not 1. This allows for the most accurate calculation for the outlier *policy*.

60.2.2 - Drug Payment Amounts for Facilities

(Rev. 10640, Issued:08-06-21, Effective:09-07-21, Implementation:09-07-21)

Effective for claims with dates of service on or after January 1, 2011 all drugs and biologicals *used in the treatment of ESRD* are reimbursed under the ESRD PPS payment amount. *For more information, please refer to Chapter 11 Benefit Policy Manual, section 20.3 Drugs and Biologicals.*

60.2.3 - Facility Billing Requirements to the A/B MAC (A)

(Rev. 10640, Issued:08-06-21, Effective:09-07-21, Implementation:09-07-21)

See Medicare Benefit Policy Manual, Chapter 11 for coverage and effective dates applicable to intravenous iron therapy services.

For claims with dates of service on or after December 1, 2000, sodium ferric gluconate complex in sucrose injection is covered by Medicare for first line treatment of iron deficiency anemia in patients undergoing chronic hemodialysis who are receiving supplemental erythropoietin therapy. Payment is made on a reasonable cost basis for claims with dates of service on or after December 1, 2000 in renal dialysis centers (freestanding facilities). Payment is made pursuant to 42 CFR 405.517 for claims with dates of service on or after January 1, 2001.

For claims with dates of service on or after October 1, 2001, Medicare also covers iron sucrose injection as a first line treatment of iron deficiency anemia when furnished intravenously to patients undergoing chronic hemodialysis who are receiving supplemental erythropoietin therapy. Payment is made under the outpatient prospective payment system for hospital outpatient departments. Payment is made on a reasonable cost basis in CAHs and in renal dialysis centers (freestanding facilities). See Chapter 17. Deductible and coinsurance apply.

Facilities bill the A/B MAC (A) using type of bill 72X and revenue code 0636. For claims with dates of service on or after December 1, 2000, report HCPCS code J3490 (Unclassified drugs) for sodium ferric gluconate complex in sucrose injection. For claims with dates of service on or after January 1, 2001, facilities report HCPCS code J2915 for sodium ferric gluconate complex in sucrose injection. Until a specific code is developed for iron sucrose injection, report HCPCS code J3490 (Unclassified drugs).

60.2.4 - Physician Billing Requirements to the A/B MAC (B)

(Rev. 10640, Issued:08-06-21, Effective:09-07-21, Implementation:09-07-21)

A. Sodium Ferric Gluconate Complex in Sucrose Injection

Sodium Ferric Gluconate Complex in sucrose injection may be payable for claims with dates of service on or after December 1, 2000 when furnished intravenously, for first line treatment of iron deficiency anemia in patients undergoing chronic hemodialysis who are receiving supplemental erythropoietin therapy. Physicians bill and A/B MACs (B) pay for HCPCS code J1756 when submitted with a primary diagnosis for chronic renal failure and a secondary diagnosis for iron deficiency anemia.

These diagnoses are listed below. Use ICD-9-CM or ICD-10-CM as applicable for the service date.

Chronic Renal Failure (Primary Diagnosis)

- ICD-9-CM – 585
- ICD-10-CM – N18.3, N18.4, N18.5, N18.6,

Iron Deficiency Anemia (Secondary Diagnosis)

- ICD-9-CM – 280.0, 280.1, 280.8, or 280.9
- ICD-10-CM – D50.0, D50.1, D50.8, D50.9, *or* D63.1

This benefit is subject to the Part B deductible and coinsurance and should be paid per current Medicare drug payment reimbursement rules.

B. Iron Sucrose Injection

Iron Sucrose injections are payable for claims with dates of service on or after October 1, 2001, when furnished intravenously, for first line treatment of iron deficiency anemia in patients undergoing chronic hemodialysis who are receiving supplemental erythropoietin therapy. Until a specific code for iron sucrose injection is developed, providers must submit HCPCS code J1756, with the appropriate explanation of drug name and dosage entered on the claim. The primary diagnosis code for chronic renal failure and one of the following secondary diagnosis codes for iron deficiency must be entered.

These diagnoses are listed below. Use ICD-9-CM or ICD-10-CM as applicable for the service date.

Chronic Renal Failure (Primary Diagnosis)

- ICD-9-CM - 585
- ICD-10-CM - N18.3, N18.4, N18.5, N18.6,

Iron Deficiency Anemia (Secondary Diagnosis)

- ICD-9-CM – 280.0, 280.1, 280.8, or 280.9
- ICD-10-CM – D50.0, D50.1, D50.8, D50.9, D63.1

Iron sucrose injection is subject to the Part B deductible and coinsurance and should be paid per current Medicare drug payment reimbursement rules. A/B MACs (B) may cover other uses of this drug at their discretion.

C. Messages for Use with Denials

The contractor shall deny claims for sodium ferric gluconate complex in sucrose injection or iron sucrose injection due to a missing diagnosis code.

The contractor shall use the following remittance advice messages and associated codes when rejecting/denying claims under this policy. This CARC/RARC combination is compliant with CAQH CORE Business Scenario Two.

Group Code: CO

CARC: 16

RARC: M76

MSN: 9.2

60.3 - Blood and Blood *Products* Furnished in Hospital Based and Independent Dialysis Facilities

(Rev. 10640, Issued:08-06-2021, Effective:09-07-2021, Implementation:09-07-2021)

Effective January 1, 2011, blood and blood products remain separately payable under the ESRD PPS. However, the staff time associated with administering blood and blood products is included in the ESRD PPS payment amount.

60.4 - Erythropoietin Stimulating Agents (ESAs)

(Rev. 10640, Issued:08-06-21, Effective:09-07-21, Implementation:09-07-21)

Coverage rules for ESAs are explained in the Medicare Benefit Policy Manual, Publication 100-02, Chapter 11.

ESAs and their administration supplies *and staff* are included in the payment for the ESRD *PPS* effective January 1, 2011. Providers must continue to report ESAs on the claim. ESAs are *eligible for* outlier

payment consideration. The Medicare allowed payment (MAP) amounts for *the* outlier *policy* include the ESA rate provided on the Average Sale Price (ASP) list.

60.4.1 - ESA Claims Monitoring Policy

(Rev. 10640, Issued:08-06-21, Effective:09-07-21, Implementation:09-07-21)

Effective for services provided on or after April 1, 2006, Medicare has implemented a national claims monitoring policy for ESAs administered in Medicare renal dialysis facilities. This policy does not apply to claims for ESAs for patients who receive their dialysis at home and self-administer their ESA.

While Medicare is not changing its coverage policy on erythropoietin use to maintain a target hematocrit level between 30% and 36%, we believe the variability in response to ESAs warrants postponing requiring monitoring until the hematocrit reaches higher levels. For dates of services April 1, 2006, and later, the Centers for Medicare & Medicaid Services (CMS) claims monitoring policy applies when the hematocrit level exceeds 39.0% or the hemoglobin level exceeds 13.0g/dL. This does not preclude the contractors from performing medical review at lower levels.

Effective for services provided on or after April 1, 2006, for claims reporting hematocrit or hemoglobin levels exceeding the monitoring threshold, the dose shall be reduced by 25% over the preceding month. Providers may report that a dose reduction did occur in response to the reported elevated hematocrit or hemoglobin level by adding a GS modifier on the claim. The definition of the GS modifier is defined as: "Dosage of ESA has been reduced and maintained in response to hematocrit or hemoglobin level." Thus, for claims reporting a hematocrit level or hemoglobin level exceeding the monitoring threshold without the GS modifier, CMS will reduce the covered dosage reported on the claim by 25%. The excess dosage is considered to be not reasonable and necessary. Providers are reminded that the patient's medical records should reflect hematocrit/hemoglobin levels and any dosage reduction reported on the claim during the same time period for which the claim is submitted.

Effective for dates of service provided on and after January 1, 2008, requests for payments or claims for ESAs for ESRD patients receiving dialysis in renal dialysis facilities reporting a hematocrit level exceeding 39.0% (or hemoglobin exceeding 13.0g/dL) shall also include modifier ED **or** EE. Claims reporting neither modifier or both modifiers will be returned to the provider for correction.

The definition of modifier ED is "The hematocrit level has exceeded 39.0% (or hemoglobin level has exceeded 13.0g/dL) 3 or more consecutive billing cycles immediately prior to and including the current billing cycle." The definition of modifier EE is "The hematocrit level has exceeded 39.0% (or hemoglobin level has exceeded 13.0g/dL) less than 3 consecutive billing cycles immediately prior to and including the current billing cycle." The GS modifier continues to be defined as stated above.

Providers may continue to report the GS modifier when the reported hematocrit or hemoglobin levels exceed the monitoring threshold for less than 3 months and a dose reduction has occurred. When both modifiers GS and EE are included, no reduction in the covered dose will occur. Claims reporting a hematocrit or hemoglobin level exceeding the monitoring threshold and the ED modifier shall have an automatic 50% reduction in the covered dose applied, even if the claim also reports the GS modifier.

Below is a chart illustrating the resultant claim actions under all possible reporting scenarios:

Hct Exceeds 39.0% or Hgb Exceeds 13.0g/dL	ED Modifier? (Hct >39% or Hgb >13g/dL ≥3 cycles)	EE Modifier? (Hct >39% or Hgb >13g/dL <3 cycles)	GS Modifier? (Dosage reduced and maintained)	Claim Action
No	N/A	N/A	N/A	Do not reduce reported dose.

Hct Exceeds 39.0% or Hgb Exceeds 13.0g/dL	ED Modifier? (Hct >39% or Hgb >13g/dL ≥3 cycles)	EE Modifier? (Hct >39% or Hgb >13g/dL <3 cycles)	GS Modifier? (Dosage reduced and maintained)	Claim Action
Yes	No	No	No	Return to provider for correction. Claim must report either modifier ED or EE.
Yes	No	No	Yes	Return to provider for correction. Claim must report either modifier ED or EE.
Yes	No	Yes	Yes	Do not reduce reported dose.
Yes	No	Yes	No	Reduce reported dose 25%.
Yes	Yes	No	Yes	Reduce reported dose 50%.
Yes	Yes	No	No	Reduce reported dose 50%.

In some cases, physicians may believe there is medical justification to maintain a hematocrit above 39.0% or hemoglobin above 13.0g/dL. Beneficiaries, physicians, and/or renal facilities may submit additional medical documentation to justify this belief under the routine appeal process. You may reinstate any covered dosage reduction amounts under this first level appeal process when you believe the documentation supports a higher hematocrit/hemoglobin level.

Providers are reminded that, in accordance with FDA labeling, CMS expects that as the hematocrit approaches 36.0% (hemoglobin 12.0g/dL), a dosage reduction occurs. Providers are expected to maintain hematocrit levels between 30.0 to 36.0% (hemoglobin 10.0-12.0g/dL). Hematocrit levels that remain below 30.0% (hemoglobin levels below 10.0g/dL) despite dosage increases, should have causative factors evaluated. The patient's medical record should reflect the clinical reason for dose changes and hematocrit levels outside the range of 30.0-36.0% (hemoglobin levels 10.0-12.0g/dL). Medicare contractors may review medical records to assure appropriate dose reductions are applied and maintained and hematological target ranges are maintained.

These hematocrit requirements apply only to ESAs furnished as an ESRD benefit under §1881(b) of the Social Security Act.

Effective January 1, 2020, the EMP is discontinued under the ESRD PPS. Prescribing practitioners should continue to prescribe ESAs in accordance with ESA dosing guidelines and ESRD facilities should continue to report what they furnish.

The type of bill 72X will no longer be subject to dose reductions or ESA dose limitations. ESRD facilities are not required to report the following modifiers:

- 1. GS - Dosage of erythropoietin stimulating agent has been reduced and maintained in response to hematocrit or hemoglobin level*
- 2. ED - Hematocrit level has exceeded 39% (or hemoglobin level has exceeded 13.0 g/dl) for 3 or more consecutive billing cycles immediately prior to and including the current cycle*
- 3. EE - Hematocrit level has not exceeded 39% (or hemoglobin level has not exceeded 13.0 g/dl) for 3 or more consecutive billing cycles immediately prior to and including the current cycle*

Medically Unlikely Edits (MUE)

For dates of service on and after January 1, 2008, the MUE for claims billing for Epogen® is reduced to 400,000 units from 500,000. The MUE for claims for Aranesp® is reduced to 1200 mcg from 1500 mcg.

It is likely that claims reporting doses exceeding the threshold reflect typographical errors and will be returned to providers for correction.

Effective January 1, 2020 the medically unlikely edits for ESAs exceeding the threshold limits above are discontinued under the ESRD PPS.

60.4.2 - Facility Billing Requirements for ESAs

(Rev. 10640, Issued:08-06-21, Effective:09-07-21, Implementation:09-07-21)

Hematocrit and Hemoglobin Levels

Renal dialysis facilities are required to report hematocrit or hemoglobin levels for their Medicare patients receiving erythropoietin products. Hematocrit levels are reported in value code 49 and reflect the most recent reading taken before the start of the billing period. Hemoglobin readings before the start of the billing period are reported in value code 48.

To report a hemoglobin or hematocrit reading for a new patient on or after January 1, 2006, the provider should report the reading that prompted the treatment of epoetin alfa. The provider may use results documented on form CMS 2728 or the patient's medical records from a transferring facility.

Effective January 1, 2012, ESRD facilities are required to report hematocrit or hemoglobin levels on all ESRD claims. Reporting the value 99.99 is not permitted when billing for an ESA.

The revenue codes for reporting Epoetin Alfa are 0634 and 0635. All other ESAs are reported using revenue code 0636. The HCPCS code for the ESA must be included:

HCPCS	HCPCS Description	Dates of Service
Q4055	Injection, Epoetin Alfa, 1,000 units (for ESRD on Dialysis)	1/1/2004 through 12/31/2005
J0886	Injection, Epoetin Alfa, 1,000 units (for ESRD on Dialysis)	1/1/2006 through 12/31/2006
Q4081	Injection, Epoetin alfa, 100 units (for ESRD on Dialysis)	1/1/2007 to present
Q4054	Injection, Darbepoetin Alfa, 1mcg (for ESRD on Dialysis)	1/1/2004 through 12/31/2005
J0882	Injection, Darbepoetin Alfa, 1mcg (for ESRD on Dialysis)	1/1/2006 to present

HCPCS	HCPCS Description	Dates of Service
J0890	Injection, Peginesatide, 0.1 mg (for ESRD on Dialysis)	1/1/2013 through 7/1/2015
Q5105	Injection, epoetin alfa, biosimilar, (Retacrit) (For ESRD on Dialysis), 100 units	7/1/2018 to present

Each administration of an ESA is reported on a separate line item with the units reported used as a multiplier by the dosage description in the HCPCS to arrive at the dosage per administration.

Route of Administration Modifiers

Patients with ESRD) receiving administrations of ESA for the treatment of anemia may receive intravenous administration or subcutaneous administrations of the ESA. Effective for claims with dates of services on or after January 1, 2012, all facilities billing for injections of ESA for ESRD beneficiaries must include the modifier JA on the claim to indicate an intravenous administration or modifier JB to indicate a subcutaneous administration. ESRD claims containing ESA administrations that are submitted without the route of administration modifiers will be returned to the provider for correction. Renal dialysis facility claims including charges for administrations of the ESA by both methods must report separate lines to identify the number of administration provided using each method.

Effective July 1, 2013, providers must identify when a drug is administered via the dialysate by appending the modifier JE (administered via dialysate).

Maximum Allowable Administrations

The maximum number of administrations of EPO for a billing cycle is 13 times in 30 days and 14 times in 31 days.

The maximum number of administrations of Aranesp for a billing cycle is 5 times in 30/ 31days.

Number of Units Administered - Subsequent claims may be submitted electronically.

60.4.4 - Payment Amount for Epoetin Alfa (EPO)

Rev. 10640, Issued:08-06-21, Effective:09-07-21, Implementation:09-07-21

Payment for ESRD-related EPO is included in the ESRD PPS for claims with dates of service on or after January 1, 2011.

60.4.4.1 - Payment for Epoetin Alfa (EPO) in Other Settings

(Rev. 10640, Issued:08-06-21, Effective:09-07-21, Implementation:09-07-21)

With the implementation of the ESRD PPS, ESRD-related EPO is included in ESRD PPS payment amount and is not separately payable on Part B claims with dates of service on or after January 1, 2011 for other providers with the exception of a hospital billing for an emergency or unscheduled dialysis session. In the hospital inpatient setting, payment under Part A is included in the DRG.

In the hospital inpatient setting, payment under Part B is made on bill type 12x. Hospitals report the drug units based on the units defined in the HCPCS description. Hospitals do not report value code 68 for units of EPO. For dates of service prior to April 1, 2006, report EPO under revenue code 0636. For dates of service from April 1, 2006 report EPO under the respective revenue code 0634 for EPO less than 10,000 units and revenue code 0635 for EPO over 10,000 units. Payment will be based on the ASP Pricing File.

In a skilled nursing facility (SNF), payment for EPO covered under the Part B EPO benefit is not included in the prospective payment rate for the resident's Medicare-covered SNF stay.

In a hospice, payment is included in the hospice per diem rate *when treatment is related to the terminal illness*.

For a service furnished by a physician or incident to a physician's service, payment is made to the physician by the A/B MAC (B) in accordance with the rules for "incident to" services. When EPO is administered in the renal facility, the service is not an "incident to" service and not under the "incident to" provision.

60.4.5.1 - Self Administered ESA Supply

(Rev. 10640, Issued:08-06-21, Effective:09-07-21, Implementation:09-07-21)

Initially, facilities may bill for up to a 2-month supply of an ESA for *home dialysis* beneficiaries who meet the criteria for selection for self-administration. After the initial two months' supply, the facility will bill for one month's supply at a time. Condition code 70 is used to indicate payment requested for a supply of an ESA furnished a beneficiary. Usually, revenue code 0635 would apply to EPO since the supply would be over 10,000 units. Facilities leave FL 46, Units of Service, blank since they are not administering the drug. For claims with dates of service on or after January 1, 2008, supplies of an ESA for *self-administration* should be billed according to the pre-determined plan of care schedule provided to the beneficiary. Submit a separate line item for each date an administration is expected to be performed with the expected dosage. In the event that the schedule was changed, the provider should note the changes in the medical record and bill according to the revised schedule. For patients beginning to self-administer an ESA at home receiving an extra month supply of the drug, bill the one month reserve supply on one claim line and include modifier EM defined as "Emergency Reserve Supply (for ESRD benefit only)".

When billing for drug wastage in accordance with the policy in chapter 17 of this manual, section 40.1 the provider must show the wastage on a separate line item with the modifier JW. The line item date of service should be the date of the last covered administration according to the plan of care or if the patient dies use the date of death.

Condition code 70 should be reported on claims billing for home dialysis patients who *self-administer* anemia management drugs including ESAs.

60.4.6.1 Reserved for Future Use

(Rev. 10640, Issued:08-06-21, Effective:09-07-21, Implementation:09-07-21)

60.4.6.2 Reserved for Future Use

(Rev. 10640, Issued:08-06-21, Effective:09-07-21, Implementation:09-07-21)

60.4.6.3 - Payment Amount for Darbepoetin Alfa (Aranesp)

(Rev. 10640, Issued:08-06-21, Effective:09-07-21, Implementation:09-07-21)

Payment for ESRD-related Aranesp is included in the ESRD PPS for claims with dates of service on or after January 1, 2011.

60.4.6.4 - Payment for Darbepoetin Alfa (Aranesp) in Other Settings

(Rev. 10640, Issued:08-06-21, Effective:09-07-21, Implementation:09-07-21)

In the hospital inpatient setting, payment under Part A for Aranesp is included in the DRG.

In the hospital inpatient setting, payment under Part B is made on bill type 12x when billed with revenue code 0636. The total number of units as a multiple of 1mcg is placed in the unit field. Reimbursement is based on the payment allowance limit for Medicare Part B drugs as found in the ASP pricing file.

In a skilled nursing facility (SNF), payment for Aranesp covered under the Part B EPO benefit is not included in the prospective payment rate for the resident's Medicare-covered SNF stay.

In a hospice, payment is included in the hospice per diem rate *when treatment is related to the terminal illness*.

For a service furnished by a physician or incident to a physician's service, payment is made to the physician by the A/B MAC (B) in accordance with the rules for 'incident to' services. When Aranesp is administered in the renal facility, the service is not an "incident to" service and not under the "incident to" provision.

With the implementation of the ESRD PPS, ESRD-related Aranesp is included in the ESRD PPS payment amount and is not separately payable on Part B claims with dates of service on or after January 1, 2011 for other providers, with the exception of a hospital billing for an emergency or unscheduled dialysis session.

60.5 - Intradialytic Parenteral/Enteral Nutrition (IDPN)

(Rev. 10640, Issued:08-06-21, Effective:09-07-21, Implementation:09-07-21)

A. General

Parenteral/enteral nutrition (PEN) administered during dialysis may be covered under Medicare, but it is not part of the Medicare ESRD benefit. Therefore, an ESRD facility or PEN supplier may bill Medicare separately for PEN solution if the patient meets all of the requirements for PEN coverage. (See Medicare Benefit Policy Manual for PEN coverage requirements.) If the ESRD facility bills, it does so as a PEN supplier and bills the appropriate DME MAC.

B. Staff Time

The ESRD facility staff time used to administer PEN solution is not covered by Medicare, and, therefore, not included in the *ESRD PPS*. (PEN is considered a self-administered therapy and generally administered in the patient's home.) Since it is not covered under Medicare, it is not part of the *ESRD PPS* nor may a facility bill Medicare separately for it.

60.6 - Vaccines Furnished to ESRD Patients

(Rev. 10640, Issued:08-06-21, Effective:09-07-2021, Implementation:09-07-2021)

The Medicare program covers hepatitis B, influenza virus and Pneumococcal pneumonia virus (PPV) vaccines and their administration when furnished to eligible beneficiaries in accordance with coverage rules. Payment may be made for both the vaccine and the administration. The costs associated with the syringe and supplies are included in the administration fee: HCPCS code A4657 should not be billed for these vaccines.

Vaccines and their *administration are reported using separate codes. See Chapter 18 of this manual for the payment* and codes required for billing vaccines and the administration of the vaccine.

Vaccines remain separately payable under the ESRD PPS.

60.7 – Reserved *For Future Use*

(Rev. 10640, Issued:08-06-21, Effective:09-07-2021, Implementation:09-07-21)

70 - Payment for Home Dialysis

(Rev. 10640, Issued:08-06-21, Effective:09-07-21, Implementation:09-07-21)

Home dialysis is dialysis performed by an appropriately trained dialysis patient at home. Hemodialysis, CCPD, IPD and CAPD may be performed at home. For renal all dialysis services furnished by an ESRD facility, the facility must accept assignment, and only the facility may be paid by the Medicare program.

For purposes of home dialysis, a skilled nursing facility (SNF) may qualify as a beneficiary's home. The services are excluded from SNF consolidated billing for its inpatients. The home dialysis services are billed by the ESRD facility.

With the implementation of the ESRD PPS on January 1, 2011, payment for all home dialysis services furnished to the ESRD beneficiary is made to an ESRD dialysis facility whether services are provided directly or under arrangements.

70.1 - Overpayments

(Rev. 10640, Issued:08-06-21, Effective:09-07-21, Implementation:09-07-21)

Any overpayments that occur are subject to recovery following the usual Medicare program rules and procedures.

80 - Home Dialysis Billing to the A/B MAC (A)

(Rev. 10640, Issued:08-06-21, Effective:09-07-21, Implementation:09-07-21)

If an ESRD patient chooses home dialysis, the ESRD dialysis facility with which the Medicare home patient is associated assumes responsibility for providing all home dialysis equipment and supplies, and home support services. For these services, the facility receives the same Medicare dialysis payment rate as it would receive for an in-facility patient under the ESRD PPS. The beneficiary is responsible for paying any unmet Part B deductible and the 20-percent coinsurance.

80.1 - Items and Services Included in the *ESRD PPS payment* for Home Dialysis

(Rev. 10640, Issued:08-06-21, Effective:09-07-21, Implementation:09-07-21)

The following items are paid for and must be furnished under the *PPS*. The facility may furnish them directly under arrangements, to all of its home dialysis patients. If the facility fails to furnish (either directly or under arrangements) any part of the items and services covered under the rate, then the facility cannot be paid any amount for the part of the items and services that the facility does furnish.

- Medically necessary dialysis equipment and dialysis support equipment;
- Home dialysis support services including the delivery, installation, maintenance, repair, and testing of home dialysis equipment, and home support equipment;
- Purchase and delivery of all necessary dialysis supplies;
- Routine ESRD related laboratory tests; and
- All dialysis services furnished by the facility's staff.

The following items and services are included in the *ESRD PPS* and may not be billed separately when furnished by a dialysis facility:

- Staff time used to administer blood;
- Declotting of shunts and any supplies used to decлот shunts by facility staff in the dialysis unit;
- Oxygen and the administration of oxygen furnished in the dialysis unit;
- Staff time used to administer separately billable parenteral items;
- Bicarbonate dialysate;
- Cardiac monitoring;
- Catheter changes (Ideal Loop);
- Suture removal;
- Dressing changes;
- Crash cart usage for cardiac arrest; or
- Staff time used to collect specimens for all laboratory tests.

Sometimes services that are not renal dialysis services (e.g., decлотting of shunts, suture removal, injecting separately billable ESRD related drugs) are furnished in a department of the hospital other than the dialysis unit (e.g., the emergency room). These services may be paid in addition to the ESRD PPS payment only if the services could not be furnished in a dialysis facility or the dialysis unit of the hospital, due to the absence of specialized equipment or staff, which can be found only in the other department. In the case of emergency services furnished in the hospital emergency room (ER), the services are paid separately subject to the additional requirement that there is a sudden onset of a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention in the ER could reasonably be expected to result in either:

- Placing the patient's health in serious jeopardy;
- Causing serious impairment to bodily functions; or
- Causing serious dysfunction of any bodily organ or part.

These situations are rare and, in the absence of documentation to the contrary, these conditions are deemed to be not met.

80.3 - Calculating Payment for Intermittent Peritoneal Dialysis (IPD)

(Rev. 10640, Issued:08-06-21, Effective:09-07-21, Implementation:09-07-21)

The value of a typical week of dialysis services generally serves as the maximum weekly payment;.

While maintenance IPD is usually accomplished in sessions of 10-12 hours duration, three times per week, it is sometimes accomplished in fewer sessions of longer duration. Regardless of the particular regimen used, under the *ESRD PPS* IPD is paid based on a weekly equivalence of three ESRD PPS payments rates per week.

IPD in the home is accomplished according to any one of several schedules. The total weekly dialysis time varies from 50 to 80 hours. For example, home IPD *may be* furnished every day for 10 hours per day, every other day for 15 hours per dialysis day, every night for 8 hours per night, etc. Regardless of the particular regimen used, under the *ESRD PPS* home IPD is paid based on a weekly equivalence of three *ESRD PPS* rates per week.

Line item billing is required for all dialysis sessions. For intermittent home dialysis the facility submits a separate line item for each dialysis session using the dates in the pre-determined plan of care and the units reported on each line should be one. In the event that the schedule was changed, the provider should note the changes in the medical record and bill according to the revised schedule.

80.4 - Calculating Payment for Continuous Ambulatory Peritoneal Dialysis (CAPD) and Continuous Cycling Peritoneal Dialysis (CCPD) Under the *ESRD PPS*

(Rev. 10640, Issued:08-06-21, Effective:09-07-21, Implementation:09-07-21)

CAPD and CCPD are furnished on a continuous basis, not in discrete sessions and, therefore, are paid on a weekly or daily basis, not on a per treatment basis. Facilities are required to report the number of days in the units field. A facility's daily payment rate is 1/7 of three times the composite rate for a single hemodialysis treatment.

The equivalent weekly or daily IPD or CAPD/CCPD payment does not depend upon the number of exchanges of dialysate fluid per day (typically 3-5) or the actual number of days per week that the patient undergoes dialysis. The weekly (or daily) rate is based on the equivalency of one week of IPD or CAPD/CCPD to one week of hemodialysis, regardless of the actual number of dialysis days or exchanges in that week.

All home dialysis support services, equipment and supplies necessary for home IPD or CAPD/CCPD are included in the *ESRD PPS* payment. No support services, equipment or supplies may be paid in addition to the *ESRD PPS*.

Line item billing is required for all dialysis sessions. For claims billing for Continuous Ambulatory Peritoneal Dialysis (CAPD) and Continuous Cycling Peritoneal Dialysis (CCPD), the provider may submit a separate dialysis line for each day of the month. If the provider is aware of an inpatient stay for the beneficiary within the month, the ESRD facility may include the date of admission and date of discharge as a billable day for the dialysis but should omit the dates within the inpatient stay. In the event that the ESRD facility is unaware of an inpatient stay during the month, the Medicare system shall detect the overlapping dates and reject only the line item dates within the inpatient stay but pay the remainder of the claim for any dates that are not within the inpatient stay.

90 - *Reserved for Future Use*

(Rev. 10640, Issued:08-06-21, Effective:09-07-21, Implementation:09-07-21)

100 - Dialysis Sessions Furnished to Patients Who are Traveling

(Rev. 10640, Issued:08-06-21, Effective:09-07-21, Implementation:09-07-21)

A. Dialysis at Another Facility

All in-facility dialysis treatments furnished by and in a facility are billed by and paid to that facility *under the ESRD PPS*. This is true even if the patient is only temporary *at a particular facility while traveling*.

B. Temporary Home Dialysis

Patients who normally dialyze in a facility may wish to dialyze temporarily as home dialysis patients while they travel or vacation.

Training services furnished to temporary home dialysis patients are covered and paid at the training rate subject to the usual rules for reimbursement of training services.

100.1 - Physician's Services Furnished to a Dialysis Patient Away From Home or Usual Facility

(Rev. 10640, Issued:08-06-21, Effective:09-07-2021, Implementation:09-07-21)

When a dialysis patient whose attending physician receives a monthly payment receives maintenance dialysis services of any kind outside the usual setting from any physician who is neither the attending physician nor that physician's substitute, the following procedures apply:

- The physician who furnished the service submits a claim to the local A/C MAC (B) of jurisdiction;
- The A/B MAC (B) will process the claim and send an MSN to the patient;
- The A/B MAC (B) that has jurisdiction over the usual dialysis setting adjusts the MCP to the usual attending physician to account for the time the patient was absent from the usual dialysis setting.
- The A/B MAC (B) that has jurisdiction over the usual dialysis setting adjusts the MCP to the usual attending physician per §140.3.E below to account for the time the patient was absent from the usual dialysis setting.

A/B MACs (B) must notify physicians that claims for services furnished to temporary patients must be identified as a claim for a temporary patient. The physician must indicate "temporary patient" on the claim.

110 - Reduction in Medicare Program Payment to Fund ESRD Networks

(Rev. 10640, Issued:08-06-21, Effective:09-07-21, Implementation:09-07-21)

A. General

Section 9335(j) of OBRA 1986 requires the Secretary to reduce the amount of each payment for each treatment by 50 cents and to allocate these amounts to ESRD network activities. This applies to all dialysis treatments furnished on or after January 1, 1987 for all treatment modalities, including training treatments. All Medicare hospital-based and independent ESRD facilities paid under the ESRD PPS are affected.

The ESRD network reduction is \$.50 per covered treatment when the full ESRD PPS rate is applicable. For ESRD claims billing for continuous modalities of dialysis performed in the beneficiary's home, the ESRD PPS rate is calculated at a daily per diem rate by taking the full ESRD PPS rate multiplied by 3 for the weekly allowable total and dividing by 7 to provide a daily treatment rate. The ESRD network reduction is also calculated at a daily rate by multiplying the \$.50 by 3 for the weekly total network reduction and dividing by 7 for a daily network reduction of \$.21.

The reduction amount is reported in the Provider Statistics and Reimbursement Report (PS&R) and CWF using value code 71 to identify monies withheld to fund ESRD networks.

The Medicare payment reduction allocated toward funding the ESRD networks for the individual claims will be indicated on the remittance record to the facility.

Facilities may not claim the 50-cent reduction as an expense on their Medicare cost reports.

C. Application of ESRD Network Funding to MSP Claims

The ESRD offset for network funding on MSP claims will be applied as follows:

- Where another payer, primary to Medicare, pays the claim in full, no ESRD offset is applicable;
- Where another payer, primary to Medicare, makes a partial payment, the ESRD offset is deducted for each treatment as described in subsection C2 from the Medicare secondary payment; and
- Where the ESRD offset amount is greater than the secondary payment amount, the entire Medicare secondary payment amount is applied towards the ESRD network funding. No Medicare secondary payment is made to the facility in this situation and no further ESRD offset is applicable. No additional ESRD offset for treatments on this claim will be made against other payments to the facility on the same remittance or on future payments for the same beneficiary.