Renal Dialysis Services (Including Hemodialysis) Payment Policy

Applicability

This Policy applies to the following Fallon Health products:
☒ Fallon Medicare Plus, Fallon Medicare Plus Central (Medicare Advantage)
☐ MassHealth ACO
☒ NaviCare HMO SNP
☒ NaviCare SCO (Medicaid-only)
☒ Summit Eldercare PACE
☒ Fallon Health Weinberg PACE
☒ Community Care (Commercial/Exchange)

Policy

This policy applies to ESRD facility billing for renal dialysis services (including hemodialysis) furnished to Fallon Medicare Plus/Plus Central, NaviCare, PACE and Community Care members with end-stage renal disease.

Dialysis is the process of removing waste products from the body by diffusion from one fluid compartment to another across a semi-permeable membrane. The commonly used dialysis procedures include hemodialysis and peritoneal dialysis. Hemodialysis is usually performed at an ESRD facility in 3 to 5 hour sessions, 3 times a week. The commonly used types of peritoneal dialysis include continuous ambulatory peritoneal dialysis (CAPD) and continuous cycling peritoneal dialysis (CCPD).

Outpatient maintenance dialysis is furnished on an outpatient basis by an ESRD facility and is paid under the ESRD Prospective Payment System (PPS). Under the ESRD PPS, certain laboratory services, drugs and biologicals, equipment, and supplies are subject to consolidated billing and are not separately payable. Under consolidated billing, ESRD facilities furnish renal dialysis services, either directly, or under an arrangement with an outside supplier. The list of services subject to ESRD consolidated billing requirements is periodically updated and is available on the CMS website: **ESRD PPS Consolidated Billing**.

Outpatient maintenance dialysis is not acute dialysis. Medicare defines acute dialysis services as dialysis that is not covered or paid under the ESRD benefit in 42 CFR 413.174. For billing of acute dialysis services refer to Medicare Claims Processing Manual, Chapter 4, §200.2.

The Plan provides payment under the ESRD Prospective Payment System (PPS) for all renal dialysis services for outpatient maintenance dialysis when they are furnished to ESRD patients for the treatment of ESRD by an ESRD facility.

The ESRD PPS provides a patient-level and facility-level adjusted single payment to ESRD facilities for renal dialysis services provided in an ESRD facility or in a member's home. (See Definitions below for the items and services considered to be Renal Dialysis Services.) The ESRD PPS combines payment for what had previously been composite rate and separately billable outpatient renal dialysis items and services into a single base rate for both adult and pediatric patients.

The Plan does not allow payment for routine or related dialysis treatments, which are covered and paid under the ESRD PPS, when furnished to ESRD patients in the outpatient department of a hospital. However, in certain medical situations in which the ESRD outpatient cannot obtain his or her regularly scheduled dialysis treatment at a certified ESRD facility, the Plan allows payment for non-routine dialysis treatments (which are not covered under the ESRD benefit) furnished to ESRD outpatients in the outpatient department of a hospital. Payment for unscheduled dialysis furnished to ESRD outpatients and paid under the OPPS is limited to the following

circumstances:

- Dialysis performed following or in connection with a dialysis-related procedure such as vascular access procedure or blood transfusions;
- Dialysis performed following treatment for an unrelated medical emergency; e.g., if a patient goes to the emergency room for chest pains and misses a regularly scheduled dialysis treatment that cannot be rescheduled, CMS allows the hospital to provide and bill Medicare for the dialysis treatment; or
- Emergency dialysis for ESRD patients who would otherwise have to be admitted as inpatients in order for the hospital to receive payment.

In these situations, non-ESRD certified hospital outpatient facilities are to bill the Plan using the Healthcare Common Procedure Coding System (HCPCS) code G0257 (Unscheduled or emergency dialysis treatment for an ESRD patient in a hospital outpatient department that is not certified as an ESRD facility). HCPCS code G0257 may only be reported on type of bill 13X (hospital outpatient service) or type of bill 85X (critical access hospital) because HCPCS code G0257 only reports services for hospital outpatients with ESRD and only these bill types are used to report services to hospital outpatients.

Dialysis services furnished to hospital in-patients are covered under Medicare Part A and paid in accordance with applicable payment rules.

Definitions

Back-Up Dialysis – Dialysis given to patients under special circumstances. Examples are: dialysis of a home dialysis patient in an ESRD facility when the patient's equipment fails, inpatient dialysis when a patient's illness requires more comprehensive care, and preoperative and postoperative dialysis provided to transplant patients.

Dialysis – Dialysis is the process of removing waste products from the body by diffusion from one fluid compartment to another across a semi-permeable membrane. Dialysis procedures can include hemodialysis, peritoneal dialysis, hemofiltration and ultrafiltration. Of these types of dialysis procedures, two are commonly used for the treatment of ESRD: hemodialysis and peritoneal dialysis.

ESRD Facility – An ESRD facility is an entity that provides outpatient maintenance dialysis services, or home dialysis training and support services, or both. ESRD facilities are classified in Section 1881 of the Act and codified in 42 CFR 413.174 as being either hospital-based or independent facilities. There is no distinction between the two facility types for the purposes of payment under the ESRD Prospective Payment System (PPS).

Hemodialysis – Blood passes through an artificial kidney machine and the waste products diffuse across a manmade membrane into a bath solution known as dialysate after which the cleansed blood is returned to the patient's body. Hemodialysis is accomplished usually in 3 to 5 hour sessions, 3 times a week.

Home Dialysis – Dialysis performed at home, including a nursing home, by an ESRD patient or caregiver who has completed an appropriate course of training as specified at 42 CFR §494.100(a).

Hospital-Based ESRD Facilities – As defined in 42 CFR 413.65(a) hospital-based or independent ESRD facilities are not considered part of the hospital and do not qualify as provider-based departments of a hospital. Hospital-based ESRD facilities may be located on a hospital campus and may share certain overhead costs and administrative functions with the hospital. However, hospital-based ESRD facilities have separate provider numbers under which they bill Medicare and are subject to unique Conditions for Coverage that differ from hospital Conditions of Participation. As defined in 42 CFR 413.65(a) hospital-based or independent ESRD facilities are not considered part of the hospital and do not qualify as provider-based departments of a hospital. Hospital-based ESRD facilities may be located on a hospital campus and may share certain overhead costs and administrative functions with the hospital. However, hospital-based ESRD facilities have separate provider numbers under which they bill Medicare and are subject

to unique Conditions for Coverage that differ from hospital Conditions of Participation. Information regarding the survey and certification of ESRD facilities may be found at the following link: **http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Dialysis.html**.

Independent ESRD Facility – Any facility that does not meet the criteria of a hospital-based ESRD facility. There are several terms used to describe independent dialysis facilities which include renal dialysis center, renal dialysis facility, self-dialysis unit, and home dialysis facility.

Peritoneal Dialysis – Waste products pass from the patient's body through the peritoneal membrane into the peritoneal (abdominal) cavity where the bath solution (dialysate) is introduced and removed periodically. Three types of peritoneal dialysis include continuous ambulatory peritoneal dialysis (CAPD), continuous cycling peritoneal dialysis (CCPD), and intermittent peritoneal dialysis (IPD).

Renal Dialysis Services – Renal dialysis services are all items and services used to furnish outpatient maintenance dialysis in the ESRD facility or in a patient's home. Renal dialysis services include but are not limited to:

- All items and services included under the composite rate as of December 31, 2010;
- Erythropoiesis stimulating agents (ESAs) and their oral or other forms of administration that are for the treatment of ESRD;
- Injectable drugs and biologicals and their oral or other forms of administration that are for the treatment of ESRD;
- Oral or other forms of non-injectable drugs and biologicals that are for the treatment of ESRD;
- Diagnostic laboratory tests that are for the treatment of ESRD;
- Home and self-dialysis training; and
- All supplies, equipment, and self-dialysis support services necessary for the effective performance of a patient's dialysis furnished in the ESRD facility or in a patient's home.
    - Support services may include:
        - visits by trained hospital or dialysis facility workers to check on the patient's self-dialysis, to help in emergencies when needed, and to check dialysis equipment and water supply;
        - Monitoring access and related declotting or referring the patient; or
        - Direct nursing services include registered nurses, licensed practical nurses, technicians, social workers, and dietitian.

Services Provided Under an Arrangement – A Medicare-certified ESRD facility may enter into written arrangements with a second ESRD facility to provide certain covered outpatient dialysis items or services to patients. When services are provided under an arrangement, the first ESRD facility retains professional and financial responsibility for those services and also for obtaining reimbursement for them. The first ESRD facility may bill the patient for the applicable coinsurance and deductible amounts. The second ESRD facility is permitted to seek payment only from the first ESRD facility, and may not bill the patient or Medicare.

Reimbursement

ESRD Payment

Section 1881(b)(14) of the Social Security Act requires a bundled prospective payment system (PPS) for renal dialysis services furnished to Medicare beneficiaries for the treatment of ESRD effective January 1, 2011. The ESRD PPS provides a patient-level and facility-level adjusted per treatment (dialysis) payment to ESRD facilities for renal dialysis services provided in an ESRD facility or in a beneficiary's home. The bundled per treatment payment includes drugs, laboratory services, supplies and capital-related costs related to furnishing maintenance dialysis. The ESRD PPS provides a training add-on for home and self-dialysis modalities and additional payment for high cost outliers when there are unusual variations in the type or amount of specific medically necessary care, when applicable.

Under the ESRD PPS, there is a drug designation process to determine whether a newly marketed and available injectable or intravenous drug or biological is or is not included for in the ESRD PPS bundle amount. In addition, as part of the drug designation process, CMS determines when an oral-only renal dialysis service drug or biological is no longer oral-only.

The ESRD PPS provides the Transitional Drug Add-on Payment Adjustment (TDAPA) for new renal dialysis drugs and biological products that qualify under 42 CFR § 413.234. The ESRD PPS also 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 42 CFR § 413.236.

Services Provided Under Arrangement

An ESRD facility may enter into written arrangements with a second ESRD facility to provide certain covered outpatient dialysis items or services to patients. When services are provided under an arrangement, the first ESRD facility retains professional and financial responsibility for those services and also for obtaining reimbursement for them.

1. Laboratory Services

Laboratory Services Included in the ESRD PPS

With the implementation of the ESRD PPS, all laboratory services furnished for the treatment of ESRD are included in the ESRD PPS and not paid separately as of January 1, 2011.

This includes:

- Laboratory tests included under the composite rate as of December 31, 2010; and
- Former separately billable Part B laboratory tests that were billed by ESRD facilities and independent laboratories for ESRD patients.

Prior to the implementation of the ESRD PPS, the costs of certain laboratory tests furnished for outpatient maintenance dialysis by either the ESRD facility's staff or an independent laboratory, were included in the composite rate calculations. Therefore, payment for all of these laboratory tests was included in the ESRD facility's composite rate and the tests could not be billed separately to the Medicare program. All laboratory tests that were included under the composite rate are included in the ESRD PPS and not paid separately under the composite rate portion of the blended payment and are not eligible for outlier payments. Therefore, composite rate laboratory services should not be reported on the claim. Composite rate laboratory tests are listed in Medicare Benefit Policy Manual Chapter 11, Section 20.2.E.1.

Former separately billable Part B laboratory tests are listed in Medicare Benefit Policy Manual Chapter 11, Section 20.2.E.2. ESRD-related lab services that were separately payable under the composite rate payment system are considered in the calculation of any applicable outlier payment under the ESRD PPS. An ESRD facility must report renal dialysis laboratory services on its claims in order for the laboratory tests to be included in the outlier payment calculation. Renal dialysis laboratory services that were or would have been paid separately under Medicare Part B prior to January 1, 2011, are priced for the outlier payment calculation using the Clinical Laboratory Fee Schedule. Further information regarding the outlier policy can be found in Medicare Benefit Policy Manual Chapter 11, Section 60.D. An ESRD facility is eligible for an outlier payment if its actual or imputed Medicare Allowable Payment (MAP) amount per treatment for ESRD outlier services exceeds a threshold.

The distinction of what is considered to be a renal dialysis laboratory test is a clinical decision determined by the ESRD patient's ordering practitioner. If a laboratory test is ordered for the treatment of ESRD, then the laboratory test is not paid separately.

Payment for all renal dialysis laboratory tests furnished under the ESRD PPS is made directly to the ESRD facility responsible for the patient's care. The ESRD facility must furnish the laboratory tests directly or under arrangement and report renal dialysis laboratory tests on the ESRD facility claim (with the exception of composite rate laboratory services).

Under the ESRD PPS, frequency requirements do not apply for the purpose of payment. Laboratory tests should be ordered as necessary and should not be restricted because of financial reasons.

(Medicare Benefit Policy Manual Chapter 11, Section 20.2; Medicare Claims Processing Manual Chapter 8, Section 50.1).

Laboratory Tests Subject to ESRD Consolidated Billing
Certain laboratory tests will be subject to Part B consolidated billing requirements and will no longer be separately payable when provided to ESRD beneficiaries by providers other than the ESRD facility. The list of laboratory tests that are routinely performed for the treatment of ESRD and subject to ESRD consolidated billing is included in Medicare Benefit Policy Manual, Chapter 11, Section 20.2. Payment for these laboratory tests is included in the ESRD PPS and is the responsibility of the ESRD facility.

The list of renal dialysis laboratory tests is not an all-inclusive list. If any laboratory test is ordered for the treatment of ESRD, then the laboratory test is considered to be included in the ESRD PPS and is the responsibility of the ESRD facility (Medicare Benefit Policy Manual, Chapter 11, Section 20.2).

An ESRD facility must report renal dialysis laboratory services on its claims in order for the laboratory tests to be included in the outlier payment calculation.

The list of laboratory tests that are subject to ESRD consolidated billing may be found at: **ESRD PPS Consolidated Billing.**

Laboratory Services Performed During an Emergency Room Service
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 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 (Medicare Claims Processing Manual, Chapter 8, Section 50.1.1).

Laboratory Services Furnished for Reasons Other Than for the Treatment of ESRD

The distinction of what is considered to be a renal dialysis laboratory test is a clinical decision determined by the ESRD patient's ordering practitioner. If a laboratory test is ordered for the treatment of ESRD, then the laboratory test is a renal dialysis service.

A patient's treating practitioner may order a laboratory test that is included on the list of laboratory tests subject to ESRD consolidated billing edits for reasons other than for the treatment of ESRD. When this occurs, the patient's physician or practitioner should notify the independent laboratory or the ESRD facility (with the appropriate clinical laboratory certification in accordance with the Clinical Laboratory Improvement Act) that furnished the laboratory service that the test is not a renal dialysis service and that entity may bill the Plan separately using the AY modifier. The AY modifier serves as an attestation that the item or service is medically necessary for the patient but is not being used for the treatment of ESRD.

Hospital outpatient clinical laboratories furnishing renal dialysis laboratory tests to ESRD patients for reasons other than for the treatment of ESRD may submit a claim for separate payment using the AY modifier. The AY modifier serves as an attestation that the item or service is medically necessary for the patient but is not being used for the treatment of ESRD.

Laboratory services furnished to monitor the medication levels or effects of drugs and biologicals that fall in drug categories excluded from the ESRD PPS base rate would not be considered to be furnished for the treatment of ESRD. For a list of drug categories excluded from the ESRD PPS

Base Rate for the Purpose of Reporting Labs, see Medicare Benefit Policy Manual, Chapter 11, Section 20.2.

Laboratory Testing for Hepatitis B

Laboratory testing for hepatitis B is a renal dialysis service. Hepatitis B testing is included in the ESRD PPS and therefore cannot be billed separately to the Plan. The Conditions for Coverage for ESRD facilities require routine hepatitis B testing (42 CFR §494.30(a)(1)). The ESRD facility is responsible for the payment of the laboratory test, regardless of frequency.

The Conditions for Coverage for ESRD facilities require routine hepatitis B testing (42 CFR §494.30(a)(1)). The ESRD facility is responsible for the payment of the laboratory test, regardless of frequency. If an ESRD patient wishes to travel, the patient's home ESRD facility should have systems in place for communicating hepatitis B test results to the destination ESRD facility.

2. Drugs and Biologicals

Drugs and Biologicals Subject to ESRD PPS Consolidated Billing

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 (Medicare Claims Processing Manual, Chapter 8, Section 60.2).

Drugs and biologicals identified for consolidated billing are designated as always renal dialysis services and therefore no separate payment is made to ESRD facilities or other providers when these drugs are furnished to ESRD beneficiaries. The list of drugs and biologicals subject to ESRD PPS consolidated billing may be viewed at: **ESRD PPS Consolidated Billing**. This is not an all-inclusive list and any drug or biological that is used for the same purpose as those drugs and biologicals on the list are also included under the ESRD PPS. Providers other than ESRD facilities furnishing those drugs must look to the ESRD facility for payment.

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. 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 and the diagnosis code for which the drug is indicated:

1. Effective January 1, 2012, ESRD facilities and other providers may receive separate payment for vancomycin by placing the AY modifier on the claim when vancomycin (HCPCS code J3390) is furnished for reasons other than for the treatment of ESRD. The ESRD facility must indicate the appropriate ICD-10-CM diagnosis code for which the vancomycin is indicated.
2. Effective January 1, 2013, ESRD facilities and other providers may receive separate payment for daptomycin by placing the AY modifier on the claim when daptomycin (HCPCS J0878) is furnished for reasons other than for the treatment of ESRD. The ESRD facility must indicate the appropriate ICD-10-CM diagnosis code for which the daptomycin is indicated.

Drugs and biologicals furnished to ESRD beneficiaries that are not used for the treatment of ESRD, may be paid separately. When drugs or biologicals are furnished to an ESRD beneficiary and are not a renal dialysis service, the ESRD facility or other provider must append the claim with the AY modifier to receive separate payment. When these drugs are administered through the dialysate the provider must append the modifier JE (Administered via Dialysate). For more information regarding separately billable ESRD drugs, refer to Medicare Claims Processing Manual, Chapter 8, §60.2.1.1.

Drugs and Biologicals Furnished for Reasons Other than for the Treatment of ESRD

Drugs and biologicals furnished by an ESRD facility that are not used for the treatment of ESRD may be billed separately when coded with the AY modifier. The AY modifier serves as an attestation that the item or service is deemed medically necessary for the dialysis patient but is not being used for the treatment of ESRD. See Medicare Claims Processing Manual, Chapter 8, §60.2.1.1 for more information.

Drugs and Biologicals Under the Composite Rate

Prior to the implementation of the ESRD PPS, certain drugs used in furnishing outpatient maintenance dialysis treatments were considered composite rate drugs and not billed separately. Payments for these drugs are included in the ESRD PPS and are not paid separately under the composite rate portion of the blended payment. Drugs that are used as a substitute for any of these drugs or are used to accomplish the same effect are also covered under the composite rate.

The following list includes the drugs and biologicals under the composite rate. Staff time and supplies used to furnish these drugs are covered under the composite rate and are not billed separately.

- Heparin
- Mannitol
- Glucose
- Antiarrhythmics
- Saline
- Antihypertensives
- Protamine
- Pressor Drugs
- Antihistamines
- Local Anesthetics
- Heparin Antidotes
- Dextrose
- Apresoline (hydralazine)
- Benadryl
- Inderal
- Dopamine
- Hydralazine
- Levophed
- Insulin
- Lanoxin
- Verapamil
- Lidocaine
- Solu-cortef
- Antibiotics*

*Antibiotics - Effective January 1, 2012, antibiotics when used at home by a patient to treat an infection of the catheter site or peritonitis associated with peritoneal dialysis are no longer considered composite rate drugs and may be billed separately by ESRD facilities, under the composite rate portion of the blended payment during the transition. Under the ESRD PPS, all antibiotics used to treat vascular access-related and peritonitis infections including those furnished in the home are included in the ESRD PPS and are not eligible for separate payment, although they may be eligible for outlier payments.

Thrombolytic drugs (such as heparin) furnished by ESRD facilities to Medicare ESRD beneficiaries for access management purposes are recognized as composite rate drugs under the ESRD PPS. Effective January 1, 2012, thrombolytics are not eligible for outlier payments. Effective January 1, 2013, payment for thrombolytic drugs is included in the ESRD PPS and may not be separately paid when furnished to an ESRD Medicare beneficiary.

Separately Billable Drugs and Biologicals

The staff time used to furnish the separately billable drugs is included in the ESRD PPS and should not be billed separately.

- Albumin may be reasonable and medically necessary for the treatment of certain medical complications in renal dialysis patients. In such cases, facilities must document medical need to the satisfaction of the Plan. If the Plan determines that the drug was medically necessary, then separate payment in addition to the ESRD facility's composite rate could have been made.
  However, if albumin was used as a substitute for any drug covered under the composite rate or used to accomplish the same effect, for example, as a volume expander, then payment for it must have been included in the ESRD facility's composite rate payment for maintenance dialysis.
- Payment for furnishing blood, blood products, or blood supplies is excluded from the ESRD PPS and will remain separately billable when they are administered in an ESRD facility. For further detail, see Medicare Claims Processing Manual, Chapter 8, §60.3.
- Immunizations may be separately billed when furnished by an ESRD facility to a Medicare ESRD Beneficiary.

Charges associated with supplies used in the administration of separately billable drugs administered to ESRD members by ESRD facilities may be paid in addition to the drug. This includes drugs and biologicals that are furnished in the member's home. These administration supply charges include:

- A4657: Injection administration-supply charge (includes the cost of alcohol swab, syringe, and gloves) and
- A4913: IV administration-supply charge (includes the cost of IV solution administration set, alcohol swab, syringe, and gloves). A4913 should only be used when an IV solution set is required for a drug to be given.

These two supply codes are eligible for payment as outlier services.

ESRD PPS Functional Categories

The ESRD PPS functional category is a distinct grouping of drugs and biologicals, as determined by CMS, whose end action effect is the treatment or management of a condition or conditions associated with ESRD. The Drug Designation Process is dependent on the functional categories.

In the Calendar Year 2011 ESRD PPS final rule, CMS established that new drugs and biological products approved after the initial implementation of the ESRD PPS that meet the definition of a renal dialysis service would be included in the bundled payment.

To add new renal dialysis drugs and biological products to the ESRD PPS bundled payment, CMS uses a drug designation process that is based on the ESRD PPS functional categories. In general, drugs and biological products are considered included in the ESRD PPS base rate if they fit within one of the ESRD PPS functional categories, which are listed in the table below. Under current law, certain oral-only drugs are paid separately under Medicare Part D until January 1, 2025.

The list of ESRD PPS Functional Categories included in the ESRD PPS base rate, always considered to be renal dialysis services, was updated in ESRD PPS Final Rule (CMS-1768-F) for Calendar Year 2023 (87 67188):

- Drugs used for access management - Drugs used to ensure access by removing clots from grafts, reverse anticoagulation if too much medication is given, and provide anesthetic for access placement.
- Drugs used for anemia management - Drugs used to stimulate red blood cell production and/or treat or prevent anemia. This category includes ESAs as well as iron)
- Drugs used for bone and mineral metabolism - Drugs used to prevent/treat bone disease secondary to dialysis. This category includes phosphate binders and calcimimetics)
- Drugs used for cellular management - Drugs used for deficiencies of naturally occurring substances needed for cellular management. This category includes levocarnitine.
- Antiemetics - Drugs/biological products used to prevent or treat nausea and vomiting secondary to dialysis. Excludes antiemetics used in conjunction with chemotherapy as these are covered under a separate benefit category.
- Anti-infectives - Drugs/biological products used to treat infections. May include antibacterial and antifungal drugs.
- Antipruritics - Drugs/biological products in this category are included for their action to treat itching secondary to dialysis but may have multiple clinical indications.
- Anxiolytics - Drugs/biological products in this category are included for the treatment of restless leg syndrome secondary to dialysis but may have multiple clinical indications.
- Drugs used to manage excess fluid - Drugs/biological products/fluids used to treat fluid excess or fluid overload.
- Fluid and electrolyte management including volume expanders - Drugs/biological products/fluids used to treat fluid excess or fluid overload.
- Drugs used for pain management - Drugs/biological products used to treat graft site pain and to treat pain medication overdose.

Oral-Only Renal Dialysis Service Drugs and Biologicals

Section 217(c) of the Protecting Access to Medicare Act of 2014 (PAMA) required CMS to establish a process to: (1) determine when a product would no longer be considered an oral-only drug; and (2) include new injectable and intravenous products into the ESRD PPS bundled payment.

In accordance with section 217(c), CMS codified in regulation a drug designation process for: (1) determining when a product is no longer an oral-only drug; and (2) including new injectable and intravenous products into the ESRD PPS. Under the drug designation process, CMS provides additional payment using a Transitional Drug Add-on Payment Adjustment (TDAPA) for qualifying new injectable or intravenous drugs and biological products under 42 Code of Federal Regulation (CFR) 413.234(c).

In the CY 2016 ESRD PPS final rule (80 FR 68968), CMS finalized regulations at 42 CFR 413.174(f)(6), which state that effective January 1, 2025, payment to an ESRD facility for renal dialysis service drugs and biologicals with only an oral form furnished to ESRD patients is incorporated within the prospective payment system rates established by CMS in Subsection (§) 413.230 and separate payment will no longer be provided.

Determination of When an Oral-Only Renal Dialysis Service Drug or Biological is No Longer Oral-Only

Previously, an oral-only renal dialysis service drug or biological was defined as a drug or biological with no injectable equivalent or other form of administration other than an oral form. An oral-only renal dialysis service drug or biological was no longer considered oral-only when a non-oral version of the oral-only drug or biological is approved by the FDA.

In the CY 2023 ESRD PPS final rule, CMS revised the regulation to include the word “functional” in the definition of oral-only drug at 42 C.F.R. § 413.234(a), effective January 1, 2025. Under the revised definition, an oral-only drug is a drug or biological product with no injectable *functional* equivalent or other form of administration other than an oral form (87 FR 67179 through 67186). The change to the definition of oral-only drug to specify “functional” equivalence is consistent with the current policy for oral-only drugs and the ESRD PPS functional category framework, helps ensure that new renal dialysis drugs and biological products are paid for under the ESRD PPS without delay, and continues to support health care practitioners’ decision-making to meet the clinical needs of their patients. Additionally, the modification promotes health equity and supports proper financial incentives for ESRD facilities, in keeping with fiduciary responsibility to the Medicare Trust Funds.

Under 42 C.F.R. § 413.174(f)(6), effective January 1, 2025, payment to an ESRD facility for renal dialysis service drugs and biologicals with only an oral form furnished to ESRD patients is incorporated within the ESRD PPS rates established by CMS in § 413.230 and separate payment will no longer be provided. Although CMS included oral-only renal dialysis service drugs and biologicals in the definition of renal dialysis services in the CY 2011 ESRD PPS final rule (75 FR 49044), CMS also finalized a policy to delay payment for these drugs under the ESRD PPS until January 1, 2014, and later updated it based on legislation to the current date of 2025. In the CY 2016 ESRD PPS final rule, CMS updated regulations at 42 C.F.R. § 413.174(f)(6) to incorporate ESRD drugs and biological products with only an oral form into the ESRD PPS bundled payment beginning January 1, 2025.

In the Calendar Year 2025 ESRD PPS Proposed Rule (CMS-1805-P), CMS said it will use the same process that it used for calcimimetics to incorporate phosphate binders into the ESRD PPS beginning January 1, 2025, which was further discussed in **MLN Matters Number: MM10065**. CMS is not following this process for any other oral drugs or biological products. For renal dialysis drugs or biological products that are not phosphate binders, manufacturers would need to apply for HCPCS codes and the Transitional Drug Add-on Payment Adjustment (TDAPA) for such drugs to be considered for TDAPA payment. Under current policy (CMS-1628-F, Calendar Year 2016 ESRD PPS Final Rule, 87 FR 69027; CMS-1768-F, Calendar Year 2023 ESRD PPS Final Rule, 87 FR 67180), if no injectable equivalent (or other form of administration) of phosphate binders is approved by the Food and Drug Administration (FDA) prior to January 1, 2025, then

CMS will pay for these drugs using the TDAPA under the ESRD PPS for at least 2 years beginning January 1, 2025. CMS will then undertake rulemaking to modify the ESRD PPS base rate to account for the cost and utilization of phosphate binders in the ESRD PPS bundled payment.

For renal dialysis drugs or biological products that are not phosphate binders, manufacturers would need to apply for HCPCS codes and the Transitional Drug Add-on Payment Adjustment (TDAPA) for such drugs to be considered for TDAPA payment.

For additional information, refer to CMS publication: **Including Oral-Only Drugs in the ESRD PPS Bundled Payment.**

Inclusion of New Renal Dialysis Drugs or Biological Products into the ESRD PPS Bundled Payment

Under 42 C.F.R. § 413.234(a), a "new renal dialysis drug or biological product" is an injectable, intravenous, oral or other form of drug or biological product that is used to treat or manage a condition(s) associated with ESRD. It must be: (1) approved by the Food and Drug Administration (FDA) on or after January 1, 2020, under section 505 of the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act; (2) commercially available; (3) have an HCPCS application submitted in accordance with the official Level II HCPCS coding procedures, and; (4) designated by CMS as a renal dialysis service under § 413.171. Oral-only drugs are excluded until January 1, 2025.

As part of the Drug Designation Process, CMS stated that it considered a new injectable or intravenous drug to be included in the ESRD PPS bundled payment (with no separate payment available) if the drug is used to treat or manage a condition for which there is an ESRD PPS functional category. At that time, CMS further stated that it would apply the transitional drug add-on payment adjustment (TDAPA) to new injectable or intravenous drugs used to treat or manage a condition for which there is not an existing ESRD PPS functional category (CMS–1628–F, Calendar Year 2016 ESRD PPS Final Rule, 80 FR 69013 through 69023).

In the CY 2019 ESRD PPS final rule, CMS updated and revised the Drug Designation Process regulations and expanded the TDAPA to all new renal dialysis drugs and biological products that are FDA approved, regardless of the form or route of administration (new injectable, IV, oral, or other form or route of administration) or whether the drug or biological product fell in an existing ESRD PPS functional category (CMS–1691–F, Calendar Year 2019 ESRD PPS Final Rule, 83 FR 56929 through 56932).

In the CY 2020 ESRD PPS final rule, CMS revised the eligibility criteria for the TDAPA for drugs in existing functional categories to exclude certain drugs approved by the FDA under section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and drugs for which the new drug application (NDA) is classified by the FDA as Type 3, 5, 7 or 8, Type 3 in combination with Type 2 or Type 4, or Type 5 in combination with Type 2, or Type 9 when the ''parent NDA'' is a Type 3, 5, 7 or 8 (CMS-1713-F, Calendar Year 2020 ESRD PPS Final Rule, 84 FR 60656 through 60672). This change helped to ensure that our TDAPA policy for new renal dialysis drugs and biological products in existing functional categories is focused on products that we consider to be truly innovative for purposes of the ESRD PPS. Renal dialysis drugs and biological products in existing ESRD PPS functional categories that fall under any of these exclusions are incorporated into the ESRD PPS bundled payment, as long as the drug or biological product does not meet the definition of an oral-only drug.

For additional information on the Drug Designation Process, refer to the following CMS website **ESRD PPS Drug Designation Process.**

ESRD PPS Transitional Drug Add-On Payment Adjustment (TDAPA)

The TDAPA is a payment adjustment under the ESRD PPS for certain new renal dialysis drugs and biological products. As discussed in the CY 2019 and CY 2020 ESRD PPS final rules, for new renal dialysis drugs and biological products that fall into an existing ESRD PPS functional category, the TDAPA helps ESRD facilities to incorporate new drugs and biological products and

make appropriate changes in their businesses to adopt such products. Furthermore, the TDAPA provides additional payments for such associated costs and promotes competition among the products within the ESRD PPS functional categories, while also focusing Medicare resources on products that are innovative. For new renal dialysis drugs and biological products that do not fall within an existing ESRD PPS functional category, the TDAPA is a pathway toward a potential base rate modification. The TDAPA requirements are set forth in the ESRD PPS regulations at 42 C.F.R. § 413.234.

Payment Amounts for New Renal Dialysis Drugs and Biological Products Currently Eligible for the TDAPA: See **Drugs and Biological Products Eligible for the TDAPA** for quarterly pricing updates.

The TDAPA Payment Process for Calcimimetics and Phosphate Binders: Calcimimetics and phosphate binders were not considered included in the ESRD PPS bundled payment and were paid separately beginning in CY 2011 (75 FR 49037 through 49053). Calcimimetics were incorporated into the ESRD PPS base rate beginning January 1, 2021, after the TDAPA payment period ended on December 31, 2020 (85 FR 71404 through 71410). In the CY 2023 ESRD PPS final rule, we stated that if no other injectable equivalent (or other form of administration) of phosphate binders is approved by the FDA prior to January 1, 2025, we would pay for these drugs using the TDAPA under the ESRD PPS for at least 2 years beginning January 1, 2025 (87 FR 67180). Phosphate binders will be paid for using the TDAPA under the ESRD PPS effective January 1, 2025, using the same process applied to calcimimetics.

As noted in the CY 2016 ESRD PPS final rule, for phosphate binders and calcimimetics— for which there is a functional category, but no money in the base rate—CMS utilizes the TDAPA to collect utilization data before adding these drugs to the ESRD PPS base rate. The TDAPA process that was applied for calcimimetics and phosphate binders will not apply for any other oral drugs or biological products (80 FR 69025). Manufacturers would need to apply for a HCPCS code and the TDAPA for any other oral drugs or biological products to be eligible for the TDAPA (89 FR 89137).

Per § 413.234(c), the TDAPA is generally based on 100 percent of average sales price (ASP). If ASP is not available, then the TDAPA is based on 100 percent of wholesale acquisition cost (WAC). If WAC is unavailable, then the payment is based on the drug manufacturer's invoice. As further specified in § 413.234(c)(4), CMS will apply a fixed increase to the calculation of the monthly TDAPA amount for two years for claims that include phosphate binders. This amount is intended to cover the incremental operational costs of making these medications available to patients (89 FR 89148).

The TDAPA Payment Process for a New Renal Dialysis Drug or Biological Product:

1. For New Renal Dialysis Drugs or Biological Products Within an Existing ESRD PPS Functional Category (§ 413.234(b)(1)):
    a. Eligibility Criteria: A new renal dialysis drug or biological product used to treat or manage a condition for which there is an ESRD PPS functional category is considered included in the ESRD PPS bundled payment. The new renal dialysis drug or biological product is paid for using the TDAPA as described in 42 C.F.R. § 413.234(c)(1), unless it is excluded from the TDAPA eligibility under 42 C.F.R. § 413.234(e).
    b. Exclusion Criteria: A new renal dialysis drug or biological product used to treat or manage a condition for which there is an ESRD PPS functional category is not eligible for payment using the TDAPA, as described in 42 C.F.R. § 413.234(c)(1), if the drug is approved by the U.S. Food and Drug Administration (FDA) under § 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) or the new drug application (NDA) for the drug is classified by FDA as Type 3, 5, 7, or 8; Type 3 in combination with Type 2 or Type 4; Type 5 in combination with Type 2; or Type 9 when the parent NDA is a Type 3, 5, 7 or 8 as described in 42 C.F.R. § 413.234(e)(1) through (7).

c. Basis of Payment: The TDAPA is based on 100 percent of average sales price (ASP). If ASP is not available, then the TDAPA is based on 100 percent of wholesale acquisition cost (WAC). If WAC is unavailable, then the payment is based on the drug manufacturer's invoice.

d. Duration of the TDAPA: The TDAPA is paid for 2 years. The TDAPA payment period begins on the effective date of the CMS Change Request (CR). During the time a new renal dialysis drug or biological product is eligible for the TDAPA, it is not an eligible ESRD outlier service as defined under 42 C.F.R. § 413.237(a)(1) and therefore is ineligible for outlier payment.

e. Payment Process:

- CMS notifies the TDAPA applicant of its TDAPA determination.
- CMS adds the new renal dialysis drug or biological product to an existing ESRD PPS functional category through administrative issuance. Specifically, CMS will include instructions for Medicare Administrative Contractors (MACs) and ESRD facilities about the products approved for the TDAPA in the ESRD PPS via the Change Request (CR) process.
- CMS pays for the new renal dialysis drug or biological product using the TDAPA for a period of 2 years.
- At the end of the TDAPA payment period, the new renal dialysis drug or biological product is paid the post-TDAPA add-on payment adjustment and no changes to the base rate are made.

f. Post TDAPA Add-on Payment Adjustment: Beginning for CY 2024, CMS pays a post-TDAPA add-on payment adjustment on all ESRD PPS claims, which provides increased payment for new renal dialysis drugs or biological products that are considered included in the ESRD PPS base rate following the end of the TDAPA period for those products. Manufacturers do not need to apply for the post-TDAPA add-on payment adjustment.

- A new renal dialysis drug or biological product is included in the calculation of the post-TDAPA add-on payment adjustment for a period of 3 years.
- CMS annually calculates the post-TDAPA add-on payment adjustment for each quarter of the upcoming CY, based on the most recent 12 months of claims data. For drugs or biological products that lack a full year’s worth of utilization data when the annual final rule is developed, CMS will publish the post-TDAPA add-on payment adjustment amount in a CR once 12 months of utilization data are available (89 FR 89135 through 98136).
- The post-TDAPA add-on payment adjustment amount for a drug or biological product is the total expenditure for a new drug divided by total ESRD PPS expenditures during the same period, reduced by a case-mix standardization factor and a 65 percent risk-sharing factor and inflated by the market basket price proxy for pharmaceuticals.
- All Part B drug manufacturers report Average Sales Price (ASP) data for Part B-covered drugs and biologicals and related items, services, supplies, and products that are paid as drugs or biologicals as described on the ASP Reporting website.
- If CMS does not receive the latest available calendar quarter of ASP data for a drug or biological product, then CMS will not apply the post-TDAPA add-on payment adjustment for that drug or biological product for the upcoming CY or any future CY.

- The amount of the post-TDAPA add-on payment adjustment may vary from quarter to quarter depending on the number of drugs and biological products included in the calculation.
- The amount of the post-TDAPA add-on payment adjustment paid on a claim will be adjusted by the applicable patient-level case-mix adjustment factors.

2. For New Renal Dialysis Drugs or Biological Products Not Within an Existing ESRD PPS Functional Category (§ 413.234(b)(2)):

   a. Eligibility Criteria: A new renal dialysis drug or biological product used to treat or manage a condition for which there is not an ESRD PPS functional category is not considered included in the ESRD PPS bundled payment. The new renal dialysis drug or biological product is paid for using the TDAPA as described in § 413.234(c)(2).

   b. Basis of Payment: Per § 413.234(c), the TDAPA is based on 100 percent of average sales price (ASP). If ASP is not available, then the TDAPA is based on 100 percent of wholesale acquisition cost (WAC). If WAC is unavailable, then the payment is based on the drug manufacturer's invoice.

   c. Duration of the TDAPA: The TDAPA is paid until sufficient claims data for rate setting analysis for the new renal dialysis drug or biological product is available, but not for less than 2 years. The TDAPA payment and data collection periods for these drugs and biological products begin on the effective date of the applicable CMS ESRD PPS annual update CR for MACs and ESRD facilities. During the time a new renal dialysis drug or biological product is eligible for the TDAPA, it is not an eligible ESRD outlier service as defined under 42 C.F.R. § 413.237(a)(1) and therefore is ineligible for outlier payment.

   d. Payment Process:

      - CMS notifies the TDAPA applicant of its TDAPA determination.
      - CMS adds a new ESRD PPS functional category or revises an existing ESRD PPS functional category through rulemaking for the condition that the new renal dialysis drug or biological product is used to treat or manage. CMS will include instructions for MACs and ESRD facilities about the products approved for the TDAPA in the ESRD PPS annual update via the CR process.
      - CMS pays for the new renal dialysis drug or biological product using the TDAPA for a period of at least 2 years until sufficient claims data for rate setting analysis is available.
      - Following payment of the TDAPA, CMS undertakes rulemaking to modify the ESRD PPS base rate, if appropriate, to account for the new renal dialysis drug or biological in the ESRD PPS bundled payment. The post-TDAPA add-on payment adjustment does not apply for these drugs or biological products.

   e. ASP Conditional Policy for the TDAPA:

      - As described in § 413.234(c), if CMS does not receive a full calendar quarter of ASP data for a new renal dialysis drug or biological product within 30 days of the last day of the 3rd calendar quarter after CMS begins applying the TDAPA for the product, CMS will no longer apply the TDAPA for that product beginning no later than 2-calendar quarters after CMS determines a full calendar quarter of ASP data is not available.
      - If CMS stops receiving the latest full calendar quarter of ASP data for a new renal dialysis drug or biological product during the applicable time period for the TDAPA, CMS will no longer apply the TDAPA for the product beginning no later than 2-calendar quarters after CMS determines that the latest full calendar quarter of ASP data is not available.

Information regarding the submission of ASP data is available on the Medicare Part B Drug Average Sales Price page.

Timeline for TDAPA Payment for New Renal Dialysis Drugs or Biological Products Within an Existing ESRD PPS Functional Category**:** Because applicants are required to provide a Healthcare Common Procedure Coding System (HCPCS) Application Confirmation Number when applying for the TDAPA, the TDAPA application should be submitted after the application for a HCPCS code. The TDAPA and HCPCS application submissions will be reviewed simultaneously on a quarterly basis, by following the CMS Level II HCPCS application deadlines for drugs and biological products. The TDAPA submissions received after the Level II HCPCS quarterly submission deadline will be reviewed in the following quarter.

CMS' goal is to provide the TDAPA for qualifying new renal dialysis drugs and biological products in a timely manner. CMS aims for an effective date for applying the TDAPA for a particular product that is one quarter after the effective date of the HCPCS code for the product, or approximately 6 months after the quarterly submission deadline. This timeframe generally allows for sufficient time for CMS analysis, decision-making, and system changes. However, a longer evaluation period may be necessary due to a number of factors, including a CMS request for further information, or the need for a more extensive CMS evaluation to determine eligibility. The effective date for the TDAPA for a particular product will be communicated to the public through administrative issuance with instructions to the ESRD facilities for reporting the drug or biological product on the claim.

For additional information on the ESRD PPS Transitional Drug Add-on Payment Adjustment, refer to the following CMS website **ESRD PPS Transitional Drug Add-on Payment Adjustment.**

3. Equipment and Supplies

All medically necessary equipment and supplies used to furnish dialysis (in-facility or in a patient's home) are included in the ESRD PPS and are not separately paid.

ESRD facilities may determine that it is medically necessary for a dialysis patient to use dressings or protective access coverings, including catheter coverings, on their access site. All medically necessary dressings or protective access coverings used during or after dialysis to protect a dialysis patient's access site including for example, coverings used for day-to-day activities such as bathing, are considered to be renal dialysis items. To the extent that dressings and protective access coverings, including catheter coverings, are determined to be medically necessary, an ESRD facility should provide them. Medicare payment for vascular access equipment and supplies is included in the ESRD PPS for all dialysis patients regardless of the method of dialysis or where they receive dialysis treatments.

Separate payment for renal dialysis equipment and supplies is not made under the ESRD PPS.

Home Dialysis Equipment and Supplies

All home dialysis equipment, supplies, and other medically necessary items for home dialysis ordered by a physician were included in the composite rate and are therefore included under the ESRD PPS. The ESRD facility with which the patient is associated assumes responsibility for providing all home dialysis equipment, supplies, and support services either directly or under arrangements to all of its home dialysis patients.

1. Home Dialysis Equipment Provided to Home Hemodialysis and Peritoneal Dialysis Patients

   Coverage of any item of home dialysis equipment used for home dialysis depends on its medical necessity. Medical necessity is established by the physician's order, and by the equipment meeting Medicare guidelines that define home dialysis equipment.

   Nonmedical items are also included in the ESRD PPS and may not be billed separately. For example, if a home dialysis patient is wheelchair bound and it is medically necessary for the patient to weigh themselves before and after a dialysis treatment, the ESRD facility is responsible for furnishing the patient with a wheelchair scale.

a. Installation and Delivery of Home Dialysis Equipment
ESRD facilities are responsible for all reasonable and necessary expenses incurred in the original installation of home dialysis equipment. This coverage is not extended to expenses attributable to home improvement (e.g., plumbing or electrical work beyond that necessary to tie in with existing plumbing and power lines). Testing and assurance of equipment performance, which may be billed for as part of the basic delivery charge, are also covered.

b. Other Requirements for Coverage of Home Dialysis Equipment
The ESRD facility is responsible for fulfilling the requirements necessary for furnishing home dialysis.

This includes but is not limited to:

- Supportive equipment that is used in conjunction with the basic dialysate delivery system. This includes blood, heparin pumps, air bubble detectors, blood leak detectors, and unipuncture devices.
- Adjustable chairs, such as recliners, as these chairs serve to preserve patients' health by allowing rapid manipulation in body position when medical circumstances warrant such changes during dialysis (e.g., when acute hypotension occurs and the patient is in danger of going into shock).

2. Home Dialysis Supplies Provided to Home Hemodialysis and Peritoneal Dialysis Patients

ESRD facilities are responsible for supplies necessary for the effective performance of all modalities of home dialysis, for example, alcohol wipes, sterile drapes, gloves, telfa pads, bandages, etc. Necessary supplies could also include but are not limited to start-up durable supplies (whether or not they are part of a start-up kit) such as weight scales, sphygmomanometer, I.V. stand, and dialysate heaters; and consumable and disposable supplies such as dialysate, tubing, and gauze pads.

Instruments and nonmedical supplies, such as scales, stopwatches, and blood pressure apparatus are included in the ESRD PPS, regardless of whether provided separately or as part of a start-up kit.

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

The intent of the TPNIES, as established in 42 CFR 413.236, is to facilitate Medicare beneficiary access to certain qualifying, new and innovative renal dialysis equipment and supplies by providing an add-on payment adjustment to support ESRD facilities in the uptake of new and innovative equipment and supplies under the ESRD PPS. The TPNIES is paid for two calendar years, beginning on January 1 and ending on December 31. Note that such new and innovative equipment or supply is not considered an outlier service.

Beginning January 1, 2021, the TPNIES policy was expanded to include certain capital-related assets (CRA) that are home dialysis machines when used in the home for a single patient. For eligible CRAs that are home dialysis machines, ESRD facilities will be paid the CRA for TPNIES beginning January 1, 2022. The CRA for TPNIES is paid for 2 calendar years, beginning on January 1 and ending on December 31. Following payment of the CRA for TPNIES, the ESRD PPS base rate will not be modified and the new CRA that is a home dialysis machine will not be an eligible outlier service.

For additional information, refer to CMS website **ESRD PPS Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES)**.

Coverage for Surgical Dressings
When dialysis access has been surgically placed in a patient to enable an ESRD facility to provide dialysis treatment, and the patient has started dialysis, the dressing changes are part of the home support provided by the ESRD facility. When surgical wounds are not related to ESRD, the patient may be eligible for care under the home health benefit.

Equipment and Supplies Used for Reasons Other Than for the Treatment of ESRD
When ESRD facilities furnish items and services that are not used for the treatment of ESRD, ESRD facilities can bill separately by using the AY modifier for the appropriate HCPCS codes used for the administration-supply of the drug and/or biological that is being used for reasons other than for the treatment of ESRD. Any equipment or supply billed using the AY modifier will not be considered an eligible outlier service. Any equipment or supply billed using the AY modifier will not be considered an eligible outlier service.

These supplies include:
- A4657: Injection administration-supply charge (includes the cost of alcohol swab, syringe, and gloves) and
- A4913: IV administration-supply charge (includes the cost of IV solution administration set, alcohol swab, syringe, and gloves). A4913 should only be used when an IV solution set is necessary for drugs or biologicals given for reasons other than for the treatment of ESRD.

4. Home Dialysis Items and Services
Effective January 1, 2011, payment for renal dialysis services furnished for home dialysis are covered under the ESRD PPS and are not separately paid. The ESRD facility receives the same Medicare dialysis payment rate for home patients as it would receive for an in-facility patient under the ESRD PPS.

The ESRD facility is responsible for the overall management of the home dialysis patient, including assuring that the patient is provided with equipment and supplies that are functional. This means the ESRD facility is responsible for delivering, installing, monitoring and maintaining supplies and equipment necessary to furnish all modalities of home dialysis.

The ESRD facility is responsible for all renal dialysis items and services which include but is not limited to:
- Medically necessary home dialysis equipment (see Home Dialysis Equipment and Supplies above);
- Home dialysis support services, which include but is not limited to the delivery, installation, maintenance, repair and testing of home dialysis equipment and support equipment;
- Procurement and delivery of all necessary home dialysis supplies;
- Renal dialysis laboratory tests;
- Renal dialysis drugs and biologicals; and
- All dialysis services furnished by the ESRD facility's staff.

Some examples (but not an all-inclusive list) of renal dialysis items and services included in the ESRD PPS and may not be billed separately when furnished by an ESRD facility are:
- Staff time used to administer blood;
- Declotting of shunts and any supplies used to declot shunts;
- Oxygen and the administration of oxygen; and
- Staff time used to administer separately billable items.

Home Dialysis Hemodialysis and Peritoneal Support Services
Home dialysis support services identified at 42 CFR 494.100 may be furnished in the home or in the ESRD facility. Support services may be provided directly or via an agreement or arrangement with another approved ESRD facility. Support services include (but are not limited to):
1. Periodic monitoring of a patient's adaptation to home dialysis and performance of dialysis, including provisions for visits to the home or the ESRD facility;
2. Emergency visits by qualified ESRD facility personnel;
3. Services provided by a qualified social worker and a qualified dietitian, made in accordance with a plan prepared and periodically reviewed by a professional team which includes the physician;
4. Individual's unscheduled visits to an ESRD facility made on an as-needed basis; e.g., assistance with difficult access situations;
5. Renal dialysis laboratory tests covered under the ESRD PPS;

6. Providing, installing, repairing, testing, and maintaining home dialysis equipment, including appropriate water testing and treatment;
7. Ordering of supplies on an ongoing basis;
8. Maintaining and submitting all required documentation to the ESRD network;
9. A record keeping system that ensures continuity of care;
10. Changing necessary tubing;
11. Watching the patient perform dialysis to assure that it is done correctly and to review any aspects of the technique that may require modification; and
12. Inspecting the access site and document any access site infections that may require a physician intervention or hospitalization.

The full range of home dialysis support services required by home patients are included in the ESRD PPS.

In-facility Dialysis Sessions Furnished to Home Patients Who Are Traveling

Patients who are normally home dialysis patients may be dialyzed by a Medicare certified ESRD facility on an in-facility basis when traveling away from home. Patients who normally dialyze in an ESRD facility may wish to dialyze temporarily in another facility or as home dialysis patients while they travel or vacation.

See Medicare Claims Processing Manual, Chapter 8, “Outpatient ESRD Hospital, Independent Facility, and Physician/Supplier Claims,” §100, for billing services when traveling.

Staff Assisted Home Dialysis

Effective January 1, 2011, renal dialysis services for patients receiving home dialysis may only be billed under Method I. Staff-assisted home dialysis using nurses to assist ESRD beneficiaries is not included in the ESRD PPS and is not a Medicare covered service.

5. Home and Self-Dialysis Training and Retraining

Home and self-dialysis training and retraining are programs provided by Medicare certified ESRD facilities that educate ESRD patients and their caregivers to perform self-dialysis in the ESRD facility or home dialysis (including CAPD and CCPD) with little or no professional assistance. Self-dialysis training can occur in the patient’s home or the in-facility when it is provided by the qualified staff of the ESRD facility. CMS expects that the patients who elect for home dialysis are good candidates for home dialysis training, and therefore, will successfully complete their method of training before reaching the maximum number of sessions allotted.

Home dialysis training services and supplies includes personnel services; dialysis supplies, parenteral items used in dialysis, written training manuals and materials, and renal dialysis laboratory tests.

Occasionally, it may be necessary to furnish additional training to an ESRD self-dialysis patient 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;
- he 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.

The ESRD PPS provides a home and self-dialysis training add-on payment adjustment when the patient is training for home or self-dialysis. The training add-on payment adjustment is applied to a maximum of 25 treatments for hemodialysis and 15 treatments for peritoneal dialysis (CAPD and CCPD). After the initial training is completed, ESRD facilities can receive the training add-on payment adjustment when ESRD patients are retraining.

For more information on the requirements for home and self-dialysis training and retraining refer to Medicare Benefit Policy Manual, Chapter 11, Section 30.2. Dialysis training services are reimbursed in accordance with Medicare Claims Processing Manual, Chapter 8, Section 50.8.

6. Other Services

ESRD members may receive other services that may be related to their ESRD diagnosis but are excluded from the ESRD PPS payment.

Coverage under the Home Health Benefit for ESRD Patients

Services that are covered under the ESRD PPS are excluded from coverage under the Medicare home health benefit.

Services can be provided to dialysis patients under the home health benefit as long as the condition that necessitates home health care is not a renal dialysis service. A member is eligible for home health benefits if coverage conditions are met provided the patient's condition is not covered by the ESRD PPS. This is true even where the primary condition is related to kidney failure. For example, Medicare will pay for home health care, such as decubitus care or for severe hypotension that is not included in the ESRD PPS.

Surgical dressing changes that are furnished for the treatment of ESRD are to be provided by the ESRD facility, but dressing changes furnished for reasons other than for the treatment of ESRD may be provided under the home health benefit provided all eligibility criteria have been met.

Skilled Nursing Facility (SNF) Patients Needing Dialysis Services

Dialysis and certain dialysis-related services including covered ambulance transportation to obtain the dialysis services are excluded from SNF consolidated billing and the services may be billed separately.

Physician's Services for ESRD Members

Physician services are excluded from the ESRD PPS. Physician's services furnished in connection with dialysis sessions for outpatients who are on maintenance dialysis in an ESRD facility or at home are reimbursed in accordance with Section 130, Chapter 8 of the Medicare Claims Processing Manual.

Emergency Renal Dialysis Services

Emergency renal dialysis services furnished in a hospital emergency room are separately paid when medical justification documented in the medical record and when the absence of immediate renal dialysis in the emergency room could reasonably be expected to result in either:

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

Renal Dialysis Services Furnished During the Creation or Revision of a Vascular Access

The creation or revision of an ESRD patient's vascular access is usually performed in hospital outpatient departments. Laboratory services, drugs and biologicals, and equipment and supplies furnished to ESRD beneficiaries for the treatment of ESRD on the day a procedure is performed to create or revise a vascular access site is not considered to be renal dialysis services. Providers furnishing renal dialysis services that are subject to the ESRD PPS consolidated billing requirements during the creation or revision of a vascular access for an ESRD beneficiary should bill those services separately with an AY modifier. The appropriate HCPCS or CPT code indicating the creation or revision of an access site is required on the claim. Items and services that are subject to the ESRD PPS consolidated billing requirements may be found at: **ESRD PPS Consolidated Billing**.

Noninvasive Vascular Studies for ESRD Patients

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 to determine if the access site is functioning correctly. An ESRD facility must

furnish all necessary services, equipment, and supplies associated with a dialysis treatment, either directly or under arrangements. The ESRD facility is financially responsible for the service.

Nutritional Services

ESRD facilities are required to evaluate a patients' nutritional status and expected to assist the patient in achieving their nutritional goals by providing education, counseling, and encouragement. These services are included in the ESRD PPS. Nutritional items, such as nutritional supplements, are not considered related to the treatment of ESRD and are not included in the ESRD PPS as renal dialysis services.

7. ESRD Prospective Payment System (PPS) Base Rate

Per Treatment Unit of Payment

Under the ESRD PPS payment is made on a per treatment basis. 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 ESRD PPS base rate is applies to both adult and pediatric patients. ESRD facilities furnishing dialysis treatments in-facility are paid for up to 3 treatments per week. ESRD facilities treating patients at home regardless of modality receive payment for 3 hemodialysis (HD) equivalent treatments per week. ESRD facilities furnishing dialysis in-facility or in a patient's home are paid for a maximum of 13 treatments during a 30 day month and 14 treatments during a 31 day month unless there is medical justification for additional treatments.

Modality	In-Facility	Home
Hemodialysis	3 per week	3 per week
Peritoneal dialysis (e.g., CAPD and CCPD)	Hemodialysis-equivalent number of sessions	Hemodialysis-equivalent number of sessions

Hemodialysis is typically furnished 3 times per week in sessions of 3 to 5 hours in duration. If the ESRD facility bills for any treatments in excess of this frequency, medical justification is required to be furnished to the Plan.

For additional information refer to Medical Benefit Policy Manual, Chapter 11, Section 50 and Medicare Claims Processing Manual, Chapter 8, Section 10.1.

Uncompleted Dialysis Treatments under the ESRD PPS

A dialysis treatment is started, when a patient is connected to the machine and a dialyzer and bloodlines are used. If a dialysis treatment is started, but the treatment is not completed for some unforeseen, but valid reason, (e.g., a medical emergency when the patient must be rushed to an emergency room), the ESRD facility is paid based on the ESRD PPS base rate. This is a rare occurrence and must be medically justified. If the patient returns the same day and completes the treatment, the facility is only paid for one treatment.

If a patient was taken to a hospital and was furnished a dialysis treatment while in the emergency room, then the ESRD facility will not receive payment for the treatment and only the hospital will be paid.

No-Shows

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 Medicare 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 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.

8. ESRD PPS Case-Mix Adjustments

The ESRD PPS includes patient-level adjustments, facility-level adjustments, and training adjustments, as well as an outlier payment. For additional information refer to Medicare Benefit Policy Manual, Chapter 11, Section 60.

Patient-level case-mix adjustments

The ESRD PPS base rate is adjusted for characteristics of both adult and pediatric patients to account for case-mix variability. The adult case-mix adjusters include variables (age, body surface area (BSA), and low body mass index (BMI)) that were part of the basic case-mix adjusted composite rate payment system. In addition, the ESRD PPS implemented in CY 2011 includes adult case-mix adjustments for six comorbidity categories (three acute and three chronic) as well as the onset of renal dialysis. Pediatric patient-level adjusters, consist of combinations of two age categories and two dialysis modalities. Based on the refinement of the ESRD PPS, effective January 1, 2016, adult case-mix payment adjustments are made for four comorbidity categories (two acute and two chronic) as discussed below.

Adult case-mix adjusters

- Body Surface Area – First determine the patient's BMI. Although height and weight are taken at intervals throughout any given month of dialysis treatment, the measurements for the purpose of payment must be taken as follows: The dry weight of the patient is measured and recorded in kilograms immediately following the last dialysis session of the month.
    - The patient height is measured and recorded in centimeters during the last dialysis session of the month. The measurement is required no less frequently than once per year.
    - The formula for the calculation of the BMI is weight in kilograms divided by height in meters squared, or kg/m2.

  If the patient has a BMI less than the threshold value of 18.5 kg/m2, use Low Body Mass Index adjuster.

  The formula for the calculation of the BSA is BSA = w0.425 * h0.725 * 0.007184 where w and h represent weight in kilograms and height in centimeters. The BSA factor is defined as an exponent equal to the value of the patient's BSA minus the reference BSA of 1.90 divided by 0.1. Using the example of adult adjusters above, the BSA adjustment factor of 1.032 is then exponentiated based on the calculated BSA factor as 1.032(BSA-1.90)/0.1. The reference BSA used to calculate the BSA is the national average among Medicare dialysis patients.

- Patient Age **–** There are 5 age categories for adults (18-44; 45-59; 60-69; 70-79; and 80 and above) in the ESRD PPS and each category has a separate case-mix adjuster. Note that, when a member reaches a birthday that results in a different age category, the age change is effective from the first day of the birthday month, regardless of the date the birthday occurs in that month. The case-mix adjustment factor corresponding to the age of the dialysis patient is multiplied by the wage index adjusted base rate as a step in the calculation of the ESRD PPS per treatment payment amount.

- Low Body Mass Index (BMI) and/or Body Surface Area (BSA) – Low BMI and BSA are two measures used to estimate body size. Both measures are strong predictors of variation in costs and are closely associated with the duration and intensity of dialysis necessary to achieve a therapeutic dialysis target for ESRD patients. Both are objective measures that are computed using height and weight data located on the patient claim. The BMI and BSA are calculated for all beneficiaries. Low BMI is associated with higher costs due to additional resources that may be necessary to address malnutrition or frailty. BSA is associated with higher costs due to more time on the dialysis machine.

  The designated low BMI adjustment factor of 1.017 is only applied for those members with a BMI value that is less than 18.5kg/m2 which is a clinical measure of being underweight and an indicator of malnutrition.

- Onset of Dialysis – An ESRD facility may only receive the onset of dialysis adjustment for adult Medicare ESRD beneficiaries. The onset period is defined as the initial 120 days of outpatient maintenance dialysis, which is designated by the first date of when regular chronic dialysis began as reported on the CMS Form 2728. The onset of dialysis adjustment factor is a multiplier used in the calculation of the ESRD PPS per treatment payment amount for dialysis furnished in either an ESRD facility or home setting. When a dialysis patient is not eligible for Medicare at the initiation of their maintenance dialysis, but is Medicare eligible at the end of 85 days, the onset of dialysis adjustment will be applied to the ESRD facility's ESRD PPS base rate for each treatment furnished in the following 35 days. However, if the patient is not Medicare eligible at any time during the initial 120 days of receiving maintenance dialysis, the onset of dialysis adjustment will not apply.

  The onset of dialysis adjustment is a one-time adjustment. It is not applied when a patient changes ESRD facilities or after a failed transplant. If a patient changes or transfers to another ESRD facility during the initial 120 days, the new ESRD facility will only receive the onset of dialysis adjustment for the remaining time. In other words, the 120 day "clock" does not start over.

  If the onset of dialysis adjustment is being applied to the ESRD PPS base rate, then those treatments would not be eligible for the comorbidity adjustment nor any applicable training adjustment(s). However, those treatments are eligible for an outlier payment when appropriate.

- Comorbidity Categories – A comorbidity is a specific patient condition that is secondary to the patient's principal diagnosis that necessitates dialysis, yet have a significant, direct effect on resource use during dialysis. Section 1881(b)(14)(D)(i) of the Social Security Act requires that the bundled ESRD PPS include a payment adjustment based on casemix that may take into account patient comorbidities. The comorbidity adjustment recognizes the increased costs associated with comorbidities by providing adjustments for specific conditions that occur concurrently with the need for dialysis.

  The two acute comorbidity categories are pericarditis and gastro-intestinal tract bleeding with hemorrhage. The Plan may make payment for the two acute comorbidity category adjustments for the month as long as the provider reports the diagnosis on the ESRD facility's claim and then for the next three months, regardless of whether or not the diagnosis code is on the claim after the first month. This adjustment applies for no greater than four consecutive months for any reported acute comorbidity category, unless there is a reoccurrence of the condition.

  The two chronic comorbidity categories are myelodysplastic syndrome and hereditary hemolytic anemia (including sickle cell anemia). The Plan may make payment for the two chronic comorbidity category adjustments as long as the provider reports the diagnosis code on the claim.

  The related comorbidity diagnosis codes can be found at the CMS ESRD Payment Web site located at: **ESRD PPS Patient-Level Adjustments.**

Pediatric case-mix adjusters: Age and dialysis modality
Pediatric patients are beneficiaries with ESRD who are under the age of 18. The same base rate is used for adult and pediatric patients, which is also adjusted by the area wage index. However, the base rate for pediatric patients is not adjusted for case-mix as adjustments used for adult patients. The pediatric payment adjustments use only two age categories (<13, age 13-17) and dialysis modality (peritoneal dialysis or hemodialysis).

Facility-level adjustments
There are three facility-level adjustments in the ESRD PPS. The first adjustment accounts for ESRD facilities furnishing a low-volume of dialysis treatments. The second adjustment reflects urban and rural differences in area wage levels using an area wage index developed from Core Based Statistical Areas (CBSAs). The third is a rural adjustment beginning in CY 2016.

ESRD facilities do not receive the low-volume adjustment, or the rural adjustment, for pediatric beneficiaries. However, they are eligible for training add-on and outlier payments.

- Low Volume Adjustment **–** ESRD facilities that qualify as being low-volume can receive the low volume payment adjustment (LVPA) applied to each dialysis treatment they furnish beginning on or after January 1, 2011.

  To be eligible for the low-volume adjustment, an ESRD facility must meet specific criteria.
  - The ESRD facility must have furnished less than 4,000 dialysis treatments in each of the 3 cost reporting years preceding its payment year. This 3 year eligibility period is based on the ESRD facility's as-filed or final settled 12-consecutive month cost reports.
  - For purposes of determining eligibility for the low-volume adjustment, the number of "treatments" is the total number of treatments furnished to Medicare and non-Medicare patients. For peritoneal dialysis (PD) patients, 1 week of PD is considered equivalent to 3 hemodialysis (HD) treatments.
  - Effective January 1, 2016, the ESRD facility must not be located within 5 road miles of another ESRD facility under common ownership. The geographic proximity criterion is applicable to all ESRD facilities that are Medicare certified to furnish outpatient maintenance dialysis treatments. For the purpose of determining the number of treatments furnished by the ESRD facility, the number of treatments considered furnished by the ESRD facility would be equal to the aggregate number of treatments furnished by the other ESRD facilities that are both under common ownership, and 5 road miles or less from the ESRD facility in question.

  ESRD Facility Attestation Instruction for Low-Volume Adjustment - In order to receive the low-volume adjustment under the ESRD PPS, each individual ESRD facility must submit an attestation statement each year to its A/B MAC (A).

  Refer to Medicare Benefit Policy Manual, Chapter 11, Section 60 B.1. for additional information on the Low-volume Adjustment.

  Beginning in CY 2025, CMS will establish two (2) tiers for LVPA payment based on treatment volume with different payment adjustments for each tier. An ESRD facility that meets all the existing LVPA criteria at § 413.232(b) will receive a 28.9 percent adjustment if it furnishes fewer than 3,000 treatments per year and will receive an 18.3 percent adjustment if it furnishes between 3,000 and 3,999 treatments per year. A facility's annual treatment count will be based on the median treatment volume over its most recent prior three (3) cost reporting years (Transmittal R12979CP).

- Wage Index **–** The wage index adjustment is applied when calculating the ESRD PPS payment in order to account for geographic differences in area wage levels. Each ESRD facility's payment is adjusted using the wage index for the CBSA in which the ESRD facility is located. Rural ESRD facilities use the statewide average.

- Rural adjustment **–** Beginning January 1, 2016, the ESRD PPS provides a 1.008 percent payment adjustment for ESRD facilities located in a rural CBSA.

Training and Retraining Add-On Payment

A training add-on payment adjustment is available under the ESRD PPS. The training add-on payment is computed by using the national average hourly wage for nurses from the Bureau of Labor Statistics. The payment accounts for 1.5 hours of nursing time for each training treatment that is furnished and is adjusted by the geographic area wage index. The training add-on payment applies to both peritoneal dialysis and hemodialysis training treatments, and added to the ESRD PPS payment, when a training treatment is provided by a Medicare certified training ESRD facility. An ESRD facility may bill a maximum of 25 training sessions per patient for hemodialysis training, and 15 sessions for CCPD and CAPD training. ESRD facilities should not expect additional reimbursement beyond the maximum sessions. CMS expects that ESRD patients who opt for home dialysis are good candidates for home dialysis training, and will

successfully complete their method of training before reaching the maximum number of allotted training treatments.

Outlier Policy
The ESRD PPS provides additional payment for high cost outliers due to unusual variations in the type or amount of medically necessary care when applicable. Outlier payments are based on a comparison of the predicted Medicare allowable payment (MAP) per treatment to actual incurred expenditure per treatment for services whichwere or would have been considered separately billable prior to the implementation of the ESRD PPS. ESRD outlier services include (42 CFR 413.237):

- Renal dialysis drugs and biological products that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B;
- Renal dialysis laboratory tests that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B;
- Renal dialysis medical or surgical supplies, including syringes, used to administer drugs and biologicals used for the treatment of ESRD that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; and
- Renal dialysis drugs and biologicals that were or would have been, prior to January 1, 2011, covered under Part D, including renal dialysis oral-only drugs effective January 1, 2025.

Effective January 1, 2025, CMS is revising the definition of ESRD Outlier Services to include renal dialysis drugs and biological products that are Composite Rate Services as defined at § 413.171. Current regulations at § 413.171 define Composite Rate Services as: “Items and services used in the provision of outpatient maintenance dialysis for the treatment of ESRD and included in the composite payment system established under section 1881(b)(7) and the basic case-mix adjusted composite payment system established under section 1881(b)(12) of the Act.” This includes all drugs and biological products that were or would have been included in the composite rate prior to the establishment of the ESRD PPS. We note that this expands outlier eligibility to longstanding renal dialysis drugs and biological products that were historically included in the composite rate, as well as newer drugs and biological products that are currently included in the calculation of the post-TDAPA add-on payment adjustment. Additional information about changes to the calculation of the predicted Medicare Allowable Payment (MAP) amount, which will be performed in the ESRD Pricer, will be provided in the ESRD PPS Annual Update Change Request 13865.

Beginning January 1, 2025, all renal dialysis drugs and biological products reported on ESRD facility claims shall be considered for the ESRD PPS outlier adjustment, with the following exceptions:
1. Drugs and biological products reported with the AY modifier, indicating that they were not provided for the treatment of ESRD, and
2. Drugs and biological products reported with the AX modifier, for which payment is made under the TDAPA.

CMS Transmittal R12979CP, Change Request 13686; MM13686
CMS Transmittal R12999BP; Change Request 13865; MM13886

The list of renal dialysis services that are included as outlier services may be found at **ESRD PPS Outlier Services**.

ESRD facilities may receive outlier payments for the treatment of both adult and pediatric dialysis patients. An ESRD facility is eligible for an outlier payment if its actual or imputed MAP amount per treatment for ESRD outlier services exceeds a threshold. The MAP amount represents the average incurred amount per treatment for services that were or would have been considered separately billable services prior to January 1, 2011. The threshold is equal to the ESRD facility’s predicted ESRD outlier services MAP amount per treatment (which is case-mix adjusted) plus the fixed dollar loss amount. In accordance with 42 CFR §413.237(c), facilities are paid 80 percent of the per treatment amount by which the imputed MAP amount for outlier services (that is, the actual incurred amount) exceeds this threshold.

Outlier Payment Calculation
The outlier payment computations use the case-mix adjusters for separately billable services. These adjusters are applied to the relevant outlier services MAP amount for either adult or pediatric patients discussed above to obtain the predicted MAP amount for outlier services, reflecting all patient-specific and any facility-specific adjustments.

An example of outlier payment calculation is provided in the Medicare Benefit Policy Manual, Chapter 11, Section 60 D.

Referral/notification/prior authorization requirements

Prior authorization is not required for hemodialysis (CPT 90999) provided by a plan provider.

Billing/coding guidelines

Claims for renal dialysis services must be submitted on an 837 Institutional Claim (Form CMS-1450).

National Provider Identifier (NPI)

There are types of dialysis facilities that provide dialysis services to ESRD beneficiaries. To ensure that provider data is correct, dialysis facilities are required to submit their National Provider Identifier (NPI) on claims. CMS has mapped the following dialysis provider numbers to the facilities 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

Type of Bill

All ESRD facilities should report their assigned NPI on the 72x type of bill, where
721 = Admit Through Discharge Claim
727 = Replacement of Prior Claim
728 = Void/cancel of Prior Claim

The following claim data are required to calculate the ESRD PPS per treatment payment amount:
For additional information refer to Medicare Claims Processing Manual, Chapter 8, Section 50.3.

- Provider number (NPI)
- Statement Covers Period (From and Through dates)
- Number of dialysis sessions in billing period
- Date of birth
- ESRD dialysis start date
- Condition Codes (73, 74, 87)
- Value Codes A8 (Weight of Patient) and A9 (Height of Patient) with amounts
- Revenue Code (0821, 0831, 0841, 0851, 0880, or 0881)
- HCPCS code 90999 on hemodialysis claims on the line reporting revenue code 082X
- Total charges

Condition Codes

Note that all ESRD claims must have one of the condition codes 71 through 76 to describe the dialysis setting on every claim. If two dialysis settings are used during the month, then two claims must be filed.

Condition Code	Definition
71	Full care in unit or transient
72	Self-care in unit
73	Training for home/self-dialysis

74	Home dialysis
76	Back-up in facility

Other Optional Condition Codes

Condition Code	Definition
59	Non-primary ESRD Facility
70	Self-Administered anemia management drugs including Erythropoietin Stimulating Agents (ESAs) and Epoetin Alfa (EPO)
80	ESRD beneficiary receiving home dialysis in nursing facilities, including SNFs (report along with condition code 74)
86	Additional hemodialysis treatments with medical justification
87	Self-care retraining
H3	Gastrointestinal (GI) Bleeding
H4	Pneumonia
H5	Pericarditis

Self Administered ESA Supply

Initially, ESRD facilities may bill for up to a 2-month supply of an ESA for home dialysis patients 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 patient. 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.

Value Codes and Amounts

ESRD 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.

Value Code	Definition
48	Hemoglobin reading
49	Hematocrit reading
A8	Weight of patient (kilograms)
A9	Height of patient (centimeters
D5	Result of last Kt/V reading
D6	The total number of minutes of dialysis provided during the billing period

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

All ESRD claims must indicate the applicable Kt/V reading for the dialysis patient.

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.

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

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

Beginning with dates of service on or after January 1, 2025, CMS is implementing Value Code D6: The total number of minutes of dialysis provided during the billing period. ESRD facilities are required to report Value Code D6 on ESRD PPS claims for in-facility maintenance hemodialysis treatments, as well as any training or retraining treatments that are provided in-facility. The ESRD

facility counts only the minutes spent dialyzing. It reports in whole minutes (rounded to the nearest whole minute and reported left of the decimal). The value in the monthly claim line is the total number of minutes of dialysis provided during the month. The designation is NM (non-monetary).

Definition: The number of minutes (rounded to the nearest whole minute) between the beginning of dialysis treatment time (i.e., when the start button on the blood pump is pushed) and the end of dialysis treatment time (i.e., when the stop button on the blood pump is pushed). ESRD facilities are not required to reduce the total count of minutes to account for disruptions due to machine failures, bathroom breaks, or other stoppages, but the number of minutes reported should not include time outside the start and end of the dialysis session (for example, time when the patient is in-center waiting to be seated in a chair). The time on dialysis machine duration begins when the actual dialysis treatment starts and ends when the actual dialysis treatment is complete. The units reported must exceed 1.

CMS Transmittal R12979CP, Change Request 13686; MM13686

Occurrence Codes and Dates

Occurrence code 51- Date of last Kt/V (K-dialyzer clearance of urea; t-dialysis time; v-patient's total body water) reading:

- In center hemodialysis patients
  - Date of last reading taken during the billing period
- Peritoneal dialysis patients and home dialysis patients
  - Date may be before the current billing period, but within four months of the date of service on the claim.

Revenue Codes

The revenue code for the appropriate treatment modality is billed (e.g., 0821 for hemodialysis). For full description of revenue codes refer to Medicare Claims Processing Manual, Chapter 8, Section 50.3. Effective January 1, 2015, ESRD facilities are required to report on the claim the drugs identified on the consolidated billing list provided at: **ESRD PPS Consolidated Billing.**

Revenue Code	Definition
0634	Erythropoietin (EPO), less than 10,000 units administered
0635	Erythropoietin (EPO), 10,000 or more units administered
0636	Darbepoetin alfa and drugs requiring detailed coding
082X	Hemodialysis
083X	Peritoneal dialysis
084X	Continuous ambulatory peritoneal dialysis (CAPD)
085X	Continuous cycling peritoneal dialysis (CCPD)
088X	Miscellaneous Dialysis - Charges for dialysis services not identified elsewhere.

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.

CPT/HCPCS

Report the appropriate CPT/HCPCS codes (not all-inclusive list), when applicable. All ESRD hemodialysis claims must include HCPCS 90999 on the line reporting revenue code 082x. CPT 90999 is billable three times per week; 13 times in 30 days and 14 times in 31 days.

CPT/HCPCS codes are required for all revenue codes except 083X, 084X, 085X, and 088X.

HCPCS codes J0882, J0887, Q4081, and Q5105 are intended for use only with patients who have ESRD and are on dialysis.

The maximum number of administrations of epoetin alfa/biosimilar for a billing cycle is 13 times in 30 days and 14 times in 31 days. The maximum number of administrations of darbepoetin alfa for a billing cycle is 5 times in 30/31days.

HCPCS Code	Definition
90999	Unlisted dialysis procedure, inpatient or outpatient
J0882	Injection, darbepoetin alfa, 1 mcg (for ESRD on Dialysis) (Aranesp)
J0887	Injection, epoetin beta, 1 microgram, (for ESRD on dialysis)
Q0481	Injection, epoetin alfa, 100 units (for ESRD on Dialysis)
Q5105	Injection, epoetin alfa, biosimilar, (Retacrit) (For ESRD on Dialysis), 100 units

Erythropoiesis Stimulating Agents (ESAs)

Payment for ESRD-related Erythropoietin Stimulating Agents (ESAs) and their administration is included in the payment for ESRD hemodialysis. Providers must continue to report ESAs on the claim. ESAs are eligible for outlier payment consideration. HCPCS codes J0882, J0887, Q4081, and Q5105 are intended for use only with patients who have ESRD and are on hemodialysis.

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.

For patients with ESRD on dialysis, both ICD-10 N18.6 and D63.1 diagnoses must be on the claim in order to designate the stage of kidney disease and type of anemia.

Route of Administration Modifiers

All ESRD claims reporting J0882, J0887, Q4081or Q5105 must also report one and only one of the following route of administration modifiers:

Modifiers	Definition
JA	Administered intravenously
JB	Administered subcutaneously
JE	Administered via dialysate

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.

HCPCS code 90999 (unlisted dialysis procedure, inpatient or outpatient) must be reported in field locator 44 for all bill types 72X. The appropriate G-modifier in field locator 44 is used for patients that received seven or more dialysis treatments in a month. For patients that have received dialysis 6 days or less in a month, use the G6 modifier.

At least one revenue code line for hemodialysis on the claim must contain one of the URR modifiers shown below. The URR modifier is not required on every hemodialysis line on the claim.

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

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

ESRD claims for hemodialysis 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.

Modifiers	Definition
V5	Any Vascular Catheter (alone or with any other vascular access)
V6	Arteriovenous Graft (or other Vascular Access not including a vascular catheter in use with two needles)
V7	Arteriovenous Fistula Only (in use with two needles)

Discarded Drug Reporting

Beginning January 1, 2025, ESRD facilities are required to report discarded billing units on a separate claim line containing a JW modifier for all renal dialysis drugs and biological products from single-dose containers or single-use packaging. When a renal dialysis drug or biological product from a single-dose container or single-use packaging is reported on an ESRD claim and there is no discarded amount, ESRD facilities are required to attest that there is no discarded amount by reporting a JZ modifier on the claim line along with the amount of the drug or biological product administered. When billing for any renal dialysis drug or biological product from a single-dose container or single use package that is provided to beneficiaries for use while receiving home dialysis services as defined in § 413.217, or oral forms of renal dialysis drugs and biological products, ESRD facilities should use the best information they have in determining the amount expected to be discarded in a given month, including fill information from the pharmacy and the patient's plan of care.The ESRD Pricer will edit ESRD facility claims for the presence of certain HCPCS codes for which either the JW or JZ modifier must be reported. The HCPCS codes that are identified as single-dose container and single-use packaging renal dialysis drugs and biological products for which the JW or JZ modifier must be reported, and which are subject to this edit, are outlined in CMS Transmittal R12979CP Attachment 1.

The list in CMS Transmittal R12979CP Attachment 1 is not an exhaustive list of the renal dialysis drugs and biological products subject to the JW and JZ reporting requirement under the ESRD Prospective Payment System (PPS). All ESRD facility claims for renal dialysis drugs and biological products from a single-dose container or single-use packaging must include either the JW or JZ modifier. When billing for a renal dialysis drug or biological product, an ESRD facility should refer to the label information to determine whether it is provided in a single-dose container or single-use packaging.

CMS Transmittal R12979CP Attachment 2 provides a list of HCPCS codes that include National Drug Codes (NDCs) for renal dialysis drugs and biological products distributed in multi-dose containers as well as single-dose containers or single-use packaging. These HCPCS codes are not subject to editing in FISS but may represent a renal dialysis drug or biological product subject to the ESRD PPS reporting requirement for the JW and JZ modifiers.

The Medicare Part B JW modifier policy in effect since 2017 generally does not apply to drugs that are not separately payable. The ESRD PPS statute generally requires a single bundled payment for renal dialysis services. Specifically, section 1881(b)(14)(A)(i) of the Social Security Act requires the Secretary to implement a payment system under which a single payment is made to a provider of services or a renal dialysis facility for renal dialysis services in lieu of any other payment. However, ESRD facilities are instructed to report the JW modifier in certain circumstances. Current guidance in Chapter 17, Section 40.1 of the Medicare Claims Processing Manual states that the ESRD facility must bill the program using the JW modifier for the amount

of Erythropoiesis Stimulating Agents (ESAs) appropriately discarded if the home dialysis patient must discard a portion of the ESA supply due to expiration of a vial, because of interruption in the patient's plan of care, or unused ESAs on hand after a patient's death. In addition, renal dialysis drugs and biological products that receive the Transitional Drug Add-on Payment Adjustment (TDAPA) that are distributed in single-dose containers or single use packaging must be billed using the JW and JZ modifiers as applicable. Most recently, the May 9, 2024, Change Request 13608, that established the TDAPA for DefenCath (taurolidine and heparin sodium), instructs facilities to use the JW modifier to report the amount of taurolidine and heparin sodium that is discarded and eligible for payment under the ESRD PPS, and to use the JZ modifier (zero drug amount discarded/not administered to any patient) on the 72x claim to report when there is no discarded amount of taurolidine and heparin sodium.

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

As further discussed in the CY 2024 ESRD PPS final rule, CMS' longstanding policy for payment under the ESRD PPS, including the calculation of the TDAPA and outlier payment adjustments, includes payment for units of renal dialysis drugs and biological products billed with the JW modifier, but does not allow payment for overfill units (88 FR 76382). That is, the current ESRD PPS payment policy is consistent with the broader Medicare Part B policy to pay for the unused and discarded amount, as well as the dose administered, up to the amount of the drug indicated on the vial or package labeling.

Lastly, CMS finalized a new policy to require the use of the JW or JZ modifier on claims to track discarded amounts of single-dose container and single-use package renal dialysis drugs and biological products paid for under the ESRD PPS, effective January 1, 2025. As discussed in the CY 2024 ESRD PPS final rule, ESRD facilities should not report discarded amounts of renal dialysis drugs or biological products from multi-use vials (88 FR 76385). Discarded amounts of renal dialysis drugs and biological products from multi-use vials should not be billed on ESRD PPS claims.

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

- ESRD facilities are reminded to ensure amounts of drugs administered to patients are accurately reported in terms of the dosage specified by the HCPCS code descriptor.
- When submitting Medicare claims, units of service should be reported in multiples of the dosage included in the HCPCS code descriptor. If the dosage given is not a multiple of the number provided in the HCPCS code description, the ESRD facility shall round up to the nearest whole number to express the number as a multiple.
- The ESRD facility must follow these steps when billing for any discarded amount of a renal dialysis drug or biological product from a single-dose container or single-use package after administering the prescribed dosage of any given drug.
    - The units billed should correspond with the labeled amount of the product that is actually purchased to prepare the dose. Where possible, ESRD facilities should use the smallest dose (vial) available for purchase from the manufacturer(s) that could provide the appropriate dose for the patient, while minimizing any discarded amounts.
    - Any discarded amount of a renal dialysis drug or biological product from a single-dose container or single-use package for which an ESRD facility bills under the ESRD PPS must be discarded and may not be used for another patient regardless of whether the other patient has Medicare.

See Transmittal R12979CP for examples illustrating appropriate usage of the JW and JZ modifiers for any renal dialysis drug or biological product from a single-dose container or single-use package that is paid for under the ESRD PPS.

CMS Transmittal R12979CP, Change Request 13686; MM13686

Modifiers	Definition
JW	Drug amount discarded/not administered to any patient
JZ	Zero drug amount discarded/not administered to any patient

Statement Covers From and Through Dates

The beginning and ending service dates of the period should be on one bill. ESRD services are subject to monthly billing requirements for repetitive services. The statement covers from and through dates must reflect the first day dialysis began in the billing month through the last day of dialysis in the billing month.

Line-item detail billing is required for ESRD claims. Each service must be submitted on a separate line with the appropriate line-item date of service.

Diagnosis Codes

Hospital-based and independent renal facilities must complete this item and it should include a principal diagnosis of end stage renal disease for patients with ESRD. Report any other diagnosis codes for comorbid conditions eligible for an adjustment.

Home and Self-Dialysis Training and Retraining

Home and self-dialysis training are provided by Medicare certified ESRD facilities to educate ESRD patients and their caregivers to perform self-dialysis in the ESRD facility or home dialysis including continuous ambulatory peritoneal dialysis (CAPD) and continuous cycling peritoneal dialysis (CCPD) with little or no professional assistance. Self-dialysis training can occur in the patient's home or the in-facility when it is provided by the qualified staff of the ESRD facility.

Home dialysis training services and supplies includes personnel services; dialysis supplies, parenteral items used in dialysis, written training manuals and materials, and renal dialysis laboratory tests.

The Plan will make a determination whether or not to permit training sessions in excess of 15 for CAPD and CCPD.

Modality	Training
Hemodialysis Training	An ESRD facility may bill a maximum of 25 training sessions per patient for hemodialysis training. Revenue code 082X, Condition Code 73
Intermittent Peritoneal Dialysis	An ESRD facility may bill no more three IPD treatments in a single week, for a total duration longer than 3 months. Revenue code 083X, Condition Code 73
Continuous Ambulatory Peritoneal Dialysis (CAPD)	An ESRD facility may bill a maximum of 15 training sessions per patient for CAPD training. Revenue Code 084X, Condition Code 73
Continuous Cycling Peritoneal Dialysis (CCPD)	An ESRD facility may bill a maximum of 15 training sessions per patient for CCPD training. Revenue Code 085X, Condition Code 73

Retraining

Payment may be made for retraining self-dialysis education after a patient or caregiver has completed the initial program, if the patient continues to be an appropriate candidate for home dialysis. Most patients receive additional training on the use of new equipment, a change in their caregiver, or a change in modality.

Providers report Condition Code 87 (ESRD self-care retraining) for retraining sessions with the appropriate revenue code.

In-Facility Back-Up Dialysis

Back-up dialysis is an in-facility dialysis treatment furnished to a home dialysis patient. Condition code 76 must appear 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 ESRD 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 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.

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

Although CAPD and 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.

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, the Plan will pay for both types of dialysis services furnished on the same day. The Plan will determine the medical necessity based on medical documentation from the ESRD facility that supports the use of back-up dialysis with another treatment modality. If a CAPD patient frequently requires back-up sessions, the Plan's medical staff may request medical records to determine if this is the appropriate mode of treatment and/or whether a different mode of treatment is more advantageous to the member.

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.

Hospital Dialysis Services for Patients with and without ESRD

The Plan does not allow payment for routine or related dialysis treatments, which are covered and paid under the ESRD PPS, when furnished to ESRD patients in the outpatient department of a hospital.

However, in certain medical situations in which the ESRD outpatient cannot obtain his or her regularly scheduled dialysis treatment at a certified ESRD facility, the Plan allows payment for non-routine dialysis treatments (which are not covered under the ESRD benefit) furnished to ESRD outpatients in the outpatient department of a hospital. Payment for unscheduled dialysis furnished to ESRD outpatients and paid under the OPPS is limited to the following circumstances:

- Dialysis performed following or in connection with a dialysis-related procedure such as vascular access procedure or blood transfusions;
- Dialysis performed following treatment for an unrelated medical emergency; e.g., if a patient goes to the emergency room for chest pains and misses a regularly scheduled dialysis treatment that cannot be rescheduled, CMS allows the hospital to provide and bill Medicare for the dialysis treatment; or
- Emergency dialysis for ESRD patients who would otherwise have to be admitted as inpatients in order for the hospital to receive payment.

In these situations, non-ESRD certified hospital outpatient facilities are to bill the Plan using the HCPCS code G0257 (Unscheduled or emergency dialysis treatment for an ESRD patient in a hospital outpatient department that is not certified as an ESRD facility).

HCPCS code G0257 may only be reported on type of bill 13X (hospital outpatient service) or type of bill 85X (critical access hospital) because HCPCS code G0257 only reports services for hospital outpatients with ESRD and only these bill types are used to report services to hospital outpatients.

HCPCS code 90935 (Hemodialysis procedure with single physician evaluation) may be reported and paid only if the patient is a hospital outpatient and does not have ESRD and is receiving hemodialysis in the hospital outpatient department. The service is reported on a type of bill 13X or type of bill 85X.

CPT code 90945 (Dialysis procedure other than hemodialysis (e.g. peritoneal dialysis, hemofiltration, or other continuous replacement therapies)), with single physician evaluation, may be reported by a hospital paid under the OPPS or CAH method I or method II on type of bill 12X, 13X or 85X.

For additional information refer to Medicare Claims Processing Manual, Chapter 4, Section 200.2, Medicare Claims Processing Manual, Chapter 8, Section 10.5, and Medicare Benefit Manual, Chapter 11, Section

Modifier AY (Service not related to treatment of ESRD)

The ESRD PPS implemented consolidated billing edits for certain renal dialysis laboratory services, drugs and biologicals, equipment, and supplies to ensure that payment for renal dialysis services is not made to providers other than the ESRD facility. A service furnished by an ESRD facility that is not for the treatment of ESRD must be submitted with an AY modifier to allow for separate payment outside of the ESRD PPS.

Separately Billable ESRD Items and Services

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

Lab Services

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.

Drugs Furnished in ESRD Facilities

All drugs and biologicals used in the treatment of ESRD are included in the ESRD PPS payment and must be billed by the ESRD facility (Medicare Claims Processing Manual, Chapter 8, Section 60.2).

ESRD facilities report drugs and biologicals furnished to ESRD patients that are not used for the treatment of ESRD with the appropriate HCPCS code, along with revenue code 0636, and modifier AY. All separately payable drugs for both hospital-based and independent facilities are paid at ASP+6% except vaccines (Medicare Claims Processing Manual, Chapter 8, Section 60.2.1 and 06.2.1.1).

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 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 (Medicare Claims Processing Manual, Chapter 8, Section 20).

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).

Vaccines Furnished to ESRD Patients

Medicare covers Hepatitis B, influenza virus, pneumococcal and COVID-19 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.

Refer to Medicare Claims Processing Manual, Chapter 18, Section 10 for information on billing and payment for vaccines and the administration of the vaccine.

ESRD facilities use Type of bill 072X when billing for Hepatitis B, influenza virus, pneumococcal and COVID-19 vaccines.

ESRD facilities report Hepatitis B, influenza virus, pneumococcal and COVID-19 vaccines under revenue code 0636 and the vaccine administration under revenue code 0771.

Hepatitis B, influenza virus, pneumococcal and COVID-19 vaccines and their administration are reported using separate CPT/HCPCS codes.

ICD-10-CM diagnosis code Z23 is to be used for all encounters for preventive vaccine immunizations, including COVID-19 immunizations.

Transitional Drug Add-on Payment Adjustment (TDAPA)

The TDAPA is a payment adjustment under the ESRD PPS for certain new renal dialysis drugs and biological products. For an example calculation, please refer to CR 10065, titled “Implementation of the Transitional Drug Add-On Payment Adjustment."

The TDAPA for new renal dialysis drugs or biological products within an existing esrd pps functional category (§ 413.234(b)(1)) is paid for 2 years. The TDAPA payment period begins on the effective date of the CMS Change Request (CR). During the time a new renal dialysis drug or biological product is eligible for the TDAPA, it is not an eligible ESRD outlier service as defined under 42 C.F.R. § 413.237(a)(1) and therefore is ineligible for outlier payment. At the end of the TDAPA payment period, the new renal dialysis drug or biological product is paid the post-TDAPA add-on payment adjustment and no changes to the base rate are made.

The TDAPA for new renal dialysis drugs or biological products not within an existing esrd pps functional category (§ 413.234(b)(2)) is paid until sufficient claims data for rate setting analysis for the new renal dialysis drug or biological product is available, but not for less than 2 years. The TDAPA payment and data collection periods for these drugs and biological products begin on the effective date of the applicable CMS ESRD PPS annual update CR for MACs and ESRD facilities. During the time a new renal dialysis drug or biological product is eligible for the TDAPA, it is not an eligible ESRD outlier service as defined under 42 C.F.R. § 413.237(a)(1) and therefore is ineligible for outlier payment. Following payment of the TDAPA, CMS undertakes rulemaking to modify the ESRD PPS base rate, if appropriate, to account for the new renal dialysis drug or biological in the ESRD PPS bundled payment. The post-TDAPA add-on payment adjustment does not apply for these drugs or biological products.

ESRD facilities should report TDAPA drugs on type of bill 072X with revenue code 0636 and the AX modifier (item furnished in conjunction with dialysis services) with the HCPCS code to receive payment for a TDAPA-eligible drug. While this drug is eligible for the TDAPA, it does not qualify toward outlier calculation. We note that ESRD facilities should only use the AX modifier for a drug or biological product that qualifies for payment using the TDAPA.

Modifiers	Definition
AX	Furnished in conjunction with dialysis – TDAPA services and TPNIES

Drugs and Biologicals Eligible for TDAPA

For payment amounts for renal dialysis drugs and biologicals eligible for the TDAPA, see **Drugs and Biological Products Eligible for the TDAPA**.

Code	Description	TDAPA Payment Period
J0601	Sevelamer carbonate 20 mg	January 1, 2025 through December 31, 2026
J0602	Sevelamer carbonate pdr 20mg	January 1, 2025 through December 31, 2026
J0603	Sevelamer hydrochloride 20mg	January 1, 2025 through December 31, 2026
J0605	Sucroferric oxyhydroxide 5mg	January 1, 2025 through December 31, 2026
J0607	Lanthanum carbonate oral 5mg	January 1, 2025 through December 31, 2026
J0608	Lanthanum carbonate pwdr 5mg	January 1, 2025 through December 31, 2026
J0609	Ferric citrate orl 3 mg iron	January 1, 2025 through December 31, 2026
J0615	Calcium acetate, oral, 23 mg	January 1, 2025 through December 31, 2026
J0901	Vadadustat, oral, 1 mg (for ESRD on dialysis)	January 1, 2025 through December 31, 2026
J0911	Instillation, taurolidine 1.35 mg and heparin sodium 100 units (central venous catheter lock for adult patients receiving chronic hemodialysis)	July 1, 2024 through June 30, 2026
J0889	Daprodustat, oral, 1 mg, (for ESRD on dialysis)	October 1, 2023, through September 30, 2025
J0879	Injection, difelikefalin, 0.1 microgram, (for ESRD on dialysis)	April 1, 2022 through March 31, 2024
J0604	Cinacalcet, oral, 1 mg, (for ESRD on dialysis)	January 1, 2018 through December 31, 2020
J0606	Injection, etelcalcetide, 0.1 mg	January 1, 2018 through December 31, 2020

On November 14, 2024, CMS issued instructions effective January 1, 2025, indicating that VAFSEO® (vadadustat) and the following oral-only phosphate binders qualify for the TDAPA under the ESRD PPS: sevelamer carbonate, sevelamer hydrochloride, sucroferric oxyhydroxide, lanthanum carbonate, ferric citrate, and calcium acetate.

CMS Transmittal R12962BP, Change Request 13865; MM13686
CMS Transmittal R12979CP, Change Request 13686; MM13686
CMS Transmittal R12999BP, Change Request 13865; MM13686
CMS Transmittal R12957CP, Change Request 13686; MM13686

J0901, Vadadustat, oral, 1 mg (for ESRD on dialysis)

On November 14, 2024, CMS issued instructions effective January 1, 2025, indicating that VAFSEO® (vadadustat) qualifies for the TDAPA under the ESRD PPS. Effective January 1, 2025, vadadustat, an oral hypoxia-inducible factor prolyl hydroxylase (HIF PH) inhibitor indicated for the treatment of anemia due to chronic kidney disease (CKD) in adults who have been receiving dialysis for at least three months, qualifies for the TDAPA as a drug or biological product used to treat or manage a condition for which there is an existing ESRD PPS functional

category - specifically, the anemia management category. The TDAPA payment period is January 1, 2025 through December 31, 2026. ESRD facilities should report the AX modifier (item furnished in conjunction with dialysis services) with the HCPCS code to get payment for the TDAPA-eligible drug. While this drug is eligible for the TDAPA, it does not qualify toward outlier payments. We note that ESRD facilities should only use the AX modifier for a drug or biological product that qualifies for payment using the TDAPA.

Because vadadustat falls within the existing ESRD PPS functional category of anemia management and is only used for treating renal dialysis patients, it is considered to be a drug that is always used for the treatment of ESRD. ESRD facilities will not receive separate payment for J0901 with or without the AY modifier, and the claims shall process the line item as covered with no separate payment under the ESRD PPS.

The ESRD PPS consolidated billing requirements have been updated to include J0901.

The payer-only value code Q8 – Total TDAPA Amount is used to capture the add-on payment.

CMS Transmittal R12962BP, Change Request 13865; MM13686
CMS Transmittal R12999BP, Change Request 13865; MM13686

TDAPA for phosphate binders

Effective January 1, 2025, oral-only phosphate binders qualify for the TDAPA. ESRD facilities should report the AX modifier (item furnished in conjunction with dialysis services) with the HCPCS for these drugs and biological products to receive payment for these drugs using the TDAPA. While these drugs are eligible for the TDAPA, they do not qualify toward outlier payment calculation. The TDAPA payment period for these oral-only phosphate binders qualify for the TDAPA is January 1, 2025 through December 31, 2026. For calendar year 2025 and 2026, TDAPA for these oral-only phosphate binders is based on 100 percent of ASP plus an additional amount derived from 6 percent of per-patient phosphate binder spending based on utilization and cost data. In addition, for CY 2025, a fixed amount of $36.41 will be added to the TDAPA calculation for each monthly claim that includes phosphate binders.

Phosphate binders will be reported on ESRD PPS claims using the following HCPCS codes:

J0601, Sevelamer carbonate (Renvela or therapeutically equivalent), oral, 20 mg (for ESRD on dialysis)

J0602, Sevelamer carbonate (Renvela or therapeutically equivalent), oral, powder, 20 mg (for ESRD on dialysis)

J0603, Sevelamer hydrochloride (Renagel or therapeutically equivalent), oral, 20 mg (for ESRD on dialysis)

J0605, Sucroferric oxyhydroxide, oral, 5 mg (for ESRD on dialysis)

J0607, Lanthanum carbonate, oral, 5 mg (for ESRD on dialysis)

J0608, Lanthanum carbonate, oral, powder, 5 mg, not therapeutically equivalent to J0607 (for ESRD on dialysis)

J0609, Ferric citrate, oral, 3 mg ferric iron, (for ESRD on dialysis)

J0615, Calcium acetate, oral, 23 mg (for ESRD on dialysis)

For an example calculation, please refer to Change Request 13865, titled “ Implementation of Changes in the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) and Payment for Dialysis Furnished for Acute Kidney Injury (AKI) in ESRD Facilities for Calendar Year (CY) 2025."

Phosphate binders are drugs that are used for the maintenance of bone and mineral metabolism. Bone and mineral metabolism is an ESRD PPS functional category where drugs and biological products that fall in this category are always considered to be used for the treatment of ESRD. ESRD facilities will not receive separate payment for phosphate binders with or without the AY

modifier, and the claims shall process the line item as covered with no separate payment under the ESRD PPS.

These eight (8) HCPCS codes for oral-only phosphate binders were added to the consolidated billing list for CY 2025.

The ESRD Pricer will add this amount to the calculation of payer only value code Q8 – Total TDAPA Amount on the monthly ESRD claim.

CMS Transmittal R12962BP, Change Request 13865; MM13686
CMS Transmittal R12999BP, Change Request 13865; MM13686

J0911, Instillation, taurolidine 1.35 mg and heparin sodium 100 units (central venous catheter lock for adult patients receiving chronic hemodialysis)

On May 9, 2024, CMS issued instructions effective July 1, 2024, indicating that DefenCath® (taurolidine and heparin) qualifies for the TDAPA under the ESRD PPS. Effective July 1, 2024, taurolidine and heparin sodium, a catheter lock solution instilled into the central venous catheter (CVC) at the conclusion of each hemodialysis session, qualifies for the TDAPA as a drug or biological product used to treat or manage a condition for which there is an existing ESRD PPS functional category - specifically, the anti-infectives category.The TDAPA payment period is July 1, 2024 through June 30, 2026. ESRD facilities should report the AX modifier (item furnished in conjunction with dialysis services) with the HCPCS code to get payment for the TDAPA-eligible drug. While this drug is eligible for the TDAPA, it doesn't qualify toward outlier calculations. We note that ESRD facilities should only use the AX modifier for a drug or biological product that qualifies for payment using the TDAPA.

The taurolidine and heparin sodium solution uses single dose packaging. Catheter lumen sizes and the volume that they hold vary. The 3ml and 5ml single dose vials are designed for a single instillation in the CVC. Facilities should use the JZ modifier (zero drug amount discarded/not administered to any patient) on the 72x claim to report when there is no discarded amount of taurolidine and heparin sodium. To the extent that the patient's lumen require an amount of DefenCath that differs from the 3ml or 5ml single dose vial, facilities should use the JW modifier (drug amount discarded/not administered to any patient) on the 72x claim to report the amount of taurolidine and heparin sodium that is discarded and eligible for payment under the TDAPA. The AX modifier should be reported in the first modifier position and the JZ or JW modifier in the second modifier position. Report the AX modifier in the first modifier position and either the JZ or the JW modifier in the second modifier position.

Because taurolidine and heparin sodium falls within the existing ESRD PPS functional category of antiinfectives and is only indicated to reduce the incidence of catheter-related bloodstream infections in adult patients with kidney failure receiving chronic hemodialysis through a CVC, it is considered to be always used for the treatment of ESRD. ESRD facilities will not receive separate payment for J0911 with or without the AY modifier and the claims shall process the line item as covered with no separate payment under the ESRD PPS.

The ESRD PPS consolidated billing requirements will be updated to include J0911.

The payer only value code Q8 – Total TDAPA Amount is used to capture the add-on payment.

CMS Transmittal R12628CP, Change Request 13608; MM13608

J0889, daprodustat, oral, 1 mg, (for ESRD on dialysis)

On July 27, 2023, CMS issued instructions, effective October 1, 2023, indicating that GlaxoSmithKline's Jesduvroq (daprodustat) was eligible for the TDAPA under the ESRD PPS. The TDAPA payment period is October 1, 2023 through September 30, 2025. ESRD facilities should report the AX modifier (item furnished in conjunction with dialysis services) with the HCPCS code to get payment for the TDAPA-eligble drug. While this drug is eligible for the TDAPA, it does not qualify toward outlier calculation. We note that ESRD facilities should only use the AX modifier for a drug or biological product that qualifies for payment using the TDAPA.

Because daprodustat falls within the existing ESRD PPS functional category of anemia management and is only used for treating renal dialysis patients, it is considered to be a drug that is always used for the treatment of ESRD. ESRD facilities will not receive separate payment for J0889 with or without the AY modifier, and the claims shall process the line item as covered with no separate payment under the ESRD PPS. While this drug is eligible for the TDAPA, it does not qualify toward outlier calculation.

The ESRD PPS consolidated billing requirements will be updated to include J0889.

The payer only value code Q8 – Total TDAPA Amount is used to capture the add-on payment.

CMS Transmittal R12157CP, Change Request 13275; MM13608

J0879 Injection, difelikefalin, 0.1 microgram, (for ESRD on dialysis)

On February 22, 2022, CMS issued instructions, effective April 1, 2022, indicating that Vifor Pharma and Cara Therapeutics' Korsuva (difelikefalin) was eligible for the TDAPA under the ESRD PPS. Payment began on April 1, 2022 and continued through March 31, 2024. ESRD facilities should report the AX modifier (item furnished in conjunction with dialysis services) with the HCPCS for this drug to receive payment for the drug using the TDAPA. While this drug is eligible for the TDAPA, it does not qualify toward outlier calculation. We note that difelikefalin is the only drug that qualifies for payment using the TDAPA and ESRD facilities should not use the AX modifier for any other drug until notified by CMS.

Furthermore, considering the single-use packaging for difelikefalin, the JW modifier should be used by facilities on the 72x claim to report the amount of difelikefalin that is discarded and eligible for payment under the ESRD PPS. The AX modifier should be reported in the first modifier position and the JW modifier in the second modifier position.

Korsuva is a drug used for the treatment of moderate-to-severe pruritus associated with chronic kidney disease in adults undergoing hemodialysis. Because difelikefalin falls within the existing ESRD PPS functional category of antipruritic, it is always considered to be used for the treatment of ESRD. ESRD facilities will not receive separate payment for J0879 with or without the AY modifier and the claims shall process the line item as covered with no separate payment under the ESRD PPS.

The ESRD PPS consolidated billing requirements will be updated to include J0879.

The payer only value code Q8 – Total TDAPA Amount is used to capture the add-on payment.

CMS Transmittal R11278CP, Change Request 12583; MM12583

J0604 Cinacalcet, oral, 1 mg, (for ESRD on dialysis)

J0606 Injection, etelcalcetide, 0.1 mg

On January 10, 2018, CMS issued instructions, effective January 1, 2018, indicating that injectable, intravenous, and oral calcimimetics qualified for the TDAPA. Payment began on January 1, 2018 and continued through December 31, 2020. ESRD facilities should report the AX modifier (Item furnished in conjunction with dialysis services) with the HCPCS for these drugs to receive payment for these drugs using the TDAPA. While these drugs are eligible for the TDAPA, they do not qualify toward outlier calculation. At this time, calcimimetics were the only drug class that qualified for payment using the TDAPA and ESRD facilities should not use the AX modifier for any other drug until notified by CMS.

J0604 and J0606 are drugs that are used for bone and mineral metabolism. Bone and mineral metabolism is an ESRD PPS functional category where drugs and biologicals that fall in this category are always considered to be used for the treatment of ESRD. ESRD facilities will not receive separate payment for J0604 and J0606 with or without the AY modifier and the claims shall process the line item as covered with no separate payment under the ESRD PPS.

The ESRD PPS consolidated billing requirements will be updated to include J0604 and J0606.

Transmittal R1999OTN also implements the payer only value code Q8 – Total TDAPA Amount, to be used to capture the add-on payment.

See Transmittal R1999OTN for an example calculation. The ESRD Pricer puts a payment at the dialysis line so that it is a per treatment payment. There is a calculation that happens in pricer to divide Q8 by the total number of dialysis treatments and then that per treatment amount is added to each dialysis line.

CMS Transmittal R1999OTN, Change Request 10065; MM10065

Post-TDAPA Add-on Payment Adjustment

Beginning January 1, 2024, the ESRD PPS provides additional payment for certain new renal dialysis drugs and biological products after the end of the TDAPA period under section 413.234(g). The post-TDAPA add-on payment adjustment is applied to all ESRD PPS payments and is calculated using utilization of the drug or biological product during the most recent twelvemonth period for which data is available. The post-TDAPA add-on payment adjustment is calculated annually and is applied for 12 calendar quarters following the end of the TDAPA period for a drug or biological product, conditional on the receipt of ASP data. The post-TDAPA add-on payment adjustment amount is then multiplied by the patient-level case-mix adjustment factors for the patient and is added on to the ESRD PPS payment.

For CY 2025 two drugs, Korsuva and Jesduvroq are set to be included in the calculation of the post-TDAPA add-on payment adjustment. Korsuva will be included for all four calendar quarters at an amount of $0.4601 and Jesduvroq will be included for only the fourth quarter at an amount currently estimated to be $0.0096. CMS will publish the final post-TDAPA add-on payment amount for Jesduvroq once a full year's worth of utilization data is available.

Q1 (January - March): $0.4601 (Korsuva only)

Q2 (April - June): $0.4601 (Korsuva only)

Q3 (July - September): $0.4601 (Korsuva only)

Q4 (October - December): $0.4697 (Korsuva and Jesduvroq)

CMS Transmittal R12962BP, Change Request 13865; MM13686
CMS Transmittal R12999BP, Change Request 13865; MM13686

Transitional Pediatric ESRD Add-on Payment Adjustment (TPEAPA)

Beginning January 1, 2024, the ESRD PPS provides the TPEAPA for all claims for services provided to pediatric ESRD patient under section 413.235(b)(2). The TPEAPA is equal to 30 percent of the per-treatment payment amount for the pediatric ESRD patient. The TPEAPA will be applied for calendar years 2024, 2025 and 2026.

CMS Transmittal R12962BP, Change Request 13865; MM13686
CMS Transmittal R12999BP, Change Request 13865; MM13686

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

The intent of the TPNIES, as established in 42 CFR 413.236, is to facilitate Medicare beneficiary access to certain qualifying, new and innovative renal dialysis equipment and supplies by providing an add-on payment adjustment to support ESRD facilities in the uptake of new and innovative equipment and supplies under the ESRD PPS. The TPNIES is paid for two calendar years, beginning on January 1 and ending on December 31. Note that such new and innovative equipment or supply is not considered an outlier service.

ESRD facilities will report the AX modifier (item furnished in conjunction with dialysis services) with the HCPCS code for the equipment or supply eligible to receive the TPNIES. When a HCPCS code on the TPNIES list is reported with the AX modifier and revenue code 027X, the TPNIES instructions will apply.

Beginning January 1, 2021, the TPNIES policy was expanded to include certain capital-related assets (CRA) that are home dialysis machines when used in the home for a single patient. For eligible CRAs that are home dialysis machines, ESRD facilities will be paid the CRA for TPNIES beginning January 1, 2022.

CMS approved payment for the first eligible CRA for TPNIES in CY 2022. Therefore, for eligible CRAs that are home dialysis machines, ESRD facilities are being paid the CRA for TPNIES as of January 1, 2022.

The CRA for TPNIES is paid for 2 calendar years, beginning on January 1 and ending on December 31. Following payment of the CRA for TPNIES, the ESRD PPS base rate will not be modified and the new CRA that is a home dialysis machine will not be an eligible outlier service.

The TPNIES is based on 65 percent of the Medicare Administrative Contractor (MAC) determined price.-determined price.

ESRD facilities will report the AX modifier (item furnished in conjunction with dialysis services) with the HCPCS code for the CRA that is eligible to receive CRA for TPNIES. When a HCPCS code on the TPNIES CRA list is reported with the AX modifier and one of the following revenue codes, the CRA for TPNIES instructions will apply:

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

The CRA for TPNIES offset amount applies to maintenance dialysis treatments within the three times per week limit. The number of dialysis treatments for the month used in the CRA for TPNIES calculation, is limited to the 13 to 14 allowable monthly treatments that are deemed medically necessary. Dialysis treatments exceeding 13 to 14 per month (3 treatments per week) that are determined reasonable and necessary by the Medicare contractors are payable; however, treatments that exceed 13 to 14 per month shall not be considered for separate pricing for CRA for TPNIES.

CMS Transmittal R11533OTN, Change Request 12347; MM12347

For additional information: **ESRD PPS Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES)**.

Equipment and Supplies Eligible for TPNIES

There are no renal dialysis equipment or supplies eligible for the TPNIES for CY 2025.

CMS Transmittal R12962BP, Change Request 13865; MM13686
CMS Transmittal R12999BP, Change Request 13865; MM13686

E1629 Tablo hemodialysis system for the billable dialysis service

For dates of service January 1, 2022 through December 31, 2023, ESRD facilities can be paid the Capital Related Assets Adjustment (CRA) for TPNIES for the Tablo Hemodialysis System, Outset Medical Inc., using HCPCS code E1629.

When reporting HCPCS code E1629 for purposes of payment under the CRA for TPNIES, ESRD facilities must report hemodialysis machine with revenue code 0823 and append the modifier AX to the HCPCS. In addition, report the following information in the remarks field of the claim when billing for a CRA for TPNIES eligible equipment.

- HCPCS
- Description of item
- Billed amount to Medicare
- Invoice amount
- Wholesale amount per item
- Discount/rebate amount per item (even if bulk discount)

CRA for TPNIES offset amount applies to maintenance dialysis treatments within the three times per week limit. The number of dialysis treatments for the month used in the CRA for TPNIES calculation, is limited to the 13 to 14 allowable monthly treatments that are deemed medically necessary.

HCPCS E1629 must be reported for each treatment that was performed on the Tablo machine. The number of dialysis treatments (13 or 14 allowable monthly treatments) should match the units billed for HCPCS E1629.

CMS Transmittal R11678BP, Change Request 12978; MM12978

Acute Kidney Injury (AKI) Claims

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.

The Plan 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. Since ESRD facilities bill for renal dialysis services by submitting the 72x type of bill for ESRD, condition code 84 will differentiate an ESRD PPS claim from an AKI claim.

ESRD facilities are required to include revenue code 082X, 083x, or 088x for the modality of dialysis furnished with the HCPCS 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.

AKI claims will require one of the following diagnosis codes:

- N17.0 Acute kidney failure with tubular necrosis
- N17.1 Acute kidney failure acute cortical necrosis
- N17.2 Acute kidney failure with medullary necrosis
- N17.8 Other acute kidney failure
- N17.9 Acute kidney failure, unspecified
- T79.5XXA Traumatic anuria, initial encounter
- T79.5XXD Traumatic anuria, subsequent encounter
- T79.5XXS Traumatic anuria, sequela
- N99.0 Post-procedural (acute)(chronic) renal failure

More information on dialysis provided for AKI patients including the required diagnosis codes for billing AKI is available on the CMS website at: **Acute Kidney Injury and ESRD Facilities.**

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

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

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

Place of service

This policy applies to ESRD facility claims for renal dialysis services for the treatment of end-stage renal disease.

Policy history

Origination date:	12/01/2024
Connection date & details:	October 2024 Connection (policy origination). January 2025 Connection (Updated to indicate that prior authorization is not required for CPT 90999; under Billing/coding guidelines, updated TDAPA section to include VAFSEO® (vadadustat) and oral-only phosphate binders as qualifying for the TDAPA under the ESRD PPS.

The criteria listed above apply to Fallon Health plan and its subsidiaries. This payment policy has been developed to provide information regarding general billing, coding, and documentation guidelines for the Plan. Even though this payment policy may indicate that a particular service or supply is considered covered, specific provider contract terms and/or member individual benefit plans may apply and this policy is not a guarantee of payment. The Plan reserves the right to apply this payment policy to all of the Plan companies and subsidiaries. The Plan routinely verifies that charges billed are in accordance with the guidelines stated in this payment policy and are appropriately documented in the medical records. Payments are subject to post-payment audits and retraction of overpayments.