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 ESRDPPS. 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.

10.7 - ESRD Services Not Provided Within the United States

(Rev. 1, 10-01-03)

Services (except for certain inpatient hospital services and related physicians and ambulance services in specified situations) that are not provided within the United States are not covered. United States includes the 50 States, the District of Columbia, the

Commonwealth of Puerto Rico, the Virgin Islands, Guam, and American Samoa. See Chapter 1 for additional information concerning specified situations that may be covered, billing and payment procedures and jurisdiction for payment.

10.8 - Transportation Services
(Rev. 1, 10-01-03)

In general, transportation services to obtain ESRD services are not covered. However, see the Medicare Benefit Policy Manual, Chapter 10, for coverage of ambulance services to renal dialysis facilities located on hospital premises and for coverage of ambulance services to nonhospital based dialysis facilities. Billing and payment instructions are provided in Chapter 15 of this manual.

10.9 – Dialysis Provider Number Series
(Rev. 771, Issued: 12-02-05, Effective: 01-03-06, Implementation: 01-03-06)

There are multiple facilities that provide dialysis services to ESRD beneficiaries. To ensure that provider data is correct, facilities are required to use a Provider Number based on facility type issued by CMS.

The Provider Number Series for Dialysis Providers are as follows (for CMS use only, effective May 23, 2007, providers are required to submit only their National Provider Identifier (NPI). The dialysis provider numbers will be mapped to the NPI):

2300-2499	Chronic Renal Dialysis Facilities (Hospital – Based)
2500-2899	Non – Hospital Renal Facilities
2900-2999	Independent Special Purpose Renal Dialysis Facility
3300-3399	Children's Hospitals (Excluded from PPS)
3500-3699	Renal Disease Treatment Centers (Hospital Satellites)
3700-3799	Hospital Based Special Purpose Renal Dialysis Facilities

All facilities should use their appropriately assigned provider numbers on the 72x type of bill. In the event that a facility changes from one type to another, the provider number must reflect the facility's present provider type.

20 - 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	**Payer Only Format**
Payer Only Condition Codes (MA, MB, MC, MD, ME, MF) (Identifies comorbid conditions for adjustments)	X(2)
Payer Only Value Code (79) (Identifies dollar amount for services applicable for the calculation for determining outlier)	• X(2) V(9)
Payer Only Value Code (Q8) (Identifies dollar amount for services applicable for the calculation of the transitional drug add-on payment)	• X(2) V(9)

Form CMS-1450	Payer Only Format
Payer Only Value Code (QG) (Identifies dollar amount for services applicable for the calculation of the transitional payment for new innovative equipment and supplies)	• X(2) V(9)

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

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

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

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

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

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

Field	Format
Quality Indicator Field	X(1)

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

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

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

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

Onset of Dialysis:

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

Patient Comorbidities:

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

<u>Chronic Comorbidities</u>

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 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 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.

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

(Rev. 3053, Issued: 08-28-14, Effective: ICD-10: Upon Implementation of ICD-10; ASC X12: 01-01, 12, Implementation ICD-10: Upon Implementation of ICD-10; ASC X12: 09-30-14)

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

The following table contains claim data required to calculate a final ESRD composite rate and the ESRD PPS rate:

Form CMS-1450	**ASC X12 837 institutional claim**
Through Date	2300 | DTP segment | 434 qualifier
Date of Birth	2010BA | DMG02

Form CMS-1450	ASC X12 837 institutional claim
Condition Code (73 or 74)	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 final ESRD PPS rate:

Form CMS-1450	ASC X12 837 institutional claim
Payer Only Condition Codes (MA, MB, MC, MD, ME, MF)	2300 | HI segment | BG qualifier
Payer Only Value Code (79)	2300 | HI segment | BE qualifier

Note: These payer only codes above are assigned by the Medicare standard systems and are not submitted on the claim by the provider. Payer only condition codes are only applicable when the appropriate corresponding diagnosis code(s) appears on the claim.

See information below in this section on co-morbidity diagnostic categories. The payer only value code 79 represents the dollar amount for services applicable for the calculation in determining an outlier payment.

The following provider data must also be passed to the ESRD PRICER to make provider-specific calculations that determine the final ESRD rate:

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

Field	Format
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)

ESRD facilities may elect to be reimbursed 100 percent by ESRD PPS no later than November 1, 2010. Facilities that do not elect to be reimbursed 100 percent by the ESRD PPS will be reimbursed by a blended payment rate which is composed of the current basic case-mix adjusted composite rate payment system and the new ESRD PPS.

Blended payment schedule:

Calendar year 2011 – 75 percent of the old payment methodology and 25 percent of new ESRD PPS payment

Calendar year 2012 – 50 percent of the old payment methodology and 50 percent of the new ESRD PPS payment

Calendar year 2013 – 25 percent of the old payment methodology and 75 percent of the new ESRD PPS payment

Calendar year 2014 – 100 percent of the ESRD PPS payment

Based on the claim and provider data shown above, the ESRD PRICER makes adjustments to the facility specific base rate to determine the final composite payment rate. The following factors are used to adjust and make calculations to the final payment rate:

- 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)

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 Co-morbidities
- 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 co-morbidity adjustment or a training add-on adjustment.

Co-morbidity Adjustment Categories

The ESRD PPS will provide adjustments for 6 categories of co-morbidity conditions, 3 categories of chronic conditions and 3 categories of acute conditions. **In the event that more than one of the co-morbidity categories is present on the claim, the claim will be adjusted for the highest paying co-morbidity category.**

Acute Co-morbidity Diagnostic Categories:

The acute co-morbidity categories will be eligible for a payment for the first month reported and the following 3 consecutive months. Acute co-morbidity conditions reported for more than 4 consecutive months will not receive additional payment. In the event that the co-morbidity 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 4 months.

Acute Categories are:

- Gastro-intestinal tract bleeding

- Bacterial pneumonia
- Pericarditis

Chronic Co-morbidity Diagnostic Categories:

When chronic co-morbidity 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.

Chronic Categories are:

- Hereditary hemolytic or sickle cell anemia
- Monoclonal gammopathy
- Myelodysplastic syndrome

Information related to the comorbid conditions eligible for adjustment can be found at the following website:

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

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

Low-Volume 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:

Outlier payments may be applied to the payment. ESRD outlier services are the following items and services that are included in the ESRD PPS bundle: (1) ESRD-related drugs and biologicals that were or would have been prior to January 1, 2011, separately billable under Medicare Part B; (2) ESRD-related laboratory tests that were or would have been, prior to January 1, 2011 separately billable under Part B; (3) 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 (4) renal dialysis service drugs that were or would have been, prior to January 1, 2011 covered under Medicare Part D. ESRD-related oral only drugs are delayed until January 1, 2014. 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.

Value Codes and Amounts

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 hematocrit reading must be obtained before the dialysis treatment. If a hematocrit value is not available facilities must report the value 99.99.

The blood sample for the hematocrit reading must be obtained before the dialysis treatment. If a hematocrit value is not available facilities must report the value 99.99.

20.1.1 - Calculation for Double Amputee Dialysis Patients

(Rev. 1389; Issued: 12-07-07; Effective: 01-01-08; Implementation: 01-07-08)

For dialysis treatments on or after January 1, 2006, we are revising the reporting requirements for value codes A8 and A9 for double amputee dialysis patients.

Weight should be calculated based on pre-amputation weight using the following formula: Pre-amputation weight = Actual weight x 1.15

Example: Current weight for double amputee patient = 75.5 kg.

Pre-Amputation weight = 75.5 x 1.15 = 89kg.

The results should be reported under value code A8.

Height should be reported under value code A9 as pre-amputation height. Where feasible this measurement may be obtained from Form 2728.

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 - *Dialysis Bill Processing Procedures*

(Rev. 12517; Issued:02-22-24; Effective: 03-25-24; Implementation: 03-25-24)

General instructions for completing the claim are in Chapter 25. The following instructions apply to facility reporting of ESRD services and to A/B MAC (A) processing of in-facility dialysis claims.

The shared system checks the Common Working File (CWF) to determine if there is Employer Group Health Plan (EGHP) insurance. Where the beneficiary is covered under the EGHP insurance, see the Medicare Secondary Payer Manual.

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.

f 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 Claims Paid Under the End Stage Renal Disease Prospective Payment System ESRD PPS*

(Rev. 12517; Issued:02-22-24; Effective: 03-25-24; Implementation: 03-25-24)

The term Medicare beneficiary identifier (Mbi) is a general term describing a beneficiary's Medicare identification number. For purposes of this manual, Medicare beneficiary identifier references both the Health Insurance Claim Number (HICN) and the Medicare Beneficiary Identifier (MBI) during the new Medicare card transition period and after for certain business areas that will continue to use the HICN as part of their processes.

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

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

Type of Bill

Acceptable codes for Medicare are:

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

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

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

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

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

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

provider numbers or Medicare beneficiary identifier, a corrected bill is also submitted using a code 721.

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

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

Condition Codes

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

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

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

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

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

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

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

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

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

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

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

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

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

H3 – Reoccurrence of GI Bleed comorbid category

H4 – Reoccurrence of Pneumonia comorbid category

H5 – Reoccurrence of Pericarditis comorbid Category

Occurrence Codes and Dates

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

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

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

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

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

Occurrence Span Code and Dates

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

74 - Noncovered Level of Care - This code is used for repetitive Part B services to show a period of inpatient hospital care or of outpatient surgery during the billing period. Use of

this code will not be necessary for ESRD claims with dates of service on or after April 1, 2007 due to the requirement of ESRD line item billing.

Document Control Number (DCN)

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

Value Codes and Amounts

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

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

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

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

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

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

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

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

39 - Pints of Blood Replaced - Code indicates the total number of pints of blood donated on the patient's behalf. Where one pint is donated, one pint is replaced. If arrangements have been made for replacement, pints are shown as replaced. Where the provider charges only for the blood processing and administration, i.e., it does not charge a "replacement deposit fee" for un-replaced pints, the blood is considered replaced for purposes of this item. In such cases, all blood charges are shown under the 039x revenue code series, Blood Administration. Hospital-based and independent renal facilities must complete this item.

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

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

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

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

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

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

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

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

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

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 000l 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.

50.4 - Line Item Detail Billing and Automated Claim Adjustments

(Rev. 1364, Issued: 11-02-07: Effective: 04-01-08; Implantation: 04-07-08)

The implementation of line item detail billing for ESRD claims effective on April 1, 2007 requires that each service be submitted on a separate line with the appropriate line item date of service. The Medicare standard systems perform line item date of service compare for RDFs claims with statement billing periods overlapping the statement billing period of another processed claim. This prevents monthly claims from receiving overlapping edits based on the statement billing period dates but rather, only when the RDF claim has a line item that duplicates another processed claim or falls within the dates of an inpatient hospital stay. Standard systems reject only those overlapping line items while any line items not overlapping another claim continue to process for

payment. As a result of this logic, the RDFs no longer have to submit the occurrence span code 74 on the monthly dialysis claim when an inpatient stay occurred during the same month.

The initial line item detail billing instruction did not implement a process for rejecting services on the RDF claim overlapping an inpatient stay when the RDF claim is received before the inpatient hospital claim. A subsequent instruction implemented for April 1, 2008 requires the Medicare Common Working File (CWF) to create an informational unsolicited response prompting the standard system to perform an automated adjustment of the processed 72x claim that contains line item dates of service that are overlapping dates of an incoming inpatient hospital claim. The admission and discharge dates of an inpatient stay are not considered overlapping dates and may be payable to the RDF.

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:09-07-2021, 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 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 erythropoeitin 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 erythropoeitin 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 erythropoeitin 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 erythropoeitin 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 1evel 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.
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
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.

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.

60.4.4.2 - Epoetin Alfa (EPO) Provided in the Hospital Outpatient Departments

(Rev. 2582, Issued: 11-02-12, Effective: 04-01-13, Implementation: 04-01-13)

When ESRD patients come to the hospital for an unscheduled or emergency dialysis treatment they may also require the administration of EPO. Effective January 1, 2005, EPO will be paid based on the ASP Pricing File.

Hospitals use type of bill 13X (or 85X for Critical Access Hospitals) and report charges under the respective revenue code 0634 for EPO less than 10,000 units and revenue code 0635 for EPO over 10,000 units. 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. Value code 49 must be reported with the hematocrit value for the hospital outpatient visits prior to January 1, 2006, and for all claims with dates of service on or after January 1, 2008.

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.

60.4.6.5 - Payment for Darbepoetin Alfa (Aranesp) in the Hospital Outpatient Department

(Rev. 2582, Issued: 11-02-12, Effective: 04-01-13, Implementation: 04-01-13)

When ESRD patients come to the hospital for an unscheduled or emergency dialysis treatment they may also require the administration of Aranesp. For patients with ESRD who are on a regular course of dialysis, Aranesp administered in a hospital outpatient department is paid the MMA Drug Pricing File rate. Effective January 1, 2005, Aranesp will be paid based on the ASP Pricing File.

Hospitals use bill type 13X (or 85X for Critical Access Hospitals) and report charges under revenue code 0636. The total number of units as a multiple of 1mcg is placed in the unit field. Value code 49 must be reported with the hematocrit value for the hospital outpatient visits prior to January 1, 2006, and for all claims with dates of service on or after January 1, 2008.

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 Method I 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 declot 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., declotting 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 that 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.

120 - Renal Transplantation and Related Services

(Rev. 1341, Issued: 09-21-07, Effective: 06-28-07, Implementation: 10-22-07)

Renal transplantation is a principal form of treatment available to patients with end-stage renal disease. See Medicare Provider Reimbursement Manual, Part I, §§2771, for a description of related payment policies. For a list of approved facilities, refer to the following Web site:

http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandComplianc/Transplant.html

120.1 - Payment for Immunosuppressive Drugs Furnished to Transplant Patients
(Rev. 1, 10-01-03)

A. General

Effective January 1, 1987, Medicare pays for FDA approved self-administered immunosuppressive drugs. Generally, under this benefit, payment is made for self-administered immunosuppressive drugs that are specifically labeled and approved for marketing as such by the FDA, as well as those prescription drugs, such as prednisone, that are used in conjunction with immunosuppressive drugs as part of a therapeutic regimen reflected in FDA approved labeling for immunosuppressive drugs. This benefit is subject to the Part B deductible and coinsurance provision. There is no time limitation on the coverage of these drugs; however, if a beneficiary loses Medicare coverage as a result of the transplant, the drugs are no longer covered. When the beneficiary reaches the age of 65 and becomes entitled, that person can have the drugs covered again. The hospital pharmacy must ask the physician to furnish the patient with a non-refillable 30-day prescription for the immunosuppressive drugs. This is because the dosage of these drugs frequently diminishes over a period of time, and it is not uncommon for the physician to change the prescription from one drug to another because of the patient's needs. Also, these drugs are expensive, and the coinsurance liability on unused drugs could be a financial burden to the beneficiary. Unless there are special circumstances, the A/B MAC (A) and A/B MAC (B) do not consider a supply of drugs in excess of 30 days to be reasonable and necessary and limits payment accordingly.

B. Payment

Payment is made on a reasonable cost basis if the beneficiary is the outpatient of a participating hospital. In all other cases, payment is made on an allowable charge basis.

C. FDA Approved Drugs

Some of the most commonly prescribed immunosuppressive drugs are:

- Sandimmune (cyclosporine), Sandoz Pharmaceutical (oral or parenteral),
- Imuran (azathioprine), Burroughs Wellcome Vial (oral),
- Atgam (antithymocyte/globulin), Upjohn (parenteral); and
- Orthoclone OKT3 (muromonab - CD3) Ortho Pharmaceutical (parenteral).

Also covered are prescription drugs used in conjunction with immunosuppressive drugs as part of a therapeutic regimen reflected in FDA approved labeling for immunosuppressive drugs.

The payment for the drug is limited to the cost of the most frequently administered dosage of the drug (adjusted for medical factors as determined by the physician).

Consult such sources as the Drug Topics Red Book, American Druggists Blue Book, and Medispan, realizing that substantial discounts are available.

130 - Physicians and Supplier (Nonfacility) Billing for ESRD Services - General

(Rev. 3053, Issued: 08-28-14, Effective: ICD-10: Upon Implementation of ICD-10; ASC X12: 01-01, 12, Implementation ICD-10: Upon Implementation of ICD-10; ASC X12: 09-30-14)

Payment for renal-related physicians' services to ESRD patients is made in either of the following ways:

- Under the Monthly Capitation Payment (MCP) (see §140 below for an explanation of the MCP); or
- Using the daily codes for ESRD services (CPT codes 90922-90925) with units that represent the number of days services were furnished.
- Under the Initial method (IM)

The A/B MAC (B) receives bills from physicians for services furnished ESRD beneficiaries.

The A/B MAC (A) receives bills from ESRD facilities.

Lab bills from CLIA certified independent dialysis facilities were billed to the A/B MAC (B) before September 1, 1997, and to the A/B MAC (A) beginning on that date. Other certified labs bill the A/C MAC (B).

130.1 - Initial Method for Physician's Services to Maintenance Dialysis Patients

(Rev. 1, 10-01-03)

Under the Initial Method (IM), do not pay for physician's routine professional dialysis services. Instead, the dialysis facility's A/B MAC (A) pays the dialysis facility for them as part of the facility's composite rate. Physician's professional services that are not routine professional dialysis services are billed to the contractor and paid in the same way as any other Medicare covered physician professional service.

1. For the physician to be paid under the IM, the following requirements must be met:

All physicians of the facility must choose the IM with respect to all of the patients treated at the facility and all of the facility's Method I home dialysis patients. (See §70.1 for a description of Method I). All of the facility's physicians must file a written statement with their A/B MAC (B) and the facility's A/B MAC (A) to this effect. For example:

> The physicians practicing at _____ dialysis facility are listed below. The signature of each physician indicates the physician's election to be paid for their routine professional dialysis services under the Initial Method. This election is effective for services furnished beginning with the second month after the month in which this statement is filed with the A/B MAC (B) and the facility's A/B MAC (A).

This written statement must be signed and dated by each physician.

2. The physician may bill the A/B MAC (B) only those physician's professional services that are not routine professional dialysis services. (See paragraph 3 below).

The election of the IM is effective for services furnished beginning with the second calendar month after the month in which all the physicians of a facility elect it. A physician may terminate the election by written notice to the A/B MAC (B) and to the facility's A/B MAC (A) that the physician thereby terminates the IM. If the A/B MAC (B) and the A/B MAC (A) receive the termination notice on or before November 1, it is effective the following January 1. If the A/B MAC (B) or the A/B MAC (A) receives it after November 1, it is effective January 1 of the second year after the calendar year in which the notice of termination is received. Note that if the IM is terminated by one physician, it is thereby terminated for all physicians at the same facility with respect to the patients treated through that facility.

3. Definitions

A. Administrative Services

Physician services that are differentiated from routine professional services and other physician services. They include supervision, as described in the definition of "supervision of staff," are not related directly to the care of an individual patient and are supportive of the facility as a whole and of benefit to patients in general. Examples of administrative services include supervision of staff, staff training, participation in staff conferences and in the management of the facility, and advising staff on the procurement of supplies.

B. Dialysis Session

The period of time that begins when the patient arrives at the facility and ends when the patient departs from the facility. In the case of home dialysis, the period begins when the patient prepares for dialysis and generally ends when the patient is disconnected from the machine. In this context, a dialysis facility includes only those parts of the building used as a facility. It does not include any areas used as a physician's private office.

C. Medical Direction

Routine professional service that entails substantial direct involvement and the physical presence of the physician in the delivery of services directly to the patient.

D. Routine Professional Services

Physicians' services furnished during a dialysis session and all services listed under "Types of routine professional services" that:

- Are personally furnished by a physician to an individual patient.
- Contribute directly to the diagnosis or treatment of an individual patient.
- Ordinarily must be performed by a physician.

E. Supervision of Staff

Administrative services that do not necessarily require the physician to be present at the dialysis session. It is a general activity primarily concerned with monitoring performance of and giving guidance to other health care personnel (such as nurses and dialysis technicians) who deliver services to patients.

F. Types of Routine Professional Services

Routine professional services include at least the following services when medically appropriate:

- Visits to the patient during dialysis, and in conjunction with review of laboratory test results,

- Nurses' notes and any other medical documentation, as a basis for:

    - Adjustment of the patient's medication, diet or the dialysis procedure;

    - Prescription of medical supplies; and

    - Evaluation of the patient's psychosocial status and the appropriateness of the modality,

- Medical direction of staff in delivering services to a patient during a dialysis session, and

- Pre-dialysis and post-dialysis examinations or examinations that could have been furnished on a pre-dialysis or post-dialysis basis.

140 - Monthly Capitation Payment Method for Physicians' Services Furnished to Patients on Maintenance Dialysis

(Rev. 1456, Issued: 02-22-08, Effective: 03-24-08, Implementation: 03-24-08)

Physicians and practitioners managing patients on dialysis (center based) are paid a monthly capitation payment (MCP) for most outpatient dialysis-related physician services furnished to a Medicare end stage renal disease (ESRD) beneficiary. The payment amount varies based on the number of visits provided within each month and the age of the ESRD beneficiary. Physicians and practitioners managing ESRD patients who dialyze at home are paid a single monthly rate based on the age of the ESRD beneficiary, regardless of the number of face-to-face physician or practitioner visits. The MCP is reported once per month for services performed in an outpatient setting that are related to the patients' ESRD.

Physicians and practitioners may receive payment for managing patients on dialysis for less than a full month of care in specific circumstances as discussed in section 140.2. Payment for ESRD related services, less than a full month, is made on a per diem bases.

Payment for ESRD-related services is made at 80 percent of the Medicare approved amount (lesser of the actual charge or applicable Medicare fee schedule amount) after the beneficiary's Part B deductible is met. The beneficiary is responsible for the Part B deductible and the 20 percent coinsurance for physician and practitioner ESRD-related services.

A. Services Included in Monthly Capitation Payment

The following physician services are included in the MCP:

- Assessment of the need for a specified diet and the need for nutritional supplementation for the control of chronic renal failure. Specification of the quantity of total protein, high biologic protein, sodium, potassium, and amount of fluids to be allowed during a given time period. For diabetic patients with chronic renal failure, the prescription usually specifies the number of calories in the diet.

- Assessment of which mode(s) of chronic dialysis (types of hemodialysis or peritoneal dialysis) are suitable for a given patient and recommendation of the type(s) of therapy for a given patient.

- Assessment and determination of which type of dialysis access is best suited for a given patient and arrangement for creation of dialysis access.

- Assessment of whether the patient meets preliminary criteria as a renal transplant candidate and presentation of this assessment to the patient and family.

- Prescription of the parameters of intradialytic management. For chronic hemodialysis therapies, this includes the type of dialysis access, the type and amount of anticoagulant to be employed, blood flow rates, dialysate flow rate, ultrafiltration rate, dialysate temperature, type of dialysate (acetate versus bicarbonate) and composition of the electrolytes in the dialysate, size of hemodialyzer (surface area) and composition of the dialyzer membrane (conventional versus high flux), duration and frequency of treatments, the type and frequency of measuring indices of clearance, and intradialytic medications to be administered. For chronic peritoneal dialysis therapies, this includes the type of peritoneal dialysis, the volume of dialysate, concentration of dextrose in the dialysate, electrolyte composition of the dialysate, duration of each exchange, and addition of medication to the dialysate, such as heparin, and the type and frequency of measuring indices of clearance. For diabetics, the quantity of insulin to be added to each exchange is prescribed.

- Assessment of whether the patient has significant renal failure-related anemia, determination of the etiology(ies) for the anemia based on diagnostic tests, and prescription of therapy for correction of the anemia, such as vitamins, oral or parenteral iron, and hormonal therapy such as erythropoietin.

- Assessment of whether the patient has hyperparathyroidism and/or renal osteodystrophy secondary to chronic renal failure and prescription of appropriate therapy, such as calcium and phosphate binders for control of hyperphosphatemia. Based upon assessment of parahormone levels, serum calcium levels, and evaluation for the presence of metabolic bone disease, the physician determines whether oral or parenteral therapy with vitamin D or its analogs is indicated and prescribes the appropriate therapy. Based upon assessment and diagnosis of bone disease, the physician may prescribe specific chelation therapy with deferoxamine and the use of hemoperfusion for removal of aluminum and the chelation.

- Assessment of whether the patient has dialysis-related arthropathy or neuropathy and adjustment of the patient's prescription accordingly. Referral of the patient for any additional needed specialist evaluation and management of these end-organ problems.

- Assessment of whether the patient has fluid overload resulting from renal failure and establishment of an estimated "ideal (dry) weight." The physician determines the need for fluid removal independent of the dialysis prescription and implements these measures when indicated.

- Determination of the need for and prescription of antihypertensive medications and their timing relative to dialysis when the patient is hypertensive in spite of correction of fluid overload.

- Periodic review of the dialysis records to ascertain whether the patient is receiving the prescribed amount of dialysis and ordering of indices of clearance, such as urea kinetics, in order to ascertain whether the dialysis prescription is producing adequate dialysis. If the indices of clearance suggest that the prescription requires alteration, the physician orders changes in the hemodialysis prescription, such as blood flow rate, dialyzer surface area, dialysis frequency, and/or dialysis duration (length of treatment). For peritoneal dialysis patients, the physician may order changes in the volume of dialysate, dextrose concentration of the dialysate, and duration of the exchanges.

- Periodic visits (at least one per month) to the patient during dialysis to ascertain whether the dialysis is working well and whether the patient is tolerating the procedure well (physiologically and psychologically). During these visits, the physician determines whether alteration in any aspect of a given patient's prescription is indicated, such as changes in the estimate of the patient's dry weight. Review of the treatment with the nurse or technician performing the therapy is also included. The frequency of these visits will vary depending upon the patient's medical status, complicating conditions, and other determinants.

- Performance of periodic physical assessments, based upon the patient's clinical stability, in order to determine the necessity for alterations in various aspects of the patient's prescription. Similarly, the physician reviews the results of periodic laboratory testing in order to determine the need for alterations in the patient's prescription, such as changes in the amount and timing of phosphate binders or dose of erythropoietin.

- Periodic assessment of the adequacy and function of the patient's dialysis access appropriate tests and antibiotic therapy.

- Interpretations of the following tests:

    - Bone mineral density studies (CPT codes 76070, 76075, 78350, and 78351);

    - Noninvasive vascular diagnostic studies of hemodialysis access (CPT codes 93925, 93926, 93930, 93931, and 93990);

    - Nerve conduction studies (CPT codes 95900, 95903, 95904, 95925, 95926, 95927, 95934, 95935, and 95936);

    - Electromyography studies (CPT codes 95860, 95861, 95863, 95864, 95867, 95867, 95869, and 95872).

- Periodic review and update of the patient's short-term and long-term care plans with staff.

- Coordination and direction of the care of patients by other professional staff, such as dieticians and social workers.

- Certification of the need for items and services such as durable medical equipment and home health care services. Care plan oversight services described by CPT code 99375 are included in the MCP and may not be separately reported.

B. Services Excluded from Monthly Capitation Payment

The following physician services furnished to the physician's ESRD patients are excluded from the MCP and should be paid in accordance with the physician fee schedule:

1. Administration of hepatitis B vaccine.

2. Surgical services such as:

    - Temporary or permanent hemodialysis catheter placement;
    - Temporary or permanent peritoneal dialysis catheter placement;
    - Repair of existing dialysis accesses;
    - Placement of catheter(s) for thrombolytic therapy;
    - Thrombolytic therapy (systemic, regional, or access catheter only; hemodialysis or peritoneal dialysis);
    - Thrombectomy of clotted cannula;
    - Arthrocentesis;
    - Bone marrow aspiration; and
    - Bone marrow biopsy.

3. Interpretation of tests that have a professional component such as:

    - Electrocardiograms (12 lead, Holter monitor, stress tests, etc.);
    - Echocardiograms;
    - 24-hour blood pressure monitor;
    - Biopsies; and
    - Spirometry and complete pulmonary function tests.

4. Complete evaluation for renal transplantation. While the physician assessment of whether the patient meets preliminary criteria as a renal transplant candidate is included under the MCP, the complete evaluation for renal transplantation is excluded from the MCP

5. Evaluation of potential living transplant donors.

6. The training of patients to perform home hemodialysis, self hemodialysis, and the various forms of self peritoneal dialysis.

7. Non-renal related physician's services. These services may be furnished by the physician providing renal care or by another physician. They may not be incidental to services furnished during a dialysis session or office visit necessitated by the renal condition. The physician must provide documentation that the illness is not related to the renal condition and that the added visits are required. The contractor's medical staff determines whether additional reimbursement is warranted for treatment of the unrelated illness. For example, the medical management of diabetes mellitus that is not related to the dialysis or furnished during a dialysis session is excluded.

8. Covered physician services furnished to hospital inpatients.

9. All physician services that antedate the initiation of outpatient dialysis.

10. Covered physician services furnished by another physician when the patient is not available to receive the outpatient services as usual; for example, when the patient is traveling out of town.

140.1 - Payment for ESRD-Related Services Under the Monthly Capitation Payment (Center Based Patients)

(Rev. 2269, Issued: 08-05-11, Effective: 01-01-11, Implementation: 11-07-11)

Physicians and practitioners managing center based patients on dialysis are paid a monthly rate for most outpatient dialysis-related physician services furnished to a Medicare ESRD beneficiary. The payment amount varies based on the number of visits provided within each month and the age of the ESRD beneficiary. Under this methodology, separate codes are billed for providing one visit per month, two to three visits per month and four or more visits per month. The lowest payment amount applies when a physician provides one visit per month; a higher payment is provided for two to three visits per month. To receive the highest payment amount, a physician or practitioner would have to provide at least four ESRD-related visits per month. The MCP is reported once per month for services performed in an outpatient setting that are related to the patients' ESRD.

The physician or practitioner who provides the complete assessment, establishes the patient's plan of care, and provides the ongoing management is the physician or practitioner who submits the bill for the monthly service.

a. Month defined.

For purposes of billing for physician and practitioner ESRD related services, the term 'month' means a calendar month. The first month the beneficiary begins dialysis

treatments is the date the dialysis treatments begin through the end of the calendar month. Thereafter, the term 'month' refers to a calendar month.

b. Determination of the age of beneficiary.

The beneficiary's age at the end of the month is the age of the patient for determining the appropriate age related ESRD-related services code.

c. Qualifying Visits Under the MCP

- General policy.

Visits must be furnished face-to-face by a physician, clinical nurse specialist, nurse practitioner, or physician's assistant.

- Visits furnished by another physician or practitioner (who is not the MCP physician or practitioner).

The MCP physician or practitioner may use other physicians or qualified nonphysician practitioners to provide some of the visits during the month. The MCP physician or practitioner does not have to be present when these other physicians or practitioners provide visits. In this instance, the rules are consistent with the requirements for hospital split/shared evaluation and management visits. The non-MCP physician or practitioner must be a partner, an employee of the same group practice, or an employee of the MCP physician or practitioner. For example, the physician or practitioner furnishing visits under the MCP may be either a W-2 employee or 1099 independent contractor.

When another physician is used to furnish some of the visits during the month, the physician who provides the complete assessment, establishes the patient's plan of care, and provides the ongoing management should bill for the MCP service.

If the nonphysician practitioner is the practitioner who performs the complete assessment and establishes the plan of care, then the MCP service should be billed under the PIN of the clinical nurse specialist, nurse practitioner, or physician assistant.

- Residents, interns and fellows.

Patient visits by residents, interns and fellows enrolled in an approved Medicare graduate medical education (GME) program may be counted towards the MCP visits if the teaching MCP physician is present during the visit.

- Patients designated/admitted as hospital observation status.

ESRD-related visits furnished to patients in hospital observation status that occur on or after January 1, 2005, should be counted for purposes of billing the MCP codes. Visits

furnished to patients in hospital observation status are included when submitting MCP claims for ESRD-related services.

- ESRD-related visits furnished to beneficiaries residing in a SNF.

ESRD-related visits furnished to beneficiaries residing in a SNF should be counted for purposes of billing the MCP codes.

- SNF residents admitted as an inpatient.

Inpatient visits are not counted for purposes of the MCP service. If the beneficiary residing in a SNF is admitted to the hospital as an inpatient, the appropriate inpatient visit code should be billed.

140.1.1 - Payment for Managing Patients on Home Dialysis
(Rev. 2269, Issued: 08-05-11, Effective: 01-01-11, Implementation: 11-07-11)

Physicians and practitioners managing ESRD patients who dialyze at home are paid a single monthly rate based on the age of the beneficiary. The MCP physician (or practitioner) must furnish at least one face-to-face patient visit per month for the home dialysis MCP service. Documentation by the MCP physician (or practitioner) should support at least one face-to-face encounter per month with the home dialysis patient. Medicare contractors may waive the requirement for a monthly face-to-face visit for the home dialysis MCP service on a case by case basis, for example, when the nephrologist's notes indicate that the physician actively and adequately managed the care of the home dialysis patient throughout the month. The management of home dialysis patients who remain a home dialysis patient the entire month should be coded using the ESRD-related services for home dialysis patients HCPCS codes.

a. Month defined.

For purposes of billing for physician and practitioner ESRD related services, the term 'month' means a calendar month. The first month the beneficiary begins dialysis treatments is the date the dialysis treatments begin through the end of the calendar month. Thereafter, the term 'month' refers to a calendar month.

b. Qualifying Visits under the MCP

- General policy.

Visits must be furnished face-to-face by a physician, clinical nurse specialist, nurse practitioner, or physician's assistant.

- Visits furnished by another physician or practitioner (who is not the MCP physician or practitioner).

The MCP physician or practitioner may use other physicians or qualified nonphysician practitioners to provide the visit(s) during the month. The MCP physician or practitioner does not have to be present when these other physicians or practitioners provide visit(s). The non-MCP physician or practitioner must be a partner, an employee of the same group practice, or an employee of the MCP physician or practitioner. For example, the physician or practitioner furnishing visits under the MCP may be either a W-2 employee or 1099 independent contractor.

When another physician is used to furnish some of the visits during the month, the physician who provides the complete assessment, establishes the patient's plan of care, and provides the ongoing management should bill for the MCP service.

If the nonphysician practitioner is the practitioner who performs the complete assessment and establishes the plan of care, then the MCP service should be billed under the PIN of the clinical nurse specialist, nurse practitioner, or physician assistant.

- Residents, interns and fellows.

Patient visits by residents, interns and fellows enrolled in an approved Medicare graduate medical education (GME) program may be counted towards the MCP visits if the teaching MCP physician is present during the visit.

140.1.2 - Patients Who Switch Modalities (Center to Home and Vice Versa)

(Rev. 1999, Issued: 07-09-10, Effective: 01-01-11, Implementation: 01-03-11)

If a home dialysis patient receives dialysis in a dialysis center or other outpatient facility during the month, the MCP physician or practitioner is paid the management fee for the home dialysis patient and cannot bill the ESRD-related services codes for managing center based patients.

This situation should be coded using the ESRD–related services codes for a home dialysis patient per full month. Physicians and practitioners should use the ESRD–related services codes for a home dialysis patient per full month when billing for outpatient ESRD-related services when a home dialysis patient receives dialysis in a dialysis center or other outpatient facility during the month.

Physicians and practitioners should use the ESRD–related services codes for a home dialysis patient per full month for patients that switch modalities regardless of whether the ESRD beneficiary went from home dialysis to center-based dialysis, or vice versa, and regardless of the proportion of the month that the beneficiary was receiving each modality.

140.2 - Payment for ESRD-related services (Per Diem)

(Rev. 1456, Issued: 02-22-08, Effective: 03-24-08, Implementation: 03-24-08)

Physicians and practitioners may receive payment for managing patients on dialysis for less than a full month of care in specific circumstances as discussed in this section. Payment for ESRD related services, less than a full month, is paid on a per diem basis.

Per diem ESRD-related services should be coded using the ESRD related services (less than full month), per day HCPCS codes for ESRD-related services furnished in the situations described below.

- Home dialysis patients (less than full month);
- Transient patients – Patients traveling away from home (less than full month);
- Partial month where there was one or more face-to-face visits without a complete assessment of the patient and the patient was either hospitalized before a complete assessment was furnished, dialysis stopped due to death, or the patient had a transplant.
- Patients who have a permanent change in their MCP physician during the month.

The ESRD-related services (less than full month), per day HCPCS codes should only be used for the circumstances described above. The per diem codes may not be used for a full month when a complete monthly assessment is not furnished.

140.2.1 - Guidelines for Physician or Practitioner Billing -- (Per Diem)

(Rev. 3311, Issued: 08-06-15, Effective: 01-01-15, Implementation: 09-08-15)

A. Home dialysis, transient patient and partial month

When submitting claims for ESRD-related services (less than full month) per day, the physician or practitioner should specify the number of days he or she was responsible for the beneficiary's outpatient ESRD-related services during the month.

Only one code should be used to report the daily management of home dialysis patients, transient patients, and for partial month scenarios. For example, if a home dialysis patient receives dialysis at home for two weeks and is hospitalized for the remainder of the month, then 14 units of the age appropriate ESRD-related per day code is billed. The MCP service is not billed.

For transient patients, the physician or practitioner responsible for the transient patient's ESRD-related care should bill the appropriate ESRD-related services, per day code. Only the physician or practitioner responsible for the traveling ESRD patient's care is permitted to bill for ESRD-related services using the per diem ESRD-related services HCPCS codes.

For home dialysis patients (less than full month) if the MCP physician or practitioner furnishes a complete monthly assessment of the ESRD beneficiary and at least one face-

to-face patient visit during the month, he or she should bill for the age appropriate home dialysis MCP service. For example, if a home dialysis patient was hospitalized during the month and at least one face-to-face outpatient visit and complete monthly assessment was furnished, the MCP physician or practitioner should bill for the full home dialysis MCP service.

For partial month scenarios resulting from hospitalization, kidney transplant, or the patient expired, if the MCP physician or practitioner furnished a complete monthly assessment of the patient, he or she should bill using the age appropriate MCP service that reflects the number of visits furnished during the month.

Example #1: An ESRD beneficiary was hospitalized on the tenth through the twentieth day of the month. On the third day of the month, the MCP physician or practitioner furnished a face-to-face visit including a complete assessment and a subsequent outpatient visit on the twenty-fifth day of the month. While the patient was hospitalized, an inpatient ESRD-related visit was furnished.

In this scenario, the MCP physician or practitioner may bill for the appropriate outpatient MCP service based on the age of the beneficiary and number of visits furnished during the month. The physician or practitioner who furnished the inpatient visit may bill for the appropriate inpatient ESRD-related service code.

Example #2: An ESRD beneficiary vacationing in Florida is away from his or her home dialysis site from August fifteenth through September seventh. On August tenth, the MCP physician furnishes a face-to-face visit. For the month of September, the MCP physician furnishes a visit on the ninth and a subsequent visit on the twenty-fifth of the month. A physician in Florida is responsible for the beneficiary's ESRD-related care from August fifteenth through September seventh.

In this scenario, the physician or practitioner responsible for the transient patient's ESRD-related care bills sixteen units of the age appropriate ESRD-related services for dialysis less than full month, per day code for the month of August and seven units of the per day code for the month of September. The MCP physician bills the MCP service with one visit for the month of August and the MCP service with two to three visits for the month of September.

If the transient beneficiary is under the care of a physician or practitioner other than his or her regular MCP physician for an entire calendar month, the physician or practitioner responsible for the transient patient's ESRD-related care must furnish a complete assessment and bill for ESRD-related services under the MCP.

B. Patient has a permanent change in their MCP physician during the month

ESRD-related services (less than full month) per day HCPCS codes should be billed in situations where an ESRD beneficiary permanently changes their MCP physician during the month. For example, the new MCP physician has the ongoing responsibility for the

evaluation and management of the patient's ESRD-related care and is not part of the same group practice or an employee of the first MCP physician. The new MCP physician should use the appropriate per diem HCPCS code when submitting claims for ESRD-related services for the remainder of the month, when the first MCP physician furnishes a complete assessment of the beneficiary during the month.

If the first MCP physician does not furnish a complete assessment of the patient during the month the patient permanently changes their MCP physician, the new MCP physician may bill for the appropriate MCP service based on the age of the patient and number of visits furnished and the first MCP physician may bill the appropriate per day HCPCS code as discussed above.

Example: An ESRD patient residing in Virginia Beach, Virginia for the first 20 days of the month, moves to Atlanta, Georgia. As a result, a different physician or practitioner is now responsible for the ongoing management of the beneficiary's ESRD-related care. Both the first and second MCP physician furnishes a visit with a complete assessment of the patient and establishes a monthly plan of care. In this situation, the first MCP physician should bill the MCP service that reflects the number of visits he or she furnished during the month and the second MCP physician should bill the age appropriate per day ESRD-related services code. Thereafter, the new MCP physician would bill for the MCP service.

In this example, if the first MCP physician does not provide a complete assessment of the patient, he or she should bill 20 units of the per day ESRD-related services code, but may not bill for the MCP during the month the beneficiary permanently changes his or her MCP physician. The second MCP physician may bill for the MCP service after furnishing a complete monthly assessment of the ESRD beneficiary that includes establishing the patient's plan of care and at least one face-to-face visit.

140.3 - Data Elements Required on Claim for Monthly Capitation Payment

(Rev. 10236, Issued: 07-31-2020, Effective: 08-31-2020, Implementation: 08-31-2020)

On Form CMS-1500

A. Elements 1 through 13 of the Form CMS-1500 are completed in accordance with the regular instructions

B. Elements 14 through 20 of the Form CMS-1500 are omitted.

C. Element 32 must contain the name and address of the facility involved with the patient's maintenance care or training, and 32a must contain the facility NPI.

D. Element 21 must show the diagnosis. Indicate in Element 19 whether the patient is in training for self-dialysis.

E. Element 24A must show the dates of service during the month that are included in the MCP. The period includes the full calendar month the MCP physician or practitioner was responsible for the beneficiary's ESRD related care.

For the first month the beneficiary begins dialysis treatments, the first date the dialysis treatments begin through the end of the calendar month should be used as the dates of service.

For outpatient ESRD-related services furnished for less than a full month, per day as discussed in 140.2 (e.g. transient patients, partial month due to hospitalization, transplant, or death), the first and last date the physician or practitioner was responsible for the beneficiary's ESRD-related care during the month should be used as the dates of service. Non-continuous dates should be billed on separate claim lines, (e.g. 1/1/08 – 1/7/08 and 1/20/08 – 1/31/08). A separate monthly claim should be submitted when the duration of ESRD-related services, per day, overlaps two different months as discussed in 140.21 (e.g. August 15 - September 7).

F. The remainder of the Form CMS-1500 is completed in accordance with the general instructions.

On ASC X12 Professional Format

Instructions for completing the ASC X12 837 professional claim format are in the related implementation guide, available on the official Washington Publishing Company website.

140.4 - Controlling Claims Paid Under the Monthly Capitation Payment Method

(Rev. 1456, Issued: 02-22-08, Effective: 03-24-08, Implementation: 03-24-08)

Contractors must be able to identify dialysis patient history records and physicians who furnish services related to dialysis.

In processing claims reimbursed under this method, contractors must assure that:

- Only one monthly payment is made for any renal disease patient per month;
- The MCP payment is made after the month has passed; i.e., do not pay the MCP in advance of the services actually furnished;
- The payment amount is based on the age of the beneficiary and the number of visits furnished during a calendar month (center based patients);
- Duplicate charges billed as a duplicate MCP or as separate charges for services covered by the monthly payment are denied;

- Where several physicians or practitioners form a team to provide the monthly continuity of services to a group of patients, make only one monthly payment for each patient.

- Concurrent services by another physician or practitioner who is part of the MCP practice team are covered and reimbursed separately only for services not included in the MCP (e.g. a visit not related to managing the patients ESRD); and

- If payment for inpatient hospital services is claimed in addition to the MCP, and assignment is taken only with respect to the MCP, follow the instructions in Pub. 100-04, chapter 1, §30.3.12.3.

Contractors must conduct periodic review of a randomly selected sample of patients' histories with reimbursement under the MCP method, to evaluate whether the number of and types of services billed separately from the MCP are appropriate considering the individual patient's medical condition.

Make separate payments for medically necessary services that are included or bundled into the MCP (e.g., test interpretations) when furnished by physicians other than the monthly capitation payment physician. According to the Renal Physicians Association, these test interpretations are billed separately only in rare circumstances.

150 - Physician's Self-Dialysis Training Services
(Rev. 1, 10-01-03)

Pay physicians for physician training services furnished to dialysis patients undergoing training by a flat fee of $500 (subject to the deductible and coinsurance requirements) for each patient under the physician's supervision during the training course. Pay this upon completion of the training course in addition to the monthly capitation payment for physician's maintenance dialysis services. If the training period is not completed, such as in instances where the patient can no longer be trained, prorate the training rate in proportion to the number of training treatments completed, but not to exceed $500. For purposes of this pro-ration, consider 25 training treatments as a complete course of training. Therefore, for an incomplete training course, pay the physician for the training services based on an amount of $20 per treatment times the number of treatments completed. This rule applies to all modes of treatment, including CAPD.

Occasionally, it is necessary to furnish additional training to an ESRD self-dialysis beneficiary after the initial training course is completed; e.g., because of a change from hemodialysis to peritoneal dialysis, a change in equipment. The amount of additional training required depends upon the transferability of the skills the patient has already learned; subsequent training would normally be very limited. Physicians' training services furnished during subsequent training of an ESRD beneficiary are covered and reimbursed in addition to the initial training fee.

Subsequent training sessions that are reimbursable under this rule must be distinguished from the ongoing services for which the original training fee is considered payment in full; e.g., answering the patient's questions arising after home dialysis has begun about the machine the patient has already been trained to use. No additional payment is made after the initial training course unless the subsequent training is required because of a change from the patient's treatment machine to a machine that he had not been trained to use in the initial training course, a change in the type of dialysis, or a change in setting or dialysis partner.

160 - Payment for Physician's Services Furnished to Dialysis Inpatients
(Rev. 1, 10-01-03)

The following instructions cover physicians services to inpatients for all types of dialysis patients; e.g., hemodialysis, intermittent peritoneal dialysis (IPD), continuous ambulatory peritoneal dialysis (CAPD), and continuous cycling peritoneal dialysis (CCPD). Note that the hospitalization need not be related to dialysis.

Payment is made on the claim only if the place of service on the claims is inpatient hospital. See §170 for proper HCPCS coding.

160.1 - Determining Whether Physician Services Furnished on Day of Dialysis
(Rev. 1, 10-01-03)

If the patient is admitted to a hospital to receive dialysis for a reason not related to the patient's ESRD condition (e.g., there was no space available in the dialysis unit), the dialysis is covered as an outpatient service. In this case, A/B MACs (B) do not pay separately for any physicians' ESRD services because these services are covered under the physician's MCP or under the add-on to the hospital's composite rate for physicians under the initial method. (See §130.1 for a description of the initial method.)

160.2 - Physicians' Services Furnished on Day of Dialysis
(Rev. 1, 10-01-03)
B3-15062.1

Supervision or direction of a dialysis treatment by a physician does not ordinarily meet the requirements for physicians' services and, therefore, is not paid for as such under the fee schedule. However, physicians are responsible for the medical care and treatment of the dialysis patients. Physicians' services furnished to those patients that meet the requirements and are medically necessary are covered. The hospital medical record must document the services furnished and the medical reasons for them.

Generally, claims from the physician receiving a procedure code payment for additional services furnished to the same patient on the day of dialysis must be reviewed by medical staff prior to payment. Follow §170.B for dialysis and evaluation and management services performed on the same day.

Payment in addition to the procedure code payment is made only if the service is not related to the treatment of the patient's ESRD, and the service was not, and could not have been, furnished during the dialysis treatment. However, an exception to this rule is physicians' surgical services; e.g., catheter insertion. Physicians' surgical services are generally billed under the appropriate procedure code for payment. If more than one physician furnishes care to the same dialysis patient, follow the usual coverage rules on concurrent care.

160.3 - Physicians' Services Furnished on Non-Dialysis Days
(Rev. 1, 10-01-03)

Physicians' services furnished on non-dialysis days are coded and paid under the same rules as any other physicians' services when non-renal related services are furnished. Renal-related services may also be paid if the physician chooses to prorate the MCP payment. Generally, these services are the physicians' hospital visits and are coded and paid as such.

160.4 - Requirements for Payment
(Rev. 1, 10-01-03)

A. General

When paying for physicians' services furnished to dialysis inpatients, whether they are ESRD patients or acute dialysis patients, there are several factors to consider.

- The payment must be for covered physicians' services;
- The services must be medically necessary; and
- The payment for the services must be reasonably related to the nature of the services actually furnished.

B. Physicians' Services - Criteria for Procedure Codes

The procedure code covers the full range of physicians' renal-related services furnished during an inpatient dialysis treatment.

In order to be paid on the basis of a procedure code, the physician must have been physically present with the patient at some time during the course of the dialysis, and the medical record (e.g., the physician's progress note or the nurse's notes in the patient's hospital medical record) must document this.

If the physician visits the dialysis inpatient on a dialysis day, but not during the dialysis treatment, do not pay the physician on the basis of a procedure code. The nature of these services is the same as physicians' services furnished to any inpatient during a hospital

visit. Therefore, use the same hospital visit codes that apply to any other physicians treating hospital inpatients.

Physicians' services furnished to patients who are dialyzed as inpatients because there is no room in the outpatient dialysis units are covered under the MCP, and physicians are not paid amounts in addition to or in place of the MCP.

Effective January 1, 1995, all evaluation and management services provided on the same day as inpatient dialysis codes should be denied without review with the exception of CPT codes 99221-99223, 99251-99255, and 99238. These codes may be billed with modifier "-25" and reviewed for possible allowance if the evaluation and management service is unrelated to the treatment of ESRD and was not and could not have been furnished during the dialysis treatment.

C. Peritoneal Dialysis

Peritoneal dialysis is typically furnished in extended periods. For example, CAPD is continuous, and the patient may actually be dialyzed seven days per week. IPD may be furnished in extended periods of 30 hours or more. The fact that a patient is dialyzed continuously for an extended period does not justify payment in excess of the average weekly allowance made for hemodialysis services. Payment in excess of this amount is made only if it is determined that the same kind and intensity of physicians' hemodialysis treatment beyond the number ordinarily furnished in a 7-day period, and the patient's condition was similar to that of a hemodialysis patient who would have required these additional services.

170 - Billing Physician Dialysis Services (codes 90935 - 90999) and Related Payment

(Rev. 1, 10-01-03)

Except when the MCP applies claims for physicians' inpatient dialysis services furnished to ESRD or acute dialysis patients are processed using physicians' inpatient dialysis services procedure codes 90935, 90937, 90945, and 90947. All A/B MACs (B) must use these codes for these services.

A/B MACs (B) make payment on the basis of ESRD procedure codes, i.e., codes 90935, 90937, 90945, or 90947, only if the place of service on the claim is inpatient hospital. This is because all physicians' outpatient renal-related services are included in payment made under the monthly capitation payment.

A. ESRD Monthly Capitation Payments

Effective January 1, 1995, monthly capitation payments are made under the physician fee schedule. For their adult patients, physicians may bill either the monthly code (CPT code 90921) or the daily code (CPT code 90922) with units that represent the number of days in a single month, but may not bill both.

To bill for a month of services for pediatric patients, providers should bill the appropriate monthly code (CPT codes 90919, 90920, or 90921). To bill for less than a month of service, providers bill the appropriate daily code (CPT codes 90923-90925) and units that represent the number of days. Providers may bill either the monthly code or the daily code, but not both. Since billing is done at the conclusion of the month, the patient's age at the end of month is the age of the patient for billing purposes.

B - Inpatient and Outpatient Dialysis Services On Same Date As An Evaluation and Management Service

CPT codes 90935 and 90937 are used to report inpatient ESRD hemodialysis and outpatient hemodialysis performed on non-ESRD patients (e.g., patients in acute renal failure requiring a brief period of dialysis prior to recovery). CPT codes 90945 and 90947 are used to report all non-hemodialysis procedures. All four of these codes include payment for any evaluation and management services related to the patients renal disease that are provided on the same date as the dialysis service. Therefore, payment for all evaluation and management services is bundled into the payment for 90935, 90937, 90945, and 90947, except for the following evaluation and management services which may be reported on the same date as a dialysis service with the use of the –25 modifier and they are significant and separately identifiable and met any medical necessity requirements:

99201-99205	Office or Other Outpatient Visit for a New Patient
99211-99215	Office or Other Outpatient Visit for an Established Patient
99221-99223	Initial Hospital Care for a New or Established Patient
99238-99239	Hospital Discharge Day Management Services
99241-99245	Office or Other Outpatient Consultations, New or Established Patient
99251-99255	Initial Inpatient Consultations, New or Established Patient
99291-99292	Critical Care Services

In the absence of one of these codes being reported with the –25 modifier and meeting the other requirements listed above, pay only the dialysis service and deny the evaluation and management service. Furthermore, payment is not allowed for more than one dialysis service per day.

180 - Noninvasive Studies for ESRD Patients - Facility and Physician Services

(Rev. 3650, Issued: 11-10-16, Effective: 02-10-17, Implementation: 02-10-17)

For Medicare coverage of noninvasive vascular studies, see the Medicare Benefit Policy Manual, Chapter 11.

For dialysis to take place there must be a means of access so that the exchange of waste products may occur. As part of the dialysis treatment, ESRD facilities are responsible for

monitoring access, and when occlusions occur, either declot the access or refer the patient for appropriate treatment. Procedures associated with monitoring access involve taking venous pressure, aspirating thrombus, observing elevated recirculation time, reduced urea reduction ratios, or collapsed shunt, etc. All such procedures are covered under the composite rate.

ESRD facilities may not monitor access through noninvasive vascular studies such as duplex and Doppler flow scans and bill separately for these procedures. Noninvasive vascular studies are not covered as a separately billable service if used to monitor a patient's vascular access site.

Medicare pays for the technical component of the procedure in the composite payment rate.

Where there are signs and symptoms of vascular access problems, Doppler flow studies may be used as a means to obtain diagnostic information to permit medical intervention to address the problem. Doppler flow studies may be considered medically necessary in the presence of signs or symptoms of possible failure of the ESRD patient's vascular access site, and when the results are used in determining the clinical course of the treatment for the patient.

The only Current Procedural Terminology (CPT) billing code for noninvasive vascular testing of a hemodialysis access site is 93990. A/B MACs (B) must deny separate billing of the technical component of this code if it is performed on any patient for whom the ESRD composite rate for dialysis is being paid, unless there is appropriate medical indication of the need for a Doppler flow study.

When a dialysis patient exhibits signs and symptoms of compromise to the vascular access site, Doppler flow studies may provide diagnostic information that will determine the appropriate medical intervention. Medicare considers a Doppler flow study medically necessary when the beneficiary's dialysis access site manifests signs or symptoms associated with vascular compromise, and when the results of this test are necessary to determine the clinical course of treatment.

Examples supporting the medical necessity for Doppler flow studies include:

a. Elevated dynamic venous pressure >200mm HG when measured during dialysis with the blood pump set on a 200cc/min.,

b. Access recirculation of 12 percent or greater,

c. An otherwise unexplained urea reduction ration <60 oercebtm abd

d. An access with a palpable "water hammer" pulse on examination, (which implies venous outflow obstruction).

Unless the documentation is provided supporting the necessity of more than one study, Medicare will limit payment to either a Doppler flow study or an arteriogram (fistulogram, venogram), but not both.

An example of when both studies may be clinically necessary is when a Doppler flow study demonstrates reduced flow (blood flow rate less than 800cc/min or a decreased flow of 25 percent or greater from previous study) and the physician requires an arteriogram to further define the extent of the problem. The patient's medical record(s) must provide documentation supporting the need for more than one imaging study.

This policy is applicable to claims from ESRD facilities and all other sources, such as independent diagnostic testing facilities, and hospital outpatient departments.

A/B MACs (B) shall develop LMRP for Doppler flow studies if this service meets the criteria listed in the Medicare Program Integrity Manual, Chapter 1. This provides guidance to contractors on the scope, purpose, and meaning of LMRP.

The professional component of the procedure is included in the monthly capitation payment (MCP) (See §140 above.) The professional component should be denied for code 93990 if billed by the MCP physician. Medically necessary services that are included or bundled into the MCP (e.g., test interpretations) are separately payable when furnished by physicians other than the MCP physician.

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 Four.

Group Code: CO
CARC: 24
RARC: N/A
MSN:16.32

Billing for monitoring of hemodialysis access using CPT codes for noninvasive vascular studies other than 93990 is considered a misrepresentation of the service actually provided and contractors will consider this action for fraud investigation. They will conduct data analysis on a periodic basis for noninvasive diagnostic studies of the extremities (including CPT codes 93922, 93923, 93924, 93925, 93926, 93930, 93931, 93965, 93970, 93971). Contractors should handle aberrant findings under normal program safeguard processes by taking whatever corrective action is deemed necessary.

190 - Appeal Rights for Denied Claims

For appeal rights if the claim is denied see Chapter 29.

200 – Utilization of REMIS for A/B MAC (B) Claims Adjudication
(Rev. 82, 02-06-04)

Renal Management Information System (REMIS) determines the Medicare coverage periods for ESRD patients and serves as the primary mechanism to store and access information in the ESRD Program Management and Medical Information System Database. REMIS is used by CMS and the renal community to monitor the Medicare status, transplant activities, dialysis activities, and Medicare utilization of ESRD patients and their Medicare provider.

The following fields are contained in the (Dialysis) auxiliary file:

- **ESRD Coverage Start Date** (The date on which the beneficiary is entitled to Medicare, in some part, because of a diagnosis of End Stage Renal Disease.)

- **ESRD Coverage Source Code** (The source of the information that establishes Medicare-based End-Stage Renal Disease Coverage; A= Part A and Dialysis Training, B= Part A and Dialyzing (No 3 month wait), C= Part A and 3 months after Dialysis, D= Part A and Functioning Transplant, E= Part A and Month of Pre-Transplant Stay, F= Part A and ESRD (Verified Source), Blank= No ESRD Involvement.)

- **ESRD Coverage Termination Date** (The date on which the beneficiary is no longer entitled to Medicare under ESRD Provisions.)

- **ESRD Coverage Termination Reason** (A code that indicates the reason Medicare-based End-Stage Renal Disease Coverage was terminated; codes: A= Month of transplant plus 36 months, B=Last month of chronic dialysis, C= Part A termination, D=Death, E=ESRD ended: other verified source.)

- **ESRD Dialysis Start Date** (A date that indicates when ESRD dialysis started.)

- **ESRD Dialysis Stop Date** (A date that indicates when ESRD dialysis ended.)

- **ESRD Transplant Start Date** (A date that indicates when a kidney transplant operation occurred.)

- **ESRD Transplant Stop Date** (A date that indicates when a kidney transplant failed.)

The above data elements are in CWF and stored in the dialysis auxiliary file, which can be used to identify a beneficiary's ESRD eligibility. This data source will assist carriers in reviewing overpayment determination and accurately processing claims.

Transmittals Issued for this Chapter

Rev #	Issue Date	Subject	Impl Date	CR #
R12517CP	02/22/2024	Update of Internet Only Manual (IOM), Pub. 100-04, Chapter 8 - Outpatient ESRD Hospital, Independent Facility, and Physician/Supplier Claims	03/25/2024	13525
R10640CP	08/06/2021	Update of Internet Only Manual (IOM), Pub. 100-04, Chapter 8 - Outpatient ESRD Hospital, Independent Facility, and Physician/Supplier Claims	09/07/2021	12079
R10236CP	07/31/2020	Update to the IOM Publication (Pub) 100-04, Medicare Claims Processing Manual, Chapters 1, 6, 8, 17, 20, 22, 24, and 31 Referencing the Active Universal Resource Locators (URLs) for the Washington Publishing Company (WPC) and the ASC X12 Organizations, and Updates to the HIPAA Eligibility Transaction System (HETS)	08/31/2020	11857
R4202CP	01/18/2019	Update to Pub. 100-04 Chapters 8, 20, and 24 to Provide Language-Only Changes for the New Medicare Card Project	02/19/2019	10964
R4105CP	08/03/2018	System Changes to Implement Epoetin Alfa Biosimilar, Retacrit for End Stage Renal Disease (ESRD) and Acute Kidney Injury (AKI) Claims	01/07/2019	10839
R4010CP	03/23/2018	Revisions to Medicare Claims Processing Manual for End Stage Renal Disease	06/26/2018	10541
R3650CP	11/10/2016	Updates to Pub. 100-04, Chapters 8, 13 and 14 to Correct Remittance Advice Messages	02/10/2016	9841
R3311CP	08/06/2015	End Stage Renal Disease (ESRD) Home Dialysis Policy	09/08/2015	9265
R3139CP	12/02/2014	Implementation of Changes in the End-Stage Renal Disease Prospective Payment System (ESRD PPS) for Calendar Year (CY) 2015	01/05/2015	8978

Rev #	Issue Date	Subject	Impl Date	CR #
R3125CP	11/14/2014	Implementation of Changes in the End-Stage Renal Disease Prospective Payment System (ESRD PPS) for Calendar Year (CY) 2015 – Rescinded and replaced by Transmittal 3139	01/05/2015	8978
R3116CP	11/06/2014	Elimination of the 50/50 Payment Rule for Laboratory Services on End Stage Renal Disease (ESRD) Claims	04/06/2015	8957
R3053CP	08/28/2014	Update to Pub. 100-04, Chapters 7 and 8 to Provide Language-Only Changes for Updating ICD-10 and ASC X12	09/30/2014	8579
R2905CP	03/14/2014	Update to Pub. 100-04, Chapters 7 and 8 to Provide Language-Only Changes for Updating ICD-10 and ASC X12 – Rescinded and replaced by Transmittal 3053	10/01/2014	8579
R2839CP	12/13/2013	Implementation of Changes in the End-Stage Renal Disease Prospective Payment System (ESRD PPS) for Calendar Year (CY) 2014	01/06/2014	8472
R2831CP	11/29/2013	Implementation of Changes in the End-Stage Renal Disease Prospective Payment System (ESRD PPS) for Calendar Year (CY) 2014 – Rescinded and replaced by Transmittal 2839	01/06/2014	8472
R2688CP	04/26/2013	Reporting End Stage Renal Disease (ESRD) Drugs Administered Through the Dialysate	07/01/2013	8256
R2545CP	01/31/2013	Changes Applicable to the Billing of Drugs on ESRD Claims	07/012013	8174
R2582CP	11/02/2012	New Erythropoietin Stimulating Agent (ESA) Peginesatide Requirements for End Stage Renal Disease (ESRD)	04/01/2013	8050
R2577CP	11/01/2012	Update to the Fiscal Intermediary Shared Systems (FISS) for the End Stage Renal Disease (ESRD) Quality Incentive Program (QIP) Adjustments for Children's Hospitals	04/01/2013	8066

Rev #	Issue Date	Subject	Impl Date	CR #
R2588CP	11/05/2012	Implementation of Changes to the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) Consolidated Billing Requirements and a Clarification of Outlier Services for Calendar Year 2013	01/07/2013	7869
R2504CP	08/02/2012	Implementation of Changes to the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) Consolidated Billing Requirements and a Clarification of Outlier Services for Calendar Year 2013 – Rescinded and replaced by Transmittal 2588	01/07/2013	7869
R2361CP	11/25/2011	Clarification and Revisions for Claims Submitted for End Stage Renal Disease (ESRD) Patients	04/02/2012	7593
R2347CP	11/18/2011	Recoupment of Incorrect Payments Made Under the End Stage Renal Disease (ESRD) Prospective Payment System (PPS) for Low-Volume Payment Adjustment	01/03/2012	7626
R2335CP	10/28/2011	Clarification and Revisions for Claims Submitted for End Stage Renal Disease (ESRD) Patients – Rescinded and replaced by Transmittal 2361	04/02/2012	7593
R2311CP	09/23/2011	Implementation of the MIPPA 153c End Stage Renal Disease (ESRD) Quality Incentive Program (QIP) and Other Requirements for ESRD Claims	01/03/2012	7460
R2281CP	08/19/2011	Implementation of Changes to the End Stage Renal Disease (ESRD) Prospective Payment System (PPS) Outlier Payment Policy and Changes to the ESRD PPS Consolidated Billing Requirements for Laboratory Services Furnished in a Hospital Emergency Room or Department	01/03/2012	7471
R2269CP	08/05/2011	Clarification of Payment for ESRD-Related Services Under the Monthly Capitation Payment	11/07/2011	7520

Rev #	Issue Date	Subject	Impl Date	CR #
R2266CP	07/29/2011	Implementation of Changes to the End Stage Renal Disease (ESRD) Prospective Payment System (PPS) Outlier Payment Policy and Changes to the ESRD PPS Consolidated Billing Requirements for Laboratory Services Furnished in a Hospital Emergency Room or Department – Rescinded and replaced by Transmittal 2281.	01/03/2012	7471
R2262CP	07/29/2011	Implementation of the MIPPA 153c End Stage Renal Disease (ESRD) Quality Incentive Program (QIP) and Other Requirements for ESRD Claims – Rescinded and replaced by Transmittal 2311	01/03/2012	7460
R2195CP	04/22/2011	End Stage Renal Disease (ESRD) Low Volume Adjustment and Establishing Quarterly Updates to the ESRD Prospective Payment System (PPS)	10/03/2011	7388
R2134CP	01/14/2011	End Stage Renal Disease (ESRD) Prospective Payment System (PPS) and Consolidated Billing for Limited Part B Services	01/03/2011	7064
R2094CP	11/17/2010	End Stage Renal Disease (ESRD) Prospective Payment System (PPS) and Consolidated Billing for Limited Part B Services – Rescinded and replaced by Transmittal 2134	01/03/2011	7064
R2033CP	08/20/2010	End Stage Renal Disease (ESRD) Prospective Payment System (PPS) and Consolidated Billing for Limited Part B Services - Rescinded and replaced by Transmittal 2094	01/03/2011	7064
R1999CP	07/09/2010	ESRD Home Dialysis MCP	01/03/2011	7003
R1932CP	03/17/2010	Dialysis Adequacy, Infection and Vascular Access Reporting	07/06/2010	6782

Rev #	Issue Date	Subject	Impl Date	CR #
R1898CP	01/29/2010	Dialysis Adequacy, Infection and Vascular Access Reporting - Rescinded and replaced by Transmittal 1932	07/06/2010	6782
R1655CP	12/31/2008	End Stage Renal Disease (ESRD) Medicare Claims Processing Manual Clarification	02/02/2009	6245
R1648CP	12/12/2008	Implementation of Changes in End Stage Renal Disease (ESRD) Payment for Calendar Year 2009	01/05/2009	6216
R1581CP	08/29/2008	Discarded Erythropoietin Stimulating Agents for Home Dialysis	12/01/2008	6133
R1503CP	05/16/2008	Revisions to the Billing Requirements for ESRD-Related Epoetin Alfa (EPO) and Darbepoetin Alfa (Aranesp) Administration Provided During Unscheduled or Emergency Dialysis Treatments in the Outpatient Hospital Setting	10/06/2008	6047
R1472CP	03/06/2008	Update of Institutional Claims References	04/07/2008	5893
R1456CP	02/22/2008	Manualization of Payment for Outpatient ESRD-Related Services	03/24/2008	5931
R1421CP	01/25/2008	Update of Institutional Claims References - Rescinded and Replaced by Transmittal 1472	04/07/2008	5893
R1412CP	01/11/2008	Reporting of Hematocrit or Hemoglobin Levels on All Claims for the Administration of Erythropoiesis Stimulating Agents (ESAs), Implementation of New Modifiers for Non-ESRD Indications, and Reporting of Hematocrit/Hemoglobin Levels on all Non-ESRD, Non-ESA Claims Requesting Payment for Anti-Anemia Drugs	04/07/2008	5699
R1389CP	12/07/2007	Implementation of Change in End Stage Renal Disease (ESRD) Payment for Calendar Year 2008	01/07/2008	5827

Rev #	Issue Date	Subject	Impl Date	CR #
R1364CP	11/02/2007	Common Working File (CWF) Informational Unsolicited Responses for RDF Claims Overlapping Patient Hospital Stays	04/07/2008	5768
R1341CP	09/21/2007	New Web Site for Approved Transplant Centers	10/22/2007	5724
R1307CP	07/20/2007	Modification to the National Monitoring Policy for Erythropoietic Stimulating Agents (ESAs) for End-Stage Renal Disease (ESRD) Patients Treated in Renal Dialysis Facilities	01/07/2008	5700
R1285CP	07/13/2007	Renal Dialysis Facility Line Item Billing Requirements for Epoetin Alfa (EPO) Submitted on End Stage Renal Disease (ESRD) Claims	01/07/2008	5545
R1212CP	03/30/2007	Requirements for Providing Route of Administration Codes for Erythropoiesis Stimulating Agents (ESAs)	06/29/2007	5480
R1043CP	08/25/2006	Revisions to the EPO/ Aranesp Monitoring Policy	10/02/2006	5251
R1041CP	08/25/2006	(HCPCS) for Renal Dialysis Facilities and Hospitals Billing for End Stage Renal Disease (ESRD) Related Epoetin Alfa (EPO)	01/01/2007	5216
R1007CP	07/28/2006	(HCPCS) for Renal Dialysis Facilities and Hospitals Billing for End Stage Renal Disease (ESRD) Related Epoetin Alfa (EPO)	01/02/2007	5216
R849CP	02/10/2006	Update to the ESRD Composite Payment Rates	02/13/2006	4291
R797CP	12/30/2005	Full Replacement of CR 4095, Diagnosis Code Requirements for Method II Home Dialysis Claims	01/30/2006	4227

Rev #	Issue Date	Subject	Impl Date	CR #
R781CP	12/16/2005	Revised Manual Instructions for Processing End Stage Renal Disease Exceptions Under the Composite Rate Reimbursement System	01/17/2006	4188
R774CP	12/02/2005	Implementation of Change in End Stage Renal Disease Payment for Calendar Year 2006	01/03/2006	4196
R771CP	12/02/2005	Revisions to Pub. 100-04, Medicare Claims Processing Manual in Preparation for the National Provider Identifier	01/03/2006	4181
R751CP	11/10/2005	National Monitoring Policy for EPO and Aranesp for End Stage Renal Disease Patients Treated in Renal Dialysis Facilities	04/03/2006	4135
R737CP	10/31/2005	New ICD-9-CM Code for Beneficiaries with Chronic Kidney Disease and new HCPCS for Reporting Epoetin Alfa and Darbepoetin Alfa	04/03/2006	4108
R736CP	10/31/2005	Clarification and Update to Hospital Billing Instructions and Payment for Epoetin Alfa and Darbepoetin Alfa for Beneficiaries with End Stage Renal Disease	04/03/2006	4103
R725CP	10/21/2005	New ICD-9-CM Code for Beneficiaries with Chronic Kidney Disease	04/03/2006	4108
R721CP	10/21/2005	Use of Value Codes 48 and 49 on End Stage Renal Disease Bills	01/03/2006	4087
R719CP	10/21/2005	Clarification and Update to Hospital Billing Instructions and Payment for Epoetin Alfa and Darbepoetin Alfa (Aranesp) for Beneficiaries with End Stage Renal Disease	04/03/2006	4103
R701CP	10/07/2005	New Diagnosis Code Requirements for Method II Home Dialysis Claims	11/07/2005	4095
R634CP	08/03/2005	Guidelines for Payment of Vaccines (Pneumococcal Pneumonia Virus, Influenza Virus, and Hepatitis B Virus) and their Administration at Renal Dialysis Facilities	01/03/2006	3936

Rev #	Issue Date	Subject	Impl Date	CR #
R610CP	07/22/2005	Guidelines for Payment of Vaccines (Pneumococcal Pneumonia Virus, Influenza Virus, and Hepatitis B Virus) and their Administration at Renal Dialysis Facilities	01/03/2006	3936
R598CP	06/27/2005	Implementation of Carrier Guidelines for End Stage Renal Disease Reimbursement For Automated Multi-Channel Chemistry Test Supplemental To Change Request 2813	01/01/2006	3890
R595CP	06/24/2005	Implementation of Carrier Guidelines for End Stage Renal Disease Reimbursement For Automated Multi-Channel Chemistry Tests Supplemental To Change Request 2813	07/25/3005	3890
R477CP	02/18/2005	New Case-Mix Adjusted End Stage Renal Disease Composite Payment Rates and New Composite Rate Exceptions Window for Pediatric ESRD Facilities	04/04/2005	3720
R447CP	01/21/2005	CWF Editing for Method Selection on DMERC Claims for EPO and Aranesp	07/05/2005	3547
R373CP	11/19/2004	New ESRD Composite Payment Rates Effective January 1, 2005	01/03/2005	3554
R370CP	11/19/2004	New Case-Mix Adjusted End Stage Renal Disease Composite Payment Rates and New Composite Rate Exceptions Window for Pediatric ESRD Facilities	04/04/2005	3572
R257CP	07/30/2004	Informs the FISS to carry at least two Payments Limits for ESRD	01/03/2005	3332
R197CP	06/04/2004	Epoetin Alfa	10/04/2004	3184
R146CP	04/23/2004	Dialysis Provider Number Series	10/04/2004	3176
R118CP	03/05/2004	Epoetin Alfa	04/05/2004	2984
R116CP	03/05/2004	DMERC Claims Processing Instructions	04/05/2004	3019
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R001CP	10/01/2003	Initial Publication of Manual	NA	NA

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